On approval of the risk assessment criteria and checklists in the sphere of medical services quality, circulation of medicines, medical products and medical devices

Unofficial translation

Joint order of the Minister of Health of the Republic of Kazakhstan dated November 15, 2018 № ДР DSM-32 and Minister of National Economy of the Republic of Kazakhstan dated November 15, 2018 № 70. Registered in the Ministry of Justice of the Republic of Kazakhstan on November 15, 2018 № 17744.

Unofficial translation

Footnote. The title is in the wording of the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.04.2019 № ҚР ДСМ-56 and the Minister of National Economy of the Republic of Kazakhstan dated 30.04.2019 № 33 (shall be enforced upon expiry of ten calendar days after its first official publication).

In accordance with paragraphs 5 and 6 of Article 141, paragraph 1 of Article 143 of the Entrepreneurial Code of the Republic of Kazakhstan **WE HEREBY ORDER:**

Footnote. The preamble is in the wording of the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 30.11.2022 № ҚР ДСМ-147 and the Minister of National Economy of the Republic of Kazakhstan dated 01.12.2022 № 115 (shall be enforced from 01.01.2023).

1. To approve:

1) risk assessment criteria in the sphere of medical services (aid) according to Annex 1 to this joint order;

2) checklist in the sphere of state control of medical services quality with regard to subjects (objects) providing inpatient and hospital replacing care according to Annex 2 to this joint order;

3) checklist in the sphere of state control of medical services quality with regard to subjects (objects) providing outpatient and polyclinic care (primary medical and sanitary care and consultative and diagnostic care) according to Annex 3 to this joint order;

4) checklist in the sphere of state control of medical services quality with regard to obstetric subjects (objects) and (or) inpatient organizations with maternity wards and neonatal pathoanatomical departments according to Annex 4 to this joint order;

5) checklist in the sphere of state control of medical services quality with regard to subjects (objects) providing cardiologic, cardiac surgical care according to Annex 5 to this joint order;

6) checklist in the sphere of state control of medical services quality with regard to subjects (objects) providing hemodialysis care according to Annex 6 to this joint order;

7) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing dental care according to Annex 7 to this joint order;

8) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing phthisiatric care according to Annex 8 to this joint order;

9) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing oncology care according to Annex 9 to this joint order;

10) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing medical and social assistance in the field of mental health care according to Annex 10 to this joint order;

11) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing laboratory services according to Annex 11 to this joint order;

12) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing emergency medical assistance, medical assistance in the form of medical aviation according to Annex 12 to this joint order;

13) checklist in the sphere of state control of medical services quality with regard to subjects (objects), carrying out the activities in the field of HIV prevention according to Annex 13 to this joint order;

14) checklist in the sphere of state control of medical services quality with regard to subjects (objects), carrying out activities in the field of blood service according to Annex 14 to this joint order;

15) risk assessment criteria in the sphere of circulation of medicines, medical devices and medical equipment according to Annex 15 to this joint order;

16) checklist in the sphere of circulation of medicines and medical devices for compliance with qualification requirements with regard to subjects (objects) of control according to Annex 16 to this joint order;

17) checklist in the sphere of circulation of medicines, medical devices and medical equipment with regard to medical organizations on drug provision issues according to Annex 17 to this joint order;

18) checklist in the sphere of circulation of medicines, medical devices and medical equipment with regard to subjects (objects) of pharmaceutical activities engaged in the production of medicines, medical devices and medical equipment according to Annex 18 to this joint order;

19) checklist in the sphere of circulation of medicines, medical devices and medical equipment with regard to subjects (objects) of pharmaceutical activities, manufacturing pharmaceuticals and medical devices according to Annex 19 to this joint order;

20) checklist in the sphere of circulation of medicines, medical devices and medical equipment with regard to subjects (objects) of pharmaceutical activities, engaged in the wholesale sale of medicines, medical devices and medical equipment according to Annex 20 to this joint order;

21) checklist in the sphere of circulation of medicines, medical devices and medical equipment with regard to subjects (objects) of pharmaceutical activities, engaged in retail sales of medicines, medical devices and medical equipment according to Annex 21 to this joint order;

22) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing pathoanatomical diagnostics according to Annex 22 to this joint order;

23) checklist in the sphere of state control of medical services quality with regard to subjects (objects), regardless the activity according to Annex 23 to this joint order;

24) checklist in the sphere of state control of medical services quality with regard to subjects (objects), providing care in the field of nuclear medicine according to Annex 24 to this joint order;

25) checklist in the sphere of circulation of medicines and medical devices in with regard to the state expert organization in the sphere of circulation of medicines and medical devices according to Annex 25 to this joint order.

Footnote. Paragraph 1 – as amended by the joint order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 30.11.2022 № ҚР ДСМ-147 and the Minister of National Economy of the Republic of Kazakhstan dated 01.12.2022 № 115 (shall be enforced from 01.01.2023); with amendments made by the joint orders of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (shall be enforced upon expiry of ten calendar days after its first official publication); Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2023 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2023 № 91 (shall be enforced upon expiry of ten calendar days after its first official publication).

2. To recognize invalid the joint order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated December 29, 2015 № 1064 and the Minister of National Economy of the Republic of Kazakhstan dated December 29, 2015 № 831 "On approval of risk assessment criteria and checklists in the sphere of medical services quality, circulation of medicines, medical products and medical equipment "(registered in the Register of state registration of regulatory legal acts for the number 12763, published March 25, 2016 in the information and the legal system "Adilet").

3. The committee of public health protection of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

1) state registration of this joint order at the Ministry of Justice of the Republic of Kazakhstan;

2) within ten calendar days from the date of state registration of this joint order sending its copy in the Kazakh and Russian languages to the Republican state enterprise on the right of economic management "Republican Center for Legal Information" for official publication and

inclusion into the Standard control bank of regulatory legal acts of the Republic of Kazakhstan ;

3) placement of this joint order on the official Internet resources of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of National Economy of the Republic of Kazakhstan after its official publication;

4) within ten working days after the state registration of this joint order in the Ministry of Justice of the Republic of Kazakhstan, submission of information on implementation of measures provided for in subparagraphs 1), 2) and 3) of this paragraph to the Legal department of the Ministry of Healthcare of the Republic of Kazakhstan.

4. Control over implementation of this joint order shall be entrusted on the Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This joint order shall be enforced upon expiry of ten calendar days after its first official publication.

Minister of Healthcare
of the Republic of Kazakhstan *E. Birtanov*
Minister of National Economy
of the Republic of Kazakhstan *T. Suleymenov*

"AGREED"
Committee on legal statistics
and special accounts
of General Prosecutor's office
of the Republic of Kazakhstan

Appendix 1
to the joint order of the
Minister of Healthcare of the
Republic of Kazakhstan
dated November 15, 2018
№ KR HCM-32 and the Minister of
National Economy of the
Republic of Kazakhstan
dated November 15, 2018 № 70

Risk assessment criteria in the sphere of provision of medical services (assistance)

Footnote. Annex 1 – as amended by the joint order of the Minister of Healthcare РК от 29.05.2023 № 90 and the Minister of National Economy РК от 29.05.2023 № 91 (shall be enforced upon expiry of ten calendar days after its first official publication).

Chapter 1. General provisions

1. These Risk assessment criteria in the sphere of provision of medical services (assistance) (hereinafter referred to as the Criteria) have been developed in accordance with paragraphs 5 and 6 of Article 141 and paragraph 1 of Article 143 of the Entrepreneur Code of the Republic of Kazakhstan, the order of the Acting Minister of National Economy of the

Republic of Kazakhstan dated June 22, 2022 № 48 "On approval of the Rules of formation by the regulating state bodies of the risk assessment and management system and on amendments to the order of the Acting Minister of National Economy of the Republic of Kazakhstan dated July 31, 2018 № 3 "On approval of the Rules for the formation of a risk assessment system by state bodies and the form of checklists"" (registered in the Register of State Registration of Regulatory Legal Acts under № 28577) and the order of the Acting Minister of National Economy of the Republic of Kazakhstan dated July 31, 2018 № 3 "On approval of the form of a checklist " (registered in the Register of State Registration of Regulatory Legal Acts under № 17371).

2. The following concepts are used in these Criteria:

1) score – quantitative measure of risk assessment;

2) minor violations – violations of the requirements of the legislation of the Republic of Kazakhstan non-compliance with which has entailed and (or) may entail formally committed, but not causing any appreciable harm to the population;

3) significant violations – violations, including non-compliance with the requirements of legislation in the sphere of healthcare, not related to gross and minor violations;

4) risk in the sphere of rendering medical services - probability of causing harm to human life or health, legitimate interests of individuals and legal entities, the state as a result of carrying out medical activity of the subject of control;

5) gross violations - deliberate or careless obvious and significant violation of the legislation of the Republic of Kazakhstan in the sphere of healthcare, non-compliance with which has entailed and (or) may entail serious consequences for the health of the population;

6) risk assessment and management system - a process of making managerial decisions aimed at reducing the probability of occurrence of unfavorable factors by categorizing subjects (objects) of control into risk levels for subsequent preventive control with visits to the subject (object) of control and (or) inspection for the compliance with qualification requirements (hereinafter referred to as the inspection for compliance with requirements) in order to minimize the possible degree of restriction of the freedom of entrepreneurship to the minimum extent possible, while ensuring an acceptable level of risk, as well as those aimed at changing the level of risk for a particular subject (object) of control and (or) exempting such subject (object) of control from preventive control with visits to the subject (object) of control and (or) inspection for compliance with requirements;

7) objective criteria for assessing the degree of risk (hereinafter – the objective criteria) - the criteria used to select subjects (objects) of control depending on the degree of risk in the sphere of rendering medical services when carrying out activities and not directly dependent on the individual subject (object) of control;

8) subjective criteria for assessing the degree of risk (hereinafter – the subjective criteria) – the criteria for assessing the degree of risk used to select subjects (objects) of control for

conducting preventive control, depending on the results of activity of a particular subject (object) of control.

3. Risk assessment criteria for conducting an inspection for compliance with requirements or authorization requirements for issued permits, requirements for notifications sent in accordance with the Law of the Republic of Kazakhstan "On Permissions and Notifications" and preventive control with a visit to the subject (object) of control are formed by determining objective and subjective criteria.

Chapter 2. Objective criteria for assessing the degree of risk for compliance inspections and preventive control of subjects (objects) of control

4. Determination of objective criteria shall be carried out by determining the risk of state control, which shall be carried out taking into account one of the following criteria:

1) the level of danger (complexity) of the subject (object) depending on the activity performed;

2) the scale of severity of possible negative consequences of harm in the process of medical activity;

3) the possibility of adverse effects on human health, legitimate interests of individuals, legal entities and the state.

5. Based on the analysis of all possible risks, control subjects (objects) shall be categorized into three degrees of risk (high, medium and low).

The subjects (objects) of high risk control include organizations providing inpatient care (district hospital, number district hospital, multidisciplinary interdistrict hospital, city hospital, multidisciplinary city hospital, multidisciplinary city children's hospital, multidisciplinary regional hospital, multidisciplinary regional children's hospital), subjects (objects) of obstetrics, organizations of emergency medical care and medical aviation, organizations carrying out activities in the field of blood service, dental polyclinic (center, office), phthisiopulmonological organizations, oncological center or dispensary, nuclear medicine centers, disaster medicine organizations, health care organizations carrying out activities in the field of HIV prevention.

Subjects (objects) of control of medium risk degree include subjects (objects) providing primary medical and sanitary care (medical station, paramedical and midwifery station, doctor's outpatient clinic, primary medical and sanitary care center, number district polyclinic, district polyclinic, city polyclinic), subjects (objects) providing specialized medical care in outpatient conditions, healthcare organizations performing pathological and anatomical diagnostics, health care organizations performing laboratory diagnostics, inpatient organizations providing medical assistance in the field of mental health, traditional medicine facilities.

The subjects (objects) of control of low-risk degree include subjects (objects) of control providing restorative treatment and medical rehabilitation and subjects (objects) of control providing palliative care and nursing care.

6. With regard to subjects (objects) of control classified as high and medium risk, compliance inspections, preventive control with a visit to the subject (object) of control, preventive control without a visit to the subject (object) of control and unscheduled inspections shall be carried out.

7. With regard to subjects (objects) of control classified as low risk, compliance checks, preventive control without a visit to the subject (object) of control and unscheduled inspections shall be carried out.

Chapter 3.
Subjective criteria for assessing the degree of risk for compliance inspections and preventive control of the subjects (objects) of control

8. Determination of subjective criteria shall be carried out using the following steps:

1) formation of a database and collection of information;

2) analyzing information and risk assessment.

9. Formation of the database and collection of information are necessary to identify subjects (objects) of control violating the legislation of the Republic of Kazakhstan.

The processes of collection and processing of information are fully automated and allow for the possibility of checking the correctness of the data obtained.

10. The following sources of information shall be used to determine subjective criteria for assessing the degree of risks for preventive control with a visit to the subject (object) of control:

1) results of previous inspections and preventive control with visits to control subjects (objects) (the severity of violations shall be established in case of non-compliance with the requirements set forth in the checklists);

2) results of monitoring of reports and information provided by the subject of control;

3) availability and number of confirmed complaints, appeals from individuals and legal entities for the period under evaluation;

4) results of analysis of information provided by state bodies and organizations;

5) the results of preventive control without visiting the subject (object) of control (final documents issued following the results of preventive control without visiting the subject (object) of control).

11. The following sources of information shall be used to determine the subjective criteria for assessing the degree of risk for conducting an inspection for compliance with the qualification requirements:

1) availability and number of confirmed complaints and appeals against subjects (objects) of control received from individuals or legal entities, state bodies;

2) results of previous inspections with regard to subjects (objects) of control;

3) results of certification, advanced training of employees of subjects of control for the last 5 years;

4) results of accreditation of subjects of control in case of urgency of issued authorizations .

12. Based on the available sources of information, the regulatory state bodies shall form subjective criteria to be evaluated.

The analysis and assessment of subjective criteria enable concentrating the compliance inspection and preventive control of the control subject (object) in respect of the control subject (object) with the highest potential risk.

At the same time, data of subjective criteria, previously recorded and used in relation to a particular subject (object) of control or data for which the statute of limitation period has expired are not used in the analysis and evaluation process in accordance with the Civil Code of the Republic of Kazakhstan.

With regard to the subjects of control who have eliminated in full the violations issued on the basis of the results of the previous preventive control with visits and (or) compliance inspection, it shall not be allowed to include them in the formation of schedules and lists for the next period of state control.

Priority of applied information sources and significance of indicators of subjective criteria shall be established in the criteria for risk assessment according to the list of subjective criteria for determining the degree of risk according to subjective criteria in the form according to Annexes 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17 to these Criteria.

Indicators of subjective criteria shall be determined for each homogeneous group of the subjects (objects) of control. Specific weight by importance of indicators of subjective criteria shall be determined depending on the importance of the indicator in risk assessment for each homogeneous group of subjects (objects) of control. Permissible values of indicators of subjective criteria are regulated by normative legal acts of the Republic of Kazakhstan.

13. Degrees of violations of requirements in the sphere of provision of medical services (assistance) are subdivided into gross, significant and minor ones.

The requirements for compliance inspections and preventive control of the subjects (objects) of control with a visit to the subject of control categorized by the degree of significance of violations and sources of information are given in Annexes 1 and 2 to these Criteria. on-compliance with the requirement determines the corresponding degree of violations.

14. The subjects (objects) of control shall be exempt from compliance inspections and preventive control of the subjects (objects) of control for the next calendar year, if the subject (object) of control has undergone an external comprehensive assessment (accreditation) for compliance of its activities with accreditation standards and has been provided with a certificate of accreditation for the inspected period.

15. Compliance inspection and preventive control with a visit to the subject (object) shall be carried out depending on the purpose and types of activities of the objects, in accordance with checklists in the sphere of provision of medical services to population according to Annexes 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 22, 23 and 24 to this joint order.

16. The basis for assigning a compliance review is a schedule approved by the regulatory state agency.

17. The basis for assigning preventive control with a visit to the subject (object) of control shall be a semi-annual list of subjects (objects) of control, approved by the first head of the regulating state body.

18. The subjects (objects) of control are transferred with the application of the information system from high risk to medium risk or from medium risk to low risk in the relevant areas of activities of the subjects of control in cases:

1) if the laws of the Republic of Kazakhstan and the criteria for assessing the degree of risk of the regulatory state bodies define cases of exemption from preventive control with a visit to the subject (object) of control or conducting inspections.

19. When the control body draws up a schedule of compliance inspections and semi-annual lists of preventive control with a visit to the subject (object) of control in respect of the same subjects (objects) of control, uniform terms of the period of their conduct shall be established.

20. For the subjects (objects) of control classified as high risk, the frequency of compliance checks shall be determined by the criteria for assessing the degree of risk, but not more often than once a year.

For control subjects (objects) classified as medium risk, the frequency of compliance audits shall be determined by the risk assessment criteria, but not more often than once every two years.

For control subjects (objects) classified as low risk, the frequency of compliance audits shall be determined by the risk assessment criteria, but not more often than once every three years.

Chapter 4. Procedure for calculating the degree of risk according to subjective criteria

21. The following procedure for calculation the indicator of risk degree shall apply to classify the subject of control to the risk degree in accordance with paragraph 3 of these Criteria.

22. Calculation of the risk level indicator by subjective criteria (R) shall be carried out in an automated mode by summing up the risk level indicator of violations based on the results of previous inspections and preventive control with visits to the subjects (objects) of control (SP) and the risk level indicator by subjective criteria, with subsequent normalization of data values into a range from 0 to 100 points.

$R_{interim}$= SP + SC, where

Rinterim– an intermediate indicator of the degree of risk according to subjective criteria,

SP – indicator of the degree of risk according to violations,

SC – indicator of the degree of risk according to subjective criteria.

The calculation shall be made for each subject (object) of control of a homogeneous group of subjects (objects) of control of each sphere of state control. In this case, the list of assessed subjects (objects) of control attributable to a homogeneous group of subjects (objects) of control of one sphere of state control forms a selective population (sample) for the subsequent normalization of data.

23. Based on the data obtained from the results of previous inspections and preventive control with visits to the subjects (objects) of control, an indicator of the risk level of violations shall be formed, assessed in points from 0 to 100.

If one gross violation is detected according to any of the sources of information specified in paragraphs 10 and 11 of these Criteria, the subject of control shall be assigned a risk level indicator of 100 points and shall be subject to a compliance check and (or) preventive control with a visit to the subject (object) of control.

If no gross violations are detected, the risk level indicator for violations shall be calculated by summing up the indicator for significant and minor violations.

When determining the indicator of significant violations, a coefficient of 0.7 shall be applied.

This indicator shall be calculated using the following formula:

$SPs = (SP_2 \times 100/SP_1) \times 0,7$, where:

SP_s – an indicator of significant violations;

SP_1 – the required number of significant violations;

SP_2 – the number of identified significant violations;

When determining the indicator of minor violations, a coefficient of 0.3 shall be applied.

This indicator shall be calculated using the following formula:

$SP_m = (SP_2 \times 100/SP_1) \times 0,3$, where:

SP_m – an indicator of minor violations;

SP_1 – the required number of minor violations;

SP_2 – the number of identified minor violations;

The violation risk score (SR) shall be calculated on a scale from 0 to 100 points and shall be determined by summing up the indicators of significant and minor violations according to the following formula:

$SP = SP_s + SP_m$, where:

SP – indicator of risk degree by violations;

SPs – an indicator of significant violations;

SPm – an indicator of minor violations.

The resulting value of the indicator of risk degree by violations is included in the calculation of the indicator of risk degree by subjective criteria.

24. Calculation of the risk level indicator by subjective criteria shall be calculated on a scale from 0 to 100 points and shall be carried out according to the following formula:

$$SC = \sum_{i=1}^{n} x_i * w_i, \text{ где}$$

x_i – an indicator of subjective criterion,

w_i – specific weight of the indicator of subjective criterion xi,

n – number of indicators.

The resulting value of the risk level indicator by subjective criteria is included in the calculation of the risk level indicator by subjective criteria.

25. The values calculated by subjects (objects) for indicator R shall be normalized into the range from 0 to 100 points. Data normalization shall be carried out for each sampling population (sample) using the following formula:

$$R = \frac{R_{\text{пром}} - R_{min}}{R_{max} - R_{min}},$$

R – indicator of risk degree (final) according to subjective criteria of an individual subject (object) of control.

R_{max} – maximum possible value on the scale of risk degree by subjective criteria for subjects (objects) included in one sampling population (sample) (upper limit of the scale)),

R_{min} – the minimum possible value on the scale of risk degree by subjective criteria for subjects (objects) included in one sampling population (sample) (the lower limit of the scale),

$R_{interim}$ – an intermediate indicator of risk degree by subjective criteria, calculated in accordance with paragraph 22 of these Criteria.

Annex 1
to the Risk assessment criteria
in the sphere of provision
of medical service (assistance)

Degrees of violations of the requirements for compliance inspection of the subjects (objects) of control

Item №	Name of requirements	Degree of violations
1	Availability of a specialist certificate for admission to clinical practice	gross
2	Availability of a license and (or) an annex to the license	gross
3	Compliance of the premises or building on the right of ownership or lease agreement, or contract of gratuitous use of immovable property (loan), or trust management of property, or public-private partnership agreement with the standards of organization of medical care of specialized services for the provided subspecialties of medical activity, as well as the corresponding sanitary rules establishing sanitary and epidemiological requirements for the objects of health cate	gross
4	Availability of functioning medical and (or) special equipment, apparatus and instruments, devices, furniture, inventory, transport and other means (if necessary), approved in the standards of organization of medical care of profile services for the provided subspecialties of medical activity and minimum standards of equipment of health care organizations with medical products	gross
5	Availability of specialists for the provided types of activities	gross
6	Availability of specialization or improvement and other types of advanced training for the last 5 (five) years on the provided subtypes of medical activity (except for the graduates of internship, residency, secondary educational institution who have completed their training not later than 5 (five) years at the time of inspection).	gross

Annex 2
to the Risk assessment criteria
in the sphere of provision
of medical service (assistance)

Degrees of violations of requirements for preventive control of the subjects (objects) of control

Item №	Name of requirements	Degree of violations

For obstetric facilities and (or) inpatient organizations with maternity wards and neonatal pathoanatomical departments		
1	Availability of an opinion on the compliance of the subject of health care to the provision of high-tech medical care when the organization provides high-tech services, including in vitro fertilization	gross
2	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis	gross
3	Availability of a written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures	significant
4	Availability of supporting documentation (emergency medical team call card form № 085/y, register of admissions and refusals to hospitalization, medical card of an inpatient form № 001/y), that the stay of an ambulance or emergency medical services team in the emergency room of a hospital does not exceed 10 minutes (time for transferring the patient to the doctor of the emergency room) from the moment of its arrival at the hospital, except when emergency medical care is needed in emergency situations. After the transfer of the patient by EMS teams or EMS department in the organization of primary health care to the receiving department of the hospital, the nurse carries out the distribution of incoming patients (triage according to the triage system) into groups, based on the priority of provision of emergency medical care . Triage according to the triage system (hereinafter referred to as triage) shall be carried out in a continuous and successive manner. Upon completion of the assessment, patients shall be marked with the color of one of the triage categories	gross

	in the form of a special-colored tag or colored tape. According to triage, there are 3 groups of patients: first group (red zone) - patients whose condition poses an immediate threat to life or who have a high risk of deterioration and require emergency medical care; second group (yellow zone) - patients whose condition poses a potential threat to health or may progress with the development of a situation requiring emergency medical care; third group (green zone) - patients whose condition does not pose an immediate threat to life and health and does not require hospitalization. Presence of a record in the medical card of patient identification by triage groups according to the triage system.	
5	Presence of a medical report issued by the doctor of the emergency room with a written justification of refusal in the absence of indications for hospitalization in a health care organization. Presence of an asset sent by the emergency room nurse to the primary health care organization at the patient's place of registration	significant
6	Availability of supporting records in medical documentation on indications for hospitalization: The need to provide pre-hospital, qualified, specialized medical care, including the use of high-tech medical services, with round-the-clock medical supervision of patients: 1) in a planned procedure - upon referral of specialists of primary health care or other health care organization: 2) for emergency indications (including weekends and public holidays) - regardless of the availability of a referral	significant
	Availability of records in the medical documentation on the examination of severe patients by the	

7	head of the department on the day of hospitalization, and daily thereafter. Patients in a moderately severe condition are examined at least once a week. Availability of the results of the patient's examination recorded in the medical card with recommendations on further tactics of patient management with mandatory identification of the medical worker making the records	significant
8	Availability of records in medical documentation confirming daily examination of inpatients by the attending physician, except for weekends and holidays. Availability of appropriate records in the medical card in case of examination and prescription of additional diagnostic and treatment manipulations by the doctor on duty	significant
9	Availability of justification in the medical card for dynamic assessment of the patient's condition according to clinical protocols of diagnosis and treatment in case of identification of the fact of additional and repeated tests conducted before hospitalization in primary health care organizations or other health care organizations, for medical reasons	significant
	Availability of supporting documentation that the following requirements have been met when issuing a maternity leave and certificate of temporary incapacity for pregnancy and childbirth: - A sheet or certificate of temporary incapacity for pregnancy and childbirth shall be issued by a medical worker (obstetrician-gynecologist), or in his/her absence, by a physician, in conjunction with the head of the department, after the conclusion of the medical consultative board from thirty weeks of pregnancy for a period of one hundred twenty-six calendar days (seventy calendar days before delivery and fifty-six calendar days after delivery) in case of normal childbirth.	

	For women residing in territories affected by nuclear tests, a sick leave certificate or certificate of disability for pregnancy and childbirth is issued from twenty-seven weeks of pregnancy and childbirth for one hundred and seventy calendar days (ninety-one calendar days before childbirth and seventy-nine calendar days after childbirth) in case of normal childbirth; 2) for women who have temporarily left their permanent place of residence within the Republic of Kazakhstan, a sheet or certificate of temporary incapacity for pregnancy and childbirth is issued (extended) in the medical organization where the birth occurred or in the women's consultation (office) at the place of observation according to the discharge (exchange card) of the obstetric organization 3) in case of complicated childbirth, birth of two or more children, the sheet or certificate of temporary incapacity for work is extended for an additional fourteen calendar days by a medical worker (obstetrician-gynecologist), or in his/ her absence - by a doctor, together with the head of the department, after the conclusion of the medical consultative board at the place of observation according to the discharge of the obstetric health care organization. In such cases, the total duration of prenatal and postnatal leave shall be one hundred and forty calendar days (seventy calendar days before delivery and seventy calendar days after delivery). For women residing in territories affected by nuclear tests, in case of complicated childbirth or the birth of two or more children, the sick leave certificate or certificate of temporary incapacity is extended for an additional fourteen calendar days; the total duration of prenatal and postnatal leave shall be one hundred and eighty-four days (ninety-one		

	calendar days before childbirth and ninety-three calendar days after childbirth); 4) In the case of childbirth between twenty-two and twenty-nine weeks of pregnancy and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, the woman shall be issued a certificate of incapacity for work for seventy calendar days after childbirth. In the case of childbirth between twenty-two and twenty-nine weeks of pregnancy and the birth of a dead fetus or a child with a body weight of five hundred grams or more, who died before seven days of life, the woman shall be issued a sick leave certificate or certificate of temporary incapacity for work for fifty-six calendar days after childbirth; 5) For women living in territories affected by nuclear tests, in the case of childbirth between twenty-two and twenty-nine weeks of pregnancy and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, a certificate of temporary incapacity shall be issued for ninety-three calendar days after childbirth. For women living in territories affected by nuclear tests, in the case of childbirth at twenty-two to twenty-nine weeks of pregnancy and the birth of a dead fetus or a child with a body weight of five hundred grams or more who died before seven days of life, a certificate of temporary incapacity shall be issued for seventy-nine calendar days after childbirth; 6) When a woman applies for a temporary incapacity certificate during pregnancy, the pregnancy and maternity leave is calculated cumulatively and granted in full regardless of the number of days actually used by her before childbirth. If a woman applies for a temporary incapacity certificate after childbirth,	
10		significant

	only the leave after childbirth shall be granted for the duration provided for in this paragraph; 7) in case of pregnancy during the period when a woman is on paid annual labor leave or unpaid leave to care for a child up to the age of three , a temporary incapacity certificate shall be issued for all days of the pregnancy and maternity leave, except as provided for in part two of subparagraph 6) of this paragraph; 8) If the mother dies during childbirth or in the postpartum period, a sick leave certificate or certificate of temporary incapacity shall be issued to the person caring for the newborn child; 9) in the case of an operation for artificial termination of pregnancy, a sick leave certificate or certificate of temporary incapacity for work shall be issued by a doctor in conjunction with the head of the department for the period of stay in the hospital and outpatient clinic where the operation was performed, and in the case of a complication - for the entire period of temporary incapacity for work. In case of spontaneous abortion (miscarriage), a sick leave certificate or certificate of temporary incapacity for work shall be issued for the entire period of temporary incapacity for work; 10) In case of embryo transfer surgery, a sick leave certificate or certificate of temporary incapacity for work is issued by the medical organization that performed the surgery from the day of embryo transfer until the pregnancy is established. Persons who have adopted a newborn child (children), as well as the biological mother in the case of surrogate motherhood directly from the maternity hospital, shall be issued a sick leave certificate or certificate of temporary incapacity for work from the day of adoption and until the expiry of fifty-six calendar days from the date of birth of the child	

11	Availability of medical documentation on compliance with the following requirements for the examination of temporary incapacity for work, issuance of certificates and certificates of temporary incapacity for work (Form № 001/y "Medical card of an inpatient", form 052/y " Medical card of an outpatient", stubs of certificates of temporary incapacity for work of patients, form № 025/y "Register for Recording Conclusions of Medical Consultative Board", form № 029/y "Book of registration of certificates of temporary incapacity for work", form № 037/y "Certificate №_____ ____ on temporary incapacity of a student, college student, vocational school, illness, quarantine and other reasons for the absence of a child attending school, pre-school organization (underline)", form № 038/y "Certificate №_____ on temporary incapacity" etc.): 1) availability of examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient) patient justifying the need for temporary release from work; 2) issuance of a sick leave certificate of temporary incapacity for work and a certificate of temporary incapacity for work on the day of discharge in case of inpatient treatment (including day care centers, rehabilitation centers) for the entire period of inpatient treatment; 3) closing of the temporary incapacity certificate and certificate of temporary incapacity for work by the date of discharge from the hospital if the ability to work has been fully restored; 4) prolongation of the temporary incapacity certificate and certificate of temporary incapacity for a period of time, taking into account the time required to visit a medical worker of the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Persons who received treatment	significant	

	outside the region of residence, the time required to arrive at their place of permanent residence (but not more than four calendar days) is taken into account; 5) issuance of a certificate of temporary incapacity for injuries sustained while under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity ; 6) issuance of a sheet and certificate of temporary incapacity for work to persons suffering from mental illness in case of untimely application to a medical organization for the past days by the conclusion of the medical consultative board of a psychoneurological dispensary or a medical worker (psychiatrist) in conjunction with the head of the medical organization; 7) issuance of a sick leave certificate and a certificate of temporary incapacity for work to persons referred by court decision for forensic medical or forensic psychiatric examination and recognized as incapable of work from the day of admission to the examination; 8) issuance of a sick leave certificate of temporary incapacity for work and a certificate of temporary incapacity for work to a person who combines training with work.	
12	Availability of informed written consent of the patient for transfusion of blood components	significant
13	Availability of records in medical documentation on compliance with the requirements for transfusion of blood components. Before transfusion of blood components, the recipient shall be examined for markers of hemotransmissible infections HIV, hepatitis B and C, and after the end of treatment the discharge epicrisis shall indicate the need for repeated examination for HIV and hepatitis B and C at the place of residence.	Gross

	Testing of recipients for HIV infection within the guaranteed scope of free medical care is carried out in state health care organizations that carry out activities in the field of HIV prevention	
	Availability of documentation on compliance with the following when performing post-mortem examination: 1) conducting a post-mortem examination of corpses after physicians have ascertained biological death, after providing the medical card of an inpatient or the medical card of an outpatient with a written order from the chief physician or his/her deputy for the medical (treatment) part of the health care organization to send for a post-mortem examination; 2) transfer of the medical card of an inpatient or medical card of an outpatient with the pathoanatomical diagnosis entered into it to the medical archive of the health care organization no later than ten working days after the post-mortem examination; 3) conducting clinical and pathoanatomical analysis in cases of patient deaths in health care organizations; 4) organization by the chief physician and head of the pathoanatomical department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 5) Transfer of medical cards of hospital patients for all deceased patients for the previous day no later than 10 a.m. of the day following the establishment of the fact of death to pathoanatomical bureaus, centralized pathoanatomical departments and pathoanatomical departments 6) registration of post-mortem examination results in the form of pathoanatomical diagnosis (pathology diagnosis includes: main disease, complication of the main	

14	disease, concomitant disease, combined main disease); 7) registration of: - medical certificate of death (preliminary, final) by a doctor specializing in " pathological anatomy (adult, pediatric)" on the day of post-mortem examination; - medical certificate of perinatal death (preliminary, final) by a doctor specializing in "pathological anatomy (adult, pediatric)" on the day of post-mortem examination; 8) registration of the autopsy results in the form of a post-mortem examination report; 9) written notification to the judicial and investigative authorities to address the issue of transferring the corpse for forensic medical examination if signs of death through violence are detected, and termination of post-mortem examination of the corpse; 10) availability of written notification of the doctor specializing in "pathological anatomy (adult, pediatric)" in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service, immediately after their detection; 11) conducting a post-mortem examination of the placenta: - In all neonatal diseases detected at the time of birth; - in cases suspected of hemolytic disease of the newborn; - in cases of early discharge and dirty waters; - in cases of maternal illness with high fever in the last trimester of pregnancy; - in case of obvious anomalies in the development or attachment of the placenta; - suspected congenital anomalies of the fetus; - in cases of pre-eclampsia, eclampsia	gross

	12) mandatory registration of a fetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 13) establishment of post-mortem examination, depending on the complexity, into the following categories: - first category; - second category; - third category; - fourth category; 14) establishment of the category of post-mortem examination by a doctor specializing in "pathological anatomy (adult, pediatric)" and the reason for the divergence of diagnoses when the final clinical and pathoanatomical diagnoses diverge; 15) availability of detailed analysis with determination of the profile and categories of iatrogenesis in all cases of iatrogenic pathology identified as a result of post-mortem examination	
	Availability of supporting documentation on compliance with the following requirements in the organization of obstetric and gynecological care at the outpatient and polyclinic level: 1) ensuring early registration of pregnant women, on the day of their application to a medical organization , without taking into account the insured status; 2) Home health care for pregnant women, maternity women, gynecological patients and the group of women of fertile age (hereinafter referred to as the WFA) of social risk, universal (compulsory) patronage observation of pregnant women up to 12 weeks and 32 weeks of pregnancy 3) dispensary observation of pregnant women for the prevention and early detection of complications of pregnancy, childbirth and the postpartum period, with the selection of women "according to risk factors" ;	

15	4) conducting prenatal screening, a comprehensive examination of pregnant women to identify the risk group for chromosomal abnormalities and congenital malformations of the intrauterine fetus; 5) Identifying pregnant women in need of timely hospitalization in day hospitals, pregnancy pathology departments of inpatient medical organizations providing obstetric and gynecological care, specialized medical organizations with extragenital pathology, in compliance with the principles of regionalization of perinatal care; 6) referring pregnant women, women in labor and maternity for specialized assistance with medical supervision, including the use of high-tech medical services to medical organizations of the republican level; 7) conducting prenatal education for pregnant women in preparation for childbirth, including partner births, informing pregnant women about warning signs, effective perinatal technologies, principles of safe motherhood, breastfeeding and perinatal care; 8) nursing of the pregnant women and maternity women as indicated; 9) consulting and providing services on family planning and reproductive health issues; 10) prevention and detection of sexually transmitted infections for referral to specialized professionals; 11) screening of women of fertile age with the appointment, if necessary, of in-depth examinations using additional methods and involvement of specialized professionals for the timely detection of extragenital and gynecological pathology and their registration in the dispensary; (12) organizing and conducting preventive examinations of the female population for the early detection of extragenital diseases;	gross

	13) examination and treatment of gynecological patients using modern medical technologies; 14) screening of gynecological patients, including rehabilitation and sanatorium-resort treatment; 15) performance of minor gynecologic surgeries using modern medical technologies; 16) conducting an expert assessment of temporary incapacity due to pregnancy, childbirth and gynecological diseases, determining the need and timing of temporary or permanent transfer of an employee for health reasons to another job, referral for medical and social assessment of women with signs of permanent loss of working capacity; 17) double HIV testing during pregnancy with the patient's informed consent and recording of the data	
16	The use of germ cells, tissues of reproductive organs by a recipient who is (are) married (matrimonial) shall be carried out with the written consent of both spouses.	minor
17	Availability of supporting documentation of the birth of ten (10) children from a single donor 6 which is the basis for discontinuing the use of that donor for recipients.	significant
18	Availability of supporting documentation on donation of germ cells, tissues of reproductive organs from the donor under the following conditions: 1) the donor freely and knowingly expresses informed consent in writing for the donation of germ cells, tissues of reproductive organs; 2) the oocyte donor is informed in writing about complications for her health in connection with the forthcoming surgical intervention; 3) the donor undergoes medical and genetic examination and there is a conclusion of a reproductologist or uroandrologist on the possibility of donating germ cells, tissues of reproductive organs.	significant

19	Oocyte donation shall be carried out in the presence of a written informed consent of the donor for superovulation induction or in a natural cycle in compliance with the requirements for donors of germ cells, tissues of reproductive organs and donors of oocytes undergo medical and genetic examinations	significant
20	Availability of supporting documentation for in vitro fertilization (hereinafter referred to as the IVF) with the use of donor oocytes is carried out according to the indications: 1. Absence of oocytes due to natural menopause. 2. Premature ovarian exhaustion syndrome, resistant ovarian syndrome, post ovariectomy, radiotherapy or chemotherapy. 3. anomalies of genital development, absence of ovaries. 4. Functional inferiority of oocytes in women with sex-linked hereditary diseases. 5. Unsuccessful repeated attempts of in vitro fertilization in case of insufficient ovarian response to superovulation induction, repeated receipt of embryos of poor quality, transfer of which did not lead to pregnancy. 6. rhesus incompatibility between male and female. 7. Anomalies in the karyotype of the woman. 8. Twin (blood) marriages with the birth of children with malformations. 9. Somatic diseases in which ovarian stimulation is contraindicated.	gross
21	Availability of supporting documentation on work with donors by an obstetrician-gynecologist (reproductologist), medical examination of the donor before each procedure of donor material collection, controls the timeliness and results of laboratory tests in accordance with the calendar plan of examination.	significant
	Availability of supporting documentation on oocyte donation	

22	according to the following algorithm : 1) selection of an oocyte donor (according to individual selection criteria and recipient's preferences); 2) examination of the donor and recipient; 3) synchronization of menstrual cycles of the donor and recipient with the help of medications in case of embryo transfer into the uterine cavity of the recipient in the donor's stimulated cycle; 4) in the procedure of transferring cryopreserved embryos, cycle synchronization is not performed; 5) procedure of oocyte collection for use by recipients or cryopreservation for a germ cell bank.	significant
23	Availability of supporting documentation on compliance with the requirements for denial of IVF using donor oocytes for the following contraindications: 1. Somatic and mental illnesses that are contraindications to pregnancy and childbirth. 2. Congenital malformations or acquired deformities of the uterine cavity, in which it is impossible to implant embryos or carry a pregnancy. 3. 3. ovarian tumors. 4. Benign uterine tumors requiring surgical treatment. 5. Acute inflammatory diseases of any localization. 6. Malignant neoplasms of any localization	gross
	Availability of supporting documentation on the use of donor sperm in assisted reproductive methods and technologies (hereinafter referred to as ARMT)). Sexual abstinence for 3-5 days is required before semen donation. Semen is obtained by masturbation. The ejaculate is collected in a special sterile, pre-labeled container. This procedure is carried out in a special room with a separate entrance, appropriate interior, sanitary unit with a washbasin. In the absence of	

24	donor sperm in the medical organization, or at the patient's request, donor sperm from other organizations that have a donor sperm bank is used. Only cryopreserved donor sperm is used after repeated (6 months after cryopreservation) negative test results for HIV, syphilis and hepatitis B and C are obtained. The use of cryopreserved (frozen-thawed) sperm ensures: 1) carrying out measures to prevent the transmission of HIV, syphilis, hepatitis and other sexually transmitted infections; 2) eliminating the possibility of meeting between the donor and the recipient. Requirements for donor semen: 1) volume of ejaculate more than 1.5 milliliters (hereinafter - ml); 2) concentration of spermatozoa in 1 ml of ejaculate 15 million or more; total number of spermatozoa in the whole ejaculate 22.5 million or more ; 3) the proportion of progressively motile forms (A+B) 32% or more; 4) the proportion of morphologically normal forms 4% or more (according to strict Krueger criteria 14% or more); 5) cryotolerance; 6) test determining immunocompetent bodies of the sperm surface (MAR-test) - as indicated.	significant
25	IVF with the use of donor sperm is performed in the following indications 1. azoospermia, severe oligoasthenozoospermia, necrospermia, akinozoospermia, globulozoospermia. 2. Condition after radiotherapy or chemotherapy. 3. developmental anomalies of the reproductive system. 4. Absence or functional inferiority of spermatozoa in men with sex-linked hereditary diseases.	gross

	5. Unsuccessful repeated attempts at in vitro fertilization with high DNA (deoxyribonucleic acid) fragmentation index of spermatozoa and repeated receipt of low-quality embryos whose transfer did not result in pregnancy. 6. rhesus incompatibility between male and female. 7. Anomalies in the male karyotype.	
26	The individual donor card is filled out and coded by a doctor. The coding scheme is free. The donor's application and his/her individual card shall be kept in a safe as documents for official use.	significant
27	Availability of supporting documentation of work with donors by a doctor-uroandrologist and a doctor-embryologist. The doctor organizes medical examinations of the donor, controls the timeliness and results of laboratory tests in accordance with the calendar plan of examination. The embryologist performs cryopreservation and thawing of sperm, assesses the quality of sperm before and after cryopreservation, provides the necessary storage conditions for sperm, and keeps records of the material. Donor sperm is registered in the logbook of donor sperm receipt and in the card of donor sperm receipt and consumption.	significant
	Availability of supporting documentation of compliance, that the embryo donors are IVF patients who have unused cryopreserved embryos left in the bank. By free decision and written informed consent of the patients, these embryos are disposed of or donated to a medical organization. Embryos transferred to the medical organization are used for donation free of charge to infertile married couple, women (recipients) who are not married (matrimonial). Embryos for donation are also obtained as a result of fertilization of donor oocytes with donor sperm.	

28	Patients are informed that the outcome of the procedure using leftover cryopreserved embryos from IVF patients is lower than using embryos derived from donor germ cells. Recipients are provided with a phenotypic profile of the donors. IVF with the use of donor embryos is performed according to the indications: 1. lack of oocytes. 2. Unfavorable medical and genetic prognosis. 3. Repeated receipt (more than three times) of embryos of poor quality, the transfer of which did not lead to pregnancy. 4. Failure to obtain or use sperm from a married couple (spousal).	gross
29	Availability of supporting documentation on compliance with assisted reproductive techniques and technologies	gross
	Availability of supporting documentation of the following functions in the provision of pre-hospital care to women during and outside pregnancy by paramedics (obstetricians, paramedics, nurses/nurses): 1) independent reception and medical examination to determine the patient's health status, identify diseases and complications of pregnancy 2) entering data into the "Register of pregnant women and women of fertile age" subsystem of the electronic portal "Register of the Attached Population" for the purpose of automated maintenance of groups of pregnant women and women of fertile age (hereinafter referred to as the WFAs) and monitoring of health indicators of pregnant women and WFAs; 3) providing emergency and emergency pre-hospital medical care to pregnant women, women in labor and delivery and women of fertile age for conditions threatening the	

30	life and health of women according to clinical protocols of diagnosis and treatment; 4) dynamic monitoring of pregnant women with chronic diseases together with district physicians and specialized professionals; 5) fulfillment of prescriptions of an obstetrician-gynecologist; 6) management of physiologic pregnancy and patronage of pregnant and maternity women with timely provision of referrals and recommendations on clinical protocols of diagnostics and treatment; 7) home medical care of pregnant women, maternity women, gynecological patients and social risk groups of women with HIV; 8) preventive medical examination of women for early detection of pre-tumor and cancerous diseases of female genital organs and other localizations (skin, mammary glands); 9) Conducting medical nursing examinations of women of all age groups who have sought medical care; 10) participation in screening and preventive examinations to detect diseases	gross
	Availability of supporting documentation on compliance with the following requirements when organizing obstetric and gynecological care at the inpatient level: 1) provision of inpatient consultative-diagnostic, therapeutic, preventive and rehabilitative care to pregnant women, women in labor and delivery, and newborns; 2) joint examination by the attending physician and the head of the department upon admission of pregnant women up to 36 weeks of pregnancy suffering from chronic diseases who require treatment in specialized departments of multidisciplinary hospitals, in order to assess the severity of the course of	

	the disease, the course of pregnancy and treatment tactics. 3) drawing up a plan for the management of pregnancy, childbirth and postpartum period, taking into account an individualized approach; 4) management of pregnancy, labor and postpartum period according to clinical protocols of diagnostics and treatment, as well as according to the management plan; 5) counseling of pregnant women, women in labor and delivery, monitoring of compliance with the level of medical care; 6) carrying out rehabilitation measures for mothers and newborns, including care for premature newborns; 7) consultations on the provision of medical care to pregnant women, women in labor, maternity and newborns using telecommunication systems;	
31	8) expert examination of temporary incapacity for work, issuance of certificates and certificates of temporary incapacity for work for maternity and gynecological patients ; 9) provision of resuscitation care and intensive care to mothers and newborns, including those with low and extremely low body weight; 10) providing medical and psychological assistance to women; 11) notification of medical organizations of a higher level of regionalization of perinatal care and local public health authorities in case of detection of a critical condition of a pregnant woman, a woman in labor or a woman in maternity during admission or stay in hospital; 12) adherence to the notification scheme in case of critical situations in women; 13) transportation of pregnant women, women in critical condition to the third level of perinatal care, to regional and republican health care organizations is carried out by	gross

	decision of the concilium with the participation of specialists from the medical team of medical aviation after hemodynamic recovery and stabilization of vital functions with notification of the receiving medical organization; 14) In case of non-transportable condition of pregnant women, women in labor and delivery to call qualified specialists "on their own", to provide primary resuscitation care in case of emergencies, to diagnose threatening conditions of mother and fetus, to decide on delivery, to conduct intensive and supportive therapy until transfer to a higher level	
Providing medical care to newborns		
	Availability of supporting documentation on compliance with the following requirements when organizing medical care for newborns at the inpatient level: 1) provision of medical care to newborns according to the levels of regionalization of perinatal care depending on indications; 2) availability in the structure of organizations of hospitals of the first level of regionalization of perinatal care: individual delivery rooms, departments for the joint stay of mother and child, vaccination room, intensive care rooms for newborns, as well as the staffing schedule of a doctor's position in the specialty " Pediatrics (neonatology)" and a round-the-clock post of a neonatal nurse; 3) Availability in hospitals of the second level of regionalization of neonatal resuscitation and intensive care rooms with a full set of resuscitation equipment, artificial ventilation devices with different ventilation modes (constant positive airway pressure), incubators, clinical and diagnostic laboratory, as well as a staffed round-the-clock post (neonatologist and children's nurse); 4) Compliance with the following requirements in hospitals of the third	

32	level of perinatal care regionalization : Availability of a 24-hour neonatal post, clinical, biochemical and bacteriological laboratory, intensive care unit for women and newborns, as well as neonatal pathology and prematurity nursing unit of joint stay with the mother. Availability of a neonatal intensive care unit, neonatal pathology and prematurity care units, equipped with modern therapeutic and diagnostic equipment, medicines, round-the-clock posts (medical and nursing), and an express laboratory. 5) Compliance with the following requirements in first level hospitals for the sick newborn: Primary resuscitation care; intensive and supportive care; oxygen therapy; invasive or non-invasive respiratory therapy; phototherapy; therapeutic hypothermia; infusion therapy and/or parenteral nutrition; treatment according to clinical protocols for diagnosis and treatment . Compliance with the following requirements in second level hospitals for a sick newborn: Provision of primary resuscitation care to the newborn and stabilization of the condition, nursing premature infants with a gestational age of more than 34 weeks; catheterization of central veins and peripheral vessels; detection and treatment of congenital malformations, intrauterine developmental delay, neonatal hypoglycemia, hyperbilirubinemia, neonatal sepsis, central nervous system damage, respiratory distress syndrome, pneumothorax, necrotizing enterocolitis and other pathologic conditions of the neonatal period; carrying out intensive care, including correction of vital functions (	gross

	respiratory, cardiovascular, metabolic disorders), invasive and non-invasive respiratory therapy, infusion therapy and parenteral nutrition; if highly specialized care is needed, the degree of readiness for transportation with the mother to a third-level obstetrics organization or an institution of national importance is determined.	
33	Availability of supporting documentation on compliance with the requirements for the provision of medical care to newborns in third-level medical organizations: 1) provision of primary resuscitation to newborns and care of newborns 2) carrying out intensive and supportive therapy: respiratory therapy, catheterization of central veins and peripheral vessels, therapeutic hypothermia, parenteral nutrition, nursing premature babies; 3) Diagnosis and treatment of congenital malformations, delayed fetal development (low birth weight by gestational age), neonatal hypoglycemia, neonatal sepsis, respiratory distress syndrome, hyperbilirubinemia, necrotizing enterocolitis, pneumothorax, bronchopulmonary dysplasia, persistent pulmonary hypertension of newborns, perinatal lesions of the central nervous system and other pathologic conditions of the neonatal period; 4) carrying out intensive and supportive therapy, therapeutic hypothermia, parenteral nutrition; 5) invasive and non-invasive respiratory therapy; 6) nursing premature babies; 7) provision of round-the-clock consultative and therapeutic-diagnostic assistance to specialists of the first and second level of regionalization, provision of emergency and urgent medical assistance with travel to a medical organization	gross

34	Availability of supporting documentation on compliance with requirements to provide a healthy newborn with basic care that includes prevention of hypothermia with "heat chain" compliance, skin-to-skin or skin-to-skin contact with the mother, early initiation of breastfeeding within the first hour (if the infant shows signs of readiness), and prevention of hospital-acquired infections	significant
35	Availability of supporting documentation on compliance with requirements to perform healthy newborn anthropometry, full examination and other measures 2 hours after delivery	significant
36	Availability of supporting documentation on compliance with the requirements of emergency medical care in case of detection of disorders of the newborn's condition, transfer to the intensive care ward or neonatal intensive care unit, if indicated	gross
37	Availability of supporting documentation on compliance with requirements for observation of the mother and healthy newborn in the delivery room by an obstetrician within two hours of birth: 1) measurement of the newborn's body temperature 15 minutes after birth, then every 30 minutes thereafter; 2) observation of the newborn for heart rate and respiratory rate, breathing pattern (detection of expiratory groaning, assessment of the degree of lower chest extension), skin coloration, activity of the sucking reflex, if necessary, determines saturation with a pulse oximeter	significant
38	Availability of supporting documentation on compliance with transfer 2 hours after birth of a healthy newborn with the mother to a mother-and-child care unit	significant
	Availability of supporting documentation on round-the-clock	

39	observation by medical staff and continuous involvement of the mother in the care of the child, except in cases of moderate and severe maternal conditions in the postpartum ward in the mother-and-child wards	significant
40	Availability of supporting documentation on compliance with the requirements for dynamic monitoring of the newborn with timely detection of violations of the newborn's condition, conducting the necessary examination, examination by the head of the department, organization of a concilium to clarify the tactics of management. Provision of emergency medical care when indicated, timely transfer to the intensive care ward or neonatal intensive care unit	gross
41	Compliance with the requirements for medical workers in the wards of joint stay of mother and child: 1) records in medical documents of counseling on the benefits of breastfeeding, the technique and frequency of manual breast milk decanting, visual assessment of breastfeeding to provide practical assistance in the correct positioning and application of the baby to the mother's breast to avoid conditions such as cracked nipples or lactostasis ; 2) Availability of records in medical documents on training the mother (parent or legal representative) in alternative methods of child feeding in the presence of contraindications to breastfeeding; counseling of maternity women on how to maintain lactation in cases of separate stay of newborns	significant
42	Availability of records in medical documentation on daily examination of newborns by a neonatologist, consultations with mothers on care, prevention of hypothermia and vaccinations	significant
	Availability of supporting documentation on compliance with the requirements for the organization	

43	of consultations by specialized professionals, with treatment and diagnostic measures and recommendations to the mother on examination, treatment and rehabilitation in the presence of three or more micro anomalies of development or detection of congenital pathology of newborns	gross
44	Availability of supporting documentation on compliance with the requirements of medical care in case of emergency conditions in the newborn (asphyxia, respiratory distress syndrome etc.) stabilization of its condition and determination of the degree of readiness for transportation with the mother to the second or third level obstetrics organization	gross
45	Availability of supporting documentation on vaccination of newborns on the basis of voluntary informed consent of parents (mother, father or legal representatives) for prophylactic vaccinations within the timeframe of prophylactic vaccinations in the Republic of Kazakhstan.	gross
46	Availability of supporting documentation on compliance with requirements for all newborns to undergo neonatal screening for phenylketonuria, congenital hypothyroidism and audiologic screening prior to discharge	gross
47	Availability of supporting documentation on compliance with the requirements for neonatologist's assessment of the severity of the condition, stabilization of the condition, assessment of the degree of readiness for transportation in case of emergencies in the newborn, and organization of its transfer with the mother (in coordination with the obstetrician-gynecologist) to the second or third level medical organization	gross
	Availability of supporting documentation on compliance with the requirements in case of suspicion and (or) detection of acute surgical	

48	pathology in a newborn baby, in case of emergency consultation of a doctor specializing in “Pediatric surgery (neonatal surgery)”. After stabilization of vital signs, the newborn shall be transferred to a surgical department of another medical organization (children's or multidisciplinary hospital) or to a neonatal (or children's) surgical department, if there shall be one in the structure of the obstetric medical organization, to provide him/her with appropriate specialized medical care	gross
49	Availability of supporting documentation on compliance with the requirements for transfer to a pediatric inpatient facility for premature newborns after 28 days of age or premature newborns after post-conceptional age of 42 weeks who require further 24-hour medical care	significant
50	Availability of mandatory post-mortem examination of the fetus and placenta in cases of medically indicated termination of pregnancy for suspected congenital anomalies in the fetus	gross
51	Availability of documentation on clinical and pathoanatomical review of all maternal and infant deaths after completion of all pathological investigations	gross
52	Availability of an agreement for provision of paid medical services in health care organizations. Availability of documents establishing the fact of co-payment	gross
53	Availability of medical documentation on consultation with a pediatric cardiologist (cardiac surgeon) when a congenital malformation of the cardiovascular system is detected in obstetrics organizations, and if medically indicated, transfer of the newborn to a specialized hospital	gross
	Availability of medical documentation on the use of opportunities for consultation with	

54	specialized national organizations, through telemedicine network in case of difficulty in verifying the diagnosis of the child, determining the tactics of management. If it is necessary to transfer the child to specialized republican organizations.	significant
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed according to the following criteria: absence of history taking; completeness of history taking; the presence of data on past, chronic and hereditary diseases, hemotransfusions, drug tolerance, allergological status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor history taking; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; conducting diagnostic tests with high , unjustified risk for the patient's health condition, justification of diagnostic tests not included in the clinical protocols; conducting diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the tests performed (in case of planned hospitalization, the tests performed	

55	at the pre-hospital stage are also taken into account), which are evaluated according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with highlighted complications, comorbidities affecting the outcome are not recognized; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical service (assistance) is assessed; 4) timeliness and quality of consultations with specialized professionals, which are evaluated according to the following criteria: lack of consultation, which led to misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take into account the consultant's opinion when making a diagnosis partially affected the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendations partially influenced the outcome of the disease;	significant

	the consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on assessment of objectivity of reasons for untimely consultation and impact of untimely diagnosis on subsequent stages of medical service (assistance) provision; 5) volume, quality and validity of treatment measures, which are assessed by the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the peculiarities of the course of the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred are evaluated, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures; 7) the achieved result, which is evaluated according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical service (assistance); absence of clinical effect of therapeutic and preventive measures	

	due to poor quality history taking and performance of diagnostic tests; absence of expected clinical effect due to ineffective therapeutic, preventive measures without taking into account the specifics of the course of the disease, comorbidities, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, volume and quality of medical care provided	
Requirements for subjects (objects) providing inpatient, inpatient substitution care		
56	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis	gross
57	Availability of an opinion on the compliance of the healthcare entity to provide high-tech medical care	gross
58	Availability of a written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures	significant
	Availability of supporting documentation (form № 085/y “ emergency medical team call card”, register of admissions and refusals to hospitalization, form № 001/y “ medical card of an inpatient”), that the stay of the EMS team or EMS department when organizing primary health care in the emergency room of the hospital does not exceed 10 minutes (time for transferring the patient to the doctor of the emergency room) from the moment	

59	of its arrival in the hospital, except for the need for emergency medical care in emergency situations. After transferring the EMS team or EMS department when organizing primary health care of the patient to the receiving department of the hospital, the nurse conducts distribution of incoming patients (triage according to triage system) into groups, based on the priority of emergency medical care provision. Triage according to triage system (hereinafter referred to as the medical triage) shall be carried out in a continuous and continuous manner. At the end of the assessment, patients are color-coded into one of the triage categories by means of a special-colored tag or colored tape. According to medical triage, there are 3 groups of patients: first group (red zone) - patients whose condition poses an immediate threat to life or who have a high risk of deterioration and require emergency medical care; second group (yellow zone) - patients whose condition poses a potential threat to health or may progress with the development of a situation requiring emergency medical care; third group (green zone) - patients whose condition does not pose an immediate threat to life and health and does not require hospitalization Presence of a record in the medical documentation on determination of the patient by groups of medical triages according to the triage system .	gross
60	Availability of supporting medical documentation (form №001/y “ Medical Card of Inpatient”) on hospitalization of a severe patient who needs constant monitoring of vital functions for medical reasons, by decision of the concilium and notification of the heads of health care organizations with subsequent transfer to another medical organization on the profile of the	significant

	disease for further examination and treatment after stabilization of the condition	
61	Availability of supporting documentation on the medical opinion of the emergency room doctor with a written justification of the refusal in the absence of indications for hospitalization in a health care organization (Journal of admissions and refusals of hospitalization from medical information systems, certificate in form №027/y (refusals of hospitalization)). The nurse of the admission department sends the active to the primary health care organization where the patient is registered	significant
62	Availability of records in medical documentation (Register of patient admission and refusals of hospitalization from the MIS, scheduled hospitalization coupons, “ Medical card of an inpatient” (form №001/y) on indications for hospitalization: the need to provide pre-hospital, qualified, specialized medical care, including the use of high-tech medical services, with round-the-clock medical supervision of patients: 1) on a planned basis - by referral of PHC specialists or other health care organization: 2) on emergency indications (including weekends and public holidays) - regardless of the availability of a referral	significant
63	Availability of supporting medical documentation (Form № 001/y “ Medical Card of Inpatient”) on the examination of heavy patients by the head of the department on the day of hospitalization, and daily thereafter. Patients in a moderately severe condition are examined at least once a week. The results of the examination of the patient are recorded in the medical card with recommendations on further tactics of patient management with the	significant

	obligatory identification of the medical worker making the entries	
64	Availability of the established clinical diagnosis in conjunction with the head of the department no later than three calendar days from the day of hospitalization of the patient in the health care organization in the form № 001/y “ Medical Card of Inpatient”.	significant
65	Availability of supporting documentation (Form № 001/y “ Medical Card of Inpatient”) on daily examination of patients in the hospital by the attending physician, except for weekends and holidays. In case of examination and appointment of additional diagnostic and therapeutic manipulations by the doctor on duty, appropriate entries are made in the medical card. If the patient's condition worsens, the doctor on duty shall notify the head of the department and (or) the attending physician, agree on changes in the process of diagnosis and treatment, and make an entry in the medical card (paper and (or) electronic) version. An entry is made in the electronic version of the medical card no later than 24 hours after the change in the patient's condition. In case of emergency conditions, the frequency of entries depends on the dynamics of the severity of the condition. Inpatient records reflect specific changes in the patient's condition and the need for correction of prescriptions, justification of the prescribed examination and treatment, evaluation and interpretation of the results obtained and the effectiveness of treatment. Frequency of examination for emergency conditions at least every 3 hours, indicating the time of emergency care by hours and minutes.	significant
	Compliance with requirements for planned hospitalization:	

66	1) availability of a referral for hospitalization in the hospital and a coupon for planned hospitalization; 2) hospitalization of the patient in accordance with the established date of planned hospitalization in the referral; 3) availability of clinical and diagnostic (laboratory, instrumental and functional) examinations and consultations of specialized professionals according to the diagnosis of the extract from the medical card of an outpatient form № 052/y.	significant
67	Availability of medical records of consultations or conciliums in case of difficulty in identifying the diagnosis, ineffectiveness of the current treatment, as well as other indications	gross
68	Availability of medical documentation of compliance with discharge criteria, such as: 1) generally accepted treatment outcomes (recovery, improvement, no change, death, transferred to another medical organization); 2) a written sick leave certificate by the patient or his/her legal representative when there is no immediate danger to the patient's life or to others; 3) cases of violation of the internal order of the health care organization, as well as obstruction of the treatment and diagnostic process, infringement of the rights of other patients to receive proper medical care (in the absence of an immediate threat to his/her life), about which a record is made in the medical record.	significant
69	Availability of a discharge epicrisis to the patient upon discharge, indicating the full clinical diagnosis, the scope of diagnostic tests, therapeutic measures and recommendations for further follow-up and treatment. The data on discharge shall be entered into the information systems on a day-to-day basis, indicating the actual time of discharge.	minor

70	Availability of documentation on compliance with the requirements for transfusion of blood components and in case of complications (orders on the establishment of the commission, algorithm of interaction of staff, “Medical card of an inpatient” form № 001/y): Before transfusion of blood components, the recipient is examined for markers of hemotransmissible infections HIV, hepatitis B and C, and after the end of treatment, the discharge epicrisis indicates the need for repeated examination for HIV and hepatitis B and C at the place of residence. The examination of recipients for HIV infection as part of the guaranteed volume of free medical care is carried out in State health-care organizations carrying out activities in the field of HIV prevention Information concerning transfusion and obstetric anamnesis shall be entered in the patient's medical card prior to the start of transfusion therapy: presence of previous transfusions, when and for which reason; whether there were any post-transfusion complications, pregnancies that ended in the birth of children with hemolytic disease of the newborn. In case of development of complications during the biological test, during transfusion or after it, a detailed record(s) is made describing the recipient's condition, vital function monitoring data, treatment methods and their effectiveness. Immediate laboratory control of the recipient's blood and urine is performed.	gross
	Availability of supporting medical documentation on the indications for hospitalization in day hospital at outpatient and polyclinic health care organizations and in hospital at home:	

71	1) acute exacerbation of chronic diseases that do not require round-the-clock medical supervision; 2) active planned rehabilitation of a group of patients with chronic diseases subject to dynamic monitoring; 3) follow-up treatment of the patient on the next day after the course of inpatient treatment on medical grounds; 4) second and third stage medical rehabilitation courses; 5) palliative care; 6) orphan diseases in children associated with a high risk of infectious complications and requiring isolation during seasonal viral diseases to receive regular substitute enzyme and antibacterial therapy. The indications for hospitalization in a day hospital at a 24-hour hospital shall be: 1) carrying out operations and interventions with special preoperative preparation and resuscitation support; 2) performance of complex diagnostic tests that require special preliminary preparation and are not available in outpatient and polyclinic health care organizations; 3) monitoring of patients whose treatment involves transfusion of blood products, intravenous infusions of blood substitutes, specific hyposensitizing therapy, injections of potent drugs, intra-articular injections of drugs; 4) treatment on the next day after inpatient treatment if there are indications for early discharge after surgical treatment; 5) palliative care; 6) chemotherapy, radiation therapy, correction of pathological conditions arising after specialized treatment of oncologic patients	significant
	Availability of medical documentation on the examination of persons for clinical indications of HIV infection upon detection of the	

following diseases, syndromes and symptoms:

1) enlargement of two or more lymph nodes of more than 1 month duration, persistent, generalized lymphadenopathy;

2) fever of unclear etiology (persistent or recurrent for more than 1 month);

3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained loss of 10% of weight or more;

4) chronic diarrhea for 14 days or more (in children), unexplained chronic diarrhea for more than a month;

5) seborrheic dermatitis, pruritic papular rash (in children);

6) angular cheilitis;

7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis);

8) shingles;

9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis, isosporosis, extrapulmonary histoplasmosis, strongyloidiasis, actinomycosis);

10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, except tuberculosis of peripheral lymph nodes;

11) hairy leukoplakia of the oral cavity, linear erythema of the gums;

12) severe protracted recurrent pneumonia and chronic bronchitis that do not succumb to conventional therapy (two or more times during the year), asymptomatic and clinically expressed lymphoid interstitial pneumonia;

13) sepsis, protracted and recurrent purulent-bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis, meningoencephalitis, bone and joint infections, purulent myositis,

72	Salmonella septicemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) pneumocystis pneumonia; 15) infections caused by the herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of the disease) skin and mucous membranes, including the eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unclear etiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the esophagus, bronchi, trachea, lungs, oral and nasal mucous membranes; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unclear etiology; 26) protracted recurrent pyoderma that does not respond to conventional therapy; 27) severe chronic inflammatory diseases of the female genital sphere of unclear etiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis after 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhea, genital herpes, viral papillomatosis etc.) with an established diagnosis; 31) viral hepatitis B and C, with confirmed diagnosis; 32) extensive plumose condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum; 34) primary dementia in previously healthy individuals; 35) patients with hemophilia and other diseases who systematically	gross

	receive transfusion of blood and its components; 36) generalized cytomegalovirus infection.	
73	Availability of an agreement for provision of paid medical services in health care organizations. Availability of documents establishing the fact of co-payment	gross
	Availability of medical documentation on compliance with the following requirements for the examination of temporary incapacity for work, issuance of a sheet and certificate of temporary incapacity for work (Form № 001/y “Medical Card of Inpatient”, form 052/y “ Medical Card of Outpatient”, stubs of sheets on temporary incapacity of patients, form № 025/y “Register for Recording Conclusions of Medical Consultative Board”, form № 029/y "Book of Registration of certificates of temporary incapacity for work”, form № 037/y “Certificate №_____ ____ on temporary incapacity of a student, college or vocational school pupil, sickness, quarantine and other reasons for absence of a child attending school or pre-school organization (underline as necessary) ", form № 038/y "Certificate №____ __ on temporary incapacity" and other): 1) availability of examination of the person and recording of data on his/ her state of health in the medical card of an outpatient (inpatient) patient justifying the need for temporary release from work; 2) issuance of a temporary incapacity certificate and certificate of temporary incapacity on the day of discharge of persons under inpatient treatment (including day hospitals, rehabilitation centers) for the entire period of inpatient treatment; 3) closing the temporary incapacity certificate and certificate of temporary incapacity on the date of	

74	discharge from the hospital if the person's ability to work has been fully restored; 4) prolongation to persons who continue to be temporarily incapacitated for a period of time, taking into account the time required for his/her visit to a medical worker of a polyclinic or calling a medical worker at home (but not more than one calendar day). Persons who received treatment outside the region of residence, the time required to arrive at their place of permanent residence is taken into account (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work in case of injuries sustained under the influence of alcohol or drugs, as well as in case of acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and certificate of temporary incapacity for work to persons suffering from mental illness in case of untimely application to a medical organization for the past days by the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical worker (psychiatrist) together with the head of the medical organization; 7) issuance of a sick leave certificate and certificate of temporary incapacity to persons referred by court decision for forensic medical or forensic psychiatric examination and recognized as incapable of work from the day of admission to the examination; 8) issuance of a sick leave certificate and a certificate of temporary incapacity at the same time to a person who combines training with work.	significant
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) of the clinical audit conducted by the Patient Support	

	Service and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed by the following criteria: absence of history taking; completeness of history taking; the presence of data on past, chronic and hereditary diseases, hemotransfusions, tolerance of drugs , allergological status; development of complications due to tactical errors in the course of treatment and diagnostic measures due to poor quality of history taking; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; performance of diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in clinical protocols; conducting diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the tests performed (in case of planned hospitalization, the tests performed at the pre-hospital stage are also taken into account), which are evaluated according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, concomitant diseases and	

75	complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, comorbidities affecting the outcome are not recognized; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the results of the examination. The assessment of the impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical service (assistance) shall be carried out; 4) timeliness and quality of consultations with specialized professionals, which are evaluated according to the following criteria: lack of consultation, which led to misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take into account the consultant's opinion when making a diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; the consultant's opinion was wrong and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical service (assistance);	significant

	5) volume, quality and validity of treatment measures, which shall be assessed by the following criteria: absence of treatment in the presence of indications prescription of treatment in the absence of indications prescription of ineffective treatment measures without taking into account the peculiarities of the course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy that led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred are evaluated, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures; 7) the achieved result, which is evaluated according to the following criteria: achievement of the expected clinical effect with compliance with the technology of medical service (assistance); lack of clinical effect of therapeutic and preventive measures due to poor history taking and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy;	

	presence of polypragmasy, which caused the development of undesirable consequences; 8) quality of medical documentation, which is assessed by the availability, completeness and quality of records in primary medical documentation, intended for recording data on the state of health of patients, reflecting the nature, volume and quality of medical care provided	
	Availability of documentation on compliance with the following steps for post-mortem examinations: 1) Post-mortem examination of corpses after doctors have ascertained biological death, after the medical card of an inpatient or the medical card of an outpatient has been submitted with a written order from the chief physician or his deputy for the medical (treatment) part of the health care organization to send for a pathoanatomical autopsy; 2) registration of post-mortem examination results in the form of pathoanatomical diagnosis (pathoanatomical diagnosis includes: main disease, complication of the main disease, concomitant disease, combined main disease); 3) transfer of the medical card of an inpatient or medical card of an outpatient with the pathoanatomical diagnosis entered into it to the medical archive of the health care organization no later than ten working days after the post-mortem examination; 4) conducting clinical and pathoanatomical dissection in cases of death of patients in health care organizations; 5) pathoanatomical autopsy in cases of suspected acute infectious, oncological diseases, pathology of childhood, lethal outcome in connection with medical manipulations in order to establish the cause of death and clarify the diagnosis of the disease with fatal outcome;	

76	6) organizing by the chief physician and the head of the pathoanatomical department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathoanatomical bureau, centralized pathoanatomical bureau and pathoanatomical department of medical records of inpatients for all deceased patients for the previous day not later than 10 a.m. of the day following the establishment of the fact of death; 8) registration of: - medical certificate of death (preliminary, final) by a doctor in the specialty of “pathological anatomy (adult, pediatric)” on the day of post-mortem examination; - medical certificate of perinatal death (preliminary, final) by a doctor in the specialty of “pathological anatomy (adult, pediatric)” on the day of the post-mortem examination; 9) registration of the autopsy results in the form of a post-mortem examination report; 10) written notification to the forensic investigative authorities to resolve the issue of transferring the corpse for forensic medical examination in case of detection of signs of death through violence and termination of post-mortem examination of the corpse; 11) availability of a written notification of a doctor specializing in “pathological anatomy (adult, pediatric)” in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service, immediately after their detection; 12) post-mortem examination of the placenta: - in case of stillbirth; - in case of all diseases of newborns detected at the time of birth;	gross

	- in cases suspected of hemolytic disease of the newborn; - in cases of early discharge and dirty water; - in cases of maternal illness with fever in the last trimester of pregnancy; - in case of obvious anomalies in the development or attachment of the placenta; - suspected congenital anomalies of the fetus; - cases of pre-eclampsia, eclampsia 13) compulsory registration of a fetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) establishment of post-mortem examination, depending on the complexity, into the following categories: - first category; - second category; - third category; - fourth category; 15) Establishment of the category of post-mortem examination by a doctor specializing in “pathological anatomy (adult, pediatric)” and the reason for the divergence of diagnoses when the final clinical and pathoanatomical diagnoses diverge 16) availability of detailed analysis with determination of the profile and categories of iatrogenesis in all cases of iatrogenic pathology identified as a result of post-mortem examination	
77	Availability of a written application of the spouse, close relatives or legal representatives of the deceased or a written will issued by the person during his/her lifetime to release the corpse without post-mortem examination, if there is no suspicion of death through violence	significant
	Availability of a record by a medical worker in the medical documentation with subsequent collection of biological materials to determine the content of a psychoactive substance and recording the results in the medical card when signs of	

78	psychoactive substance use are detected during the application for medical assistance to a health care organization without issuing a medical examination conclusion to establish the fact of psychoactive substance use and state of intoxication.	minor
79	Availability of medical documentation on treatment and diagnostic measures, drug provision, organization of therapeutic nutrition and appropriate care of the patient from the moment of admission to the health care organization (Medical card of inpatient" form № 001/y)	significant
80	Availability of medical documentation on the use of opportunities for consultation with specialized national organizations, through telemedicine network in case of difficulty in verifying the diagnosis of the child, determining the tactics of management. If necessary, the child shall be transferred to specialized republican organizations.	significant
81	Availability of medical documentation on the provision of supportive care (support for adequate feeding, water balance, pain control, fever management, oxygen therapy)	significant
82	Availability of medical documentation of the use of less painful alternative treatments, if available, that are as effective, to avoid unnecessary painful procedures	significant
83	Availability of medical documentation on daily examination of the child by a doctor, examination by the head of the department (on admission on the first day, repeatedly at least once a week)	significant
	Availability of medical documentation on compliance with the requirements of anesthesiology and resuscitation care: 1) provision of specialized medical care to patients in emergency and planned procedures, including high-tech medical services;	

84	2) determination of the method of anesthesia, implementation of medical preoperative preparation and implementation of different methods of anesthesia for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring of patients' condition in the postanesthetic period in the post anesthesia care units until recovery of consciousness and stabilization of the function of vital organs; 4) assessment of the degree of dysfunction of vital organs and systems and implementation of an expanded set of resuscitation and intensive care measures in various critical situations, including methods of extracorporeal detoxification, hyperbaric oxygenation, electrocardiostimulation; 5) intensive monitoring (express control of the state of life support systems, as well as metabolism with the use of laboratory and functional diagnostics methods, respiratory and circulatory monitoring), full and targeted correction of disorders; 6) carrying out resuscitation measures for patients (if indicated) in other departments; 7) establishing indications for further treatment of patients in OARIT, as well as transfer of patients from OARIT to specialized departments after stabilization of the function of vital organs with recommendations for treatment and examination for the next 24 hours; 8) consulting doctors of other departments on issues of practical anesthesiology and resuscitation; 9) analyze the efficiency of the department and the quality of medical care, develop and implement measures to improve the quality of medical care and reduce the mortality rate	significant
85	Availability of medical documentation on compliance of	significant

	treatment and diagnostic measures with the recommendations of clinical protocols	
86	Availability of medical documentation on provision of the first stage of medical rehabilitation for the main disease (form № 001/y “Medical card of inpatient”, “form № 047/y” rehabilitation card).	significant
87	Availability of medical documentation on the examination by the head of the department upon admission of neurosurgical patients and subsequently on the necessity of the disease (Medical card of inpatient form № 001/y)	significant
Requirements for the subjects (objects) providing outpatient and polyclinic care (primary health care and consultative-diagnostic care)		
88	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis	Gross
89	Presence of written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures	significant
90	Availability of medical records of an outpatient on compliance of treatment and diagnostic measures with recommendations of clinical protocols	significant
91	Availability of documentation on compliance with the following requirements when organizing and conducting a medical consultative board: 1) availability of the order of the head of the medical organization: - on the establishment of the medical advisory commission; - on the composition, number of members (at least three doctors), - the work and schedule of the medical consultative board 2) availability of the conclusion of the medical consultative board	significant

92	Availability of documentation on compliance by primary health care organizations in conducting preventive medical examinations of target population groups: 1) availability of lists of target groups of persons subject to screening examinations; 2) ensuring continuity with specialized medical organizations to conduct these examinations; 3) informing the population about the need to undergo screening examinations; 4) entering data on passing of screening examinations in the medical information system; 5) monthly analysis of the conducted screening examinations with submission of information to local public health authorities by the 5th day of the month following the reporting month following the reporting month.	significant
93	Availability of documentation on compliance with the levels of provision of medical rehabilitation to patients: 1) primary level - medical organizations of primary medical and sanitary care that have in their structure a rehabilitation room/unit, day hospital and provide medical rehabilitation to patients whose condition is assessed from 1 to 2 points on the Rehabilitation routing scale (hereinafter referred to as the RRS); 2) secondary level - medical organizations that have specialized departments and (or) centers in their structure, carrying out medical rehabilitation in outpatient, inpatient substitution and inpatient conditions, providing medical rehabilitation to patients whose condition is assessed from 2 to 4 points according to the RRS; 3) tertiary level - specialized medical organizations with departments and (or) centers providing medical rehabilitation, including with the use of high-tech services, in outpatient,	significant

	inpatient substitution and inpatient settings, to patients whose condition is assessed from 2 to 4 points on the RRS.	
94	Availability of documentation on compliance of TB care at the outpatient and polyclinic level with the following requirements: 1) carrying out information and awareness-raising work on prevention, early detection of tuberculosis; 2) planning (formation of lists of persons to be examined, drawing up a schedule), organization and conduct of fluorographic examination with registration of the examination results in medical documentation; 3) planning (compiling lists of persons to be examined, drawing up a schedule), organizing and conducting tuberculin diagnostics of children and adolescents, documenting the results of the examination in medical records, and conducting follow-up examinations of tuberculin-positive children); 4) referral for examination of persons suspected of tuberculosis according to the diagnostic algorithm of examination 5) referral of persons with positive results of fluorographic examination, children and adolescents with first-time positive and hyperergic tuberculin test, with increase of tuberculin sensitivity by 6 mm or more, children with adverse reactions and complications to tuberculosis vaccination to a phthisiatrist; 6) planning, organization and implementation of tuberculosis vaccination; 7) controlled treatment of latent tuberculosis infection (hereinafter referred to as LTI) as prescribed by a phthisiatrist, including in video monitoring mode; 8) examination of exposed persons;	gross

	9) outpatient directly supervised or video-observed treatment of TB patients; 10) diagnosis and treatment of adverse reactions to TB drugs as prescribed by a phthisiatrist; 11) diagnosis and treatment of concomitant diseases; 12) maintenance of medical records of TB patients on outpatient treatment, including multidrug-resistant and extensively drug-resistant TB; 13) regular data entry into the National Register of tuberculosis patients within the scope of competence	
95	Availability of documentation on compliance with the requirements for oncologic care in the form of outpatient care: Formation of groups of persons at risk of developing oncologic diseases; Examination by a doctor to determine the patient's condition and establish a diagnosis; laboratory and instrumental examination of the patient in order to make a diagnosis; dynamic monitoring of oncologic patients; selection and referral for hospitalization of oncological patients to receive specialized medical care, including high-tech medical services; additional examination of persons with suspected MN in order to verify the diagnosis; determining the patient's management and treatment tactics; conducting outpatient antitumor therapy; conducting outpatient antitumor therapy	significant
96 7	Availability of mandatory confidential medical screening for HIV infection of persons on clinical and epidemiological indications, including sexual partners of pregnant	significant

	women, persons who applied voluntarily and anonymously	
97	Availability of documentation on compliance with the requirements of the following activities by an obstetrician-gynecologist when a woman first applies for pregnancy and wishes to keep it: 1) availability of history taking, presence of diseases in the pregnant woman and relatives (diabetes mellitus, arterial hypertension, tuberculosis, mental disorders, oncologic diseases etc.), birth of children with congenital malformations and hereditary diseases; 2) presence of a record of diseases (somatic and gynecological), surgeries, transfusions of blood and its components in childhood and adulthood; 3) presence of a “risk” group for congenital and hereditary pathology for referral to a doctor in the specialty of “Medical Genetics” (without ultrasound screening and analysis of maternal serum markers) for the following indications: the age of the pregnant woman is 37 years and older, presence in the anamnesis of cases of pregnancy termination on genetic grounds and/or birth of a child with CHD or chromosomal pathology, presence in the anamnesis of cases of birth of a child (or relatives) with a monogenic hereditary disease, family carrier of a chromosomal or gene mutation, aggravated obstetric history (stillbirth, habitual non-pregnancy, etc.); 4) availability of the result of blood sampling of pregnant women for analysis of maternal serum markers in the first trimester of pregnancy and appointment of ultrasound screening in the first, second and third trimesters of pregnancy; 5) Availability of a record of reproductive features;	significant

	6) the presence of a record of the spouse's health status, blood group and Rhesus affiliation; 7) Availability of a record of the nature of production, where the spouses work, bad habits; 8) availability of examination for early registration of pregnant women up to 12 weeks and registration on the day of detection of pregnancy for timely examination; 9) presence of contraindications to carrying the pregnancy; 10) availability of a management plan taking into account the identified factors	
	Availability of documentation on compliance with the requirements of an obstetrician-gynecologist for the provision and organization of obstetric and gynecological care to women during pregnancy, after childbirth, provision of family planning and reproductive health services, as well as prevention, diagnosis and treatment of gynecological diseases of the reproductive system 1) availability of visits for dispensary monitoring of pregnant women for the prevention and early detection of complications of pregnancy, childbirth and the postpartum period, with the allocation of women “according to risk factors”; 2) availability of the results of prenatal screening, a comprehensive examination of pregnant women to identify the risk group for chromosomal abnormalities and congenital malformations (hereinafter referred to as the CM) of the intrauterine fetus; 3) timely hospitalization of pregnant women in need of hospitalization in day care hospitals, pregnancy pathology departments of inpatient-level medical organizations providing obstetric and gynecological care, specialized medical organizations with extragenital pathology, in	

98	compliance with the principles of regionalization of perinatal care; 4) referral of pregnant women, women in labor and delivery for specialized care with medical supervision, including the use of high-tech medical services, to medical organizations at the republican level; 5) availability of records on prenatal education of pregnant women on preparation for childbirth, including partner births, availability of information for pregnant women on warning signs, effective perinatal technologies, principles of safe motherhood, breastfeeding and perinatal care; 6) patronization of pregnant women and maternity women as indicated; 7) counseling and providing services on family planning and reproductive health care; 8) identification of sexually transmitted infections for referral to specialized professionals; 9) availability of examination of women of fertile age with the appointment, if necessary, of in-depth examination using additional methods and involvement of specialized professionals for timely detection of extragenital and gynecologic pathology and taking them on the dispensary register; 10) based on the results of the examination, inclusion of a woman in the group of dynamic monitoring of women of fertile age, depending on the state of reproductive and somatic health for timely preparation for the planned pregnancy in order to improve the outcome of pregnancy for mother and child; 11) availability of preventive examinations of the female population for early detection of extragenital diseases; 12) availability of examination and treatment of gynecological patients using modern medical technologies; 13) availability of identified and examined gynecological patients for	gross	

	preparation for hospitalization in specialized medical organizations; 14) results of preventive medical examination of gynecological patients, including rehabilitation and sanatorium-resort treatment; 15) the number of small gynecologic surgeries performed using modern medical technologies; 16) lists of pregnant women, maternity women and gynecological patients to ensure continuity of interaction in examination and treatment 17) availability of expert examination of temporary incapacity for pregnancy, childbirth and gynecological diseases, determination of the necessity and terms of temporary or permanent transfer of an employee for health reasons to another job, referral for medical and social assessment of women with signs of permanent loss of working capacity	
99	Availability of results and additional data of follow-up examinations and investigations in the Individual Card of a pregnant and postpartum woman and the Exchange Card of a pregnant and postpartum woman at each visit of a pregnant woman to an obstetrician-gynecologist	significant
100	Availability of home care by a midwife or foster nurse for pregnant women, who do not show up for an appointment within 3 days after the scheduled date	significant
101	Availability of the conclusion of the medical consultative board on possible pregnancy in women with contraindications to pregnancy due to extragenital pathology	significant
102	Availability of an agreement for provision of paid medical services in health care organizations. Availability of documents establishing the fact of co-payment	gross
	Availability of documentation on compliance by the paramedical staff	

103	of the medical unit of the educational organization with the following requirements: 1) availability of a unified list of students in educational organizations ; 2) availability of the list of students (target groups) subject to screening examinations; 3) organization and implementation of immunoprophylaxis with subsequent post-vaccinal observation of the vaccinated person; 4) control over compliance with the deadlines for compulsory medical examinations of all school staff and food service workers; 5) keeping accounting and reporting documentation	significant
	Availability of medical documentation on compliance with the following requirements for the examination of temporary incapacity for work, issuance of a sheet and certificate of temporary incapacity for work (Form № 001/y “Medical Card of Inpatient”, form 052/y “ Medical Card of Outpatient”, stubs of sheets on temporary incapacity of patients, form № 025/y “Register for Recording Conclusions of Medical Consultative Board”, form № 029/y "Book of Registration of certificates of temporary incapacity for work”, form № 037/y “Certificate №_____ ____ on temporary incapacity of a student, college or vocational school pupil, sickness, quarantine and other reasons for absence of a child attending school or pre-school organization (underline as necessary) ", form № 038/y "Certificate №____ __ on temporary incapacity" and other): 1) examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient) patient justifying the need for temporary release from work; 2) issuance of a sheet and certificate of temporary incapacity for work on the day of discharge of persons	

104	under inpatient treatment (including day hospitals, rehabilitation centers) for the entire period of inpatient treatment; 3) closing of the temporary incapacity certificate and certificate of temporary incapacity for work by the date of discharge from the hospital, if the ability to work has been fully restored; 4) extension of the temporary disability sick leave certificate and certificate of temporary incapacity for work for a period of time, taking into account the time required to visit a medical worker of the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Persons who received treatment outside the region of residence, the time required to arrive at the place of his/her permanent residence (but not more than four calendar days) is taken into account; 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and certificate of temporary incapacity for work for persons suffering from mental illness in case of untimely application to a medical organization for the past days by the conclusion of the medical consultative board of a psychoneurological dispensary or a medical worker (psychiatrist) together with the head of the medical organization; 7) issuance of a sick leave certificate and a certificate of temporary incapacity for work to persons referred by court decision for forensic medical or forensic psychiatric examination and recognized as incapable of work from the day of admission to the examination; 8) issuance of a sick leave certificate of temporary incapacity for work	significant

	and a certificate of temporary incapacity for work to a person who combines training with work.	
	Compliance with the following requirements when issuing a sick leave certificate and certificate of temporary incapacity for work for maternity: - a sick leave certificate or certificate of temporary incapacity for work for pregnancy and childbirth is issued by a medical worker (obstetrician-gynecologist) or, in his/ her absence, by a physician, together with the head of the department after the conclusion of the medical advisory board from thirty weeks of pregnancy for a period of one hundred and twenty-six calendar days (seventy calendar days before childbirth and fifty-six calendar days after childbirth) in the case of normal labor. Women living in territories affected by nuclear tests shall be issued a sick leave certificate or certificate of incapacity for maternity work from twenty-seven weeks of pregnancy and childbirth for one hundred and seventy calendar days (ninety-one calendar days before childbirth and seventy-nine calendar days after childbirth) in the case of normal childbirth; 2) women who have temporarily left their permanent place of residence within the Republic of Kazakhstan, a sick leave certificate or certificate of temporary incapacity for work for pregnancy and childbirth shall be issued (prolonged) in the medical organization where the birth took place or in the women's consultation (office) at the place of observation according to the discharge (exchange card) of the obstetric organization 3) in case of complicated childbirth, birth of two or more children, a sick leave certificate or certificate of temporary incapacity for work is extended for an additional fourteen calendar days by a medical worker (obstetrician-gynecologist), or in his/ her absence - by a doctor, together	

105	with the head of the department, after the conclusion of the medical consultative board at the place of observation according to the discharge of the obstetric health care organization. In such cases, the total duration of prenatal and postnatal leave shall be one hundred and forty calendar days (seventy calendar days before delivery and seventy calendar days after delivery). Women living in the territories affected by nuclear tests, in case of complicated childbirth, birth of two or more children, a sick leave certificate or certificate of temporary incapacity for work is extended for an additional fourteen calendar days, the total duration of prenatal and postnatal leave shall be one hundred and eighty-four days (ninety-one calendar days before childbirth and ninety-three calendar days after childbirth); 4) In the case of births between twenty-two and twenty-nine weeks of pregnancy and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, the woman shall be issued a sick leave certificate or certificate of incapacity for work for seventy calendar days after the birth. In the case of births between twenty-two and twenty-nine weeks of pregnancy and the birth of a dead fetus or a child with a body weight of five hundred grams or more, who died before seven days of life, the woman shall be issued a sick leave certificate or certificate of temporary incapacity for work for fifty-six calendar days after childbirth; 5) women living in the territories affected by nuclear testing, in the case of childbirth between twenty-two and twenty-nine weeks of pregnancy and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, a sick leave certificate or certificate of temporary incapacity for work shall be issued	significant

for ninety-three calendar days after childbirth.

Women living in the territories affected by nuclear tests, in the case of childbirth at twenty-two to twenty-nine weeks of pregnancy and the birth of a dead fetus or a child with a body weight of five hundred grams or more who died before seven days of life, a sick leave certificate or certificate of temporary incapacity for work shall be issued for seventy-nine calendar days after childbirth;

6) When a woman applies for a certificate of temporary incapacity for work during pregnancy, maternity leave is calculated cumulatively and is granted in full regardless of the number of days actually used before childbirth.

If a woman applies for a certificate of temporary incapacity for work after childbirth, only the leave after childbirth is granted for the duration provided for in this paragraph;

7) in case of pregnancy during the period when a woman is on paid annual labor leave or unpaid leave to care for a child up to the age of three , a certificate of temporary incapacity for work shall be issued for all days of maternity leave, except as provided for in part two of subparagraph 6) of this paragraph;

8) in case of death of the mother during childbirth or in the postpartum period, a sick leave certificate or certificate of temporary incapacity for work shall be issued to the person caring for the newborn;

9) in case of an operation for artificial termination of pregnancy, a sick leave certificate or certificate of temporary incapacity for work shall be issued by a doctor together with the head of the department for the period of stay in the hospital and outpatient department where the operation was performed, and in case of a complication - for the entire period of temporary incapacity for work.

	In case of spontaneous abortion (miscarriage), a sick leave certificate or certificate of temporary incapacity for work shall be issued for the entire period of temporary incapacity for work; 10) in case of embryo transfer surgery, a sick leave certificate or certificate of temporary incapacity for work shall be issued by the medical organization that performed the surgery, from the day of embryo transfer until the pregnancy is established. Persons who have adopted a newborn child (children), as well as the biological mother in the case of surrogacy directly from the maternity hospital a sick leave certificate or certificate of temporary incapacity for work shall be issued from the date of adoption and until the expiration of fifty-six calendar days from the date of birth of the child	
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed according to the following criteria: absence of history taking; completeness of history taking; presence of data on past, chronic and hereditary diseases, hemotransfusions, drug tolerance, allergological status; development of complications as a result of tactical errors made in the course of treatment and diagnostic measures due to poor history taking; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or absence of a conclusion based on the results of	

	diagnostic tests, resulting in incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; performance of diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in clinical protocols; diagnostic tests that are uninformative for making a correct diagnosis and resulted in unjustified increase of treatment time and cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalization, the investigations conducted at the pre-hospital stage shall be taken into account), which shall be assessed according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome is not distinguished with the distinguished complications, comorbidities affecting the outcome are not recognized; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of	

106	incorrect and (or) untimely diagnosis on the subsequent stages of medical service (assistance) is assessed; 4) timeliness and quality of consultations with specialized professionals, which are evaluated according to the following criteria: lack of consultation, which led to misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take into account the consultant's opinion when making a diagnosis partially affected the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendations partially influenced the outcome of the disease; the consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on assessment of objectivity of reasons for untimely consultation and impact of untimely diagnosis on subsequent stages of medical service (assistance); 5) volume, quality and validity of treatment measures, which are assessed by the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the peculiarities of the course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new	significant

	pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is assessed according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical service (assistance); absence of clinical effect of therapeutic and preventive measures due to poor history taking and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the availability, completeness and quality of records in primary medical documentation designed to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided	
107	Availability of documentation on compliance with the requirements to provide a guaranteed volume of free medical care	gross
	Availability of documentation on compliance with the requirements of surgical (abdominal, thoracic, coloproctological) care to patients at the outpatient and polyclinic level 1) Availability of records by a doctor specializing in “Therapy (adolescent therapy, dietetics)”, “Emergency and	

	urgent medical care", "General medical practice (family medicine)" when a patient comes to a health care organization providing primary health care with complaints and symptoms of surgical nature, referrals for patient consultation to specialized professionals. 2) whether indications for surgery, assessment of the scope of surgical intervention, type of anesthesia, risks of intra- and postoperative complications, obtaining the patient's written consent for the operation have been determined in the case of surgical treatment at the outpatient and polyclinic level (in CDP organizations and inpatient substitute care). 3) Whether a specialized professional of the outpatient clinic monitors the condition of patients discharged from the hospital in the postoperative period.	
108	4) In the case of long-term treatment of patients after surgical intervention , a specialized professional should consult with doctors of medical control commissions and, based on their conclusions, refer patients to medical and social assessment (hereinafter referred to as the MSA) in order to conduct an initial examination and (or) re-evaluation (re-evaluation) to determine temporary (up to 1 year) and permanent disability) 5) Compliance with the requirement for a profile specialist of a polyclinic (number district, district, city), clinical and diagnostic department/ center in case of suspicion and (or) establishment of the diagnosis of acute surgical pathology to ensure the call and transportation of the patient by an ambulance brigade to a hospital with round-the-clock medical supervision, providing urgent surgical care; in case of unstable hemodynamics and life-threatening condition of the patient - to the nearest hospital	gross

	6) compliance with the requirements of temporary disability expert assessment	
109	Availability of documentation on compliance with the requirements of primary health care organizations for dynamic monitoring of persons with chronic diseases, compliance with the frequency and timing of observation, the mandatory minimum and frequency of diagnostic tests	significant
110	Documentation of compliance with requirements for active home visits by primary health care staff	significant
111	Availability of documentation on compliance with pediatric care requirements: 1) consultative, diagnostic, therapeutic and preventive care, dynamic monitoring; 2) patronages and active visits to pregnant women, newborns and infants according to the universal-progressive model of the patronage service; 3) Planning, organizing and carrying out vaccination in accordance with the terms of preventive vaccinations; 4) referring children for consultations with specialized professionals when indicated; 5) detection of acute and chronic diseases, timely implementation of emergency and planned treatment measures; (6) Referral of children to a 24-hour hospital, day hospital and organization of in-patient care at home, if indicated; 7) dynamic monitoring of children with chronic diseases on the dispensary register, treatment and recuperation; (8) Restorative treatment and medical rehabilitation of children; (9) Screening of newborns and young children; (10) Organization of children's health improvement before they enter preschool or school institutions ;	significant

	(11) Informational work with parents and family members or legal representatives on issues of rational nutrition, prevention of childhood diseases and formation of a healthy lifestyle.	
112	Availability of documentation on compliance with the requirements for traumatological and orthopedic care at the outpatient and polyclinic level 1) assessment by a traumatologist of the patient's general condition, his/her traumatological and orthopedic status, provision of emergency medical care, additional laboratory and instrumental tests to clarify the diagnosis and, if medically indicated in cases requiring inpatient medical care, referral of the patient to the appropriate departments where specialized medical care in the traumatological and orthopedic profile is provided. 2) In the absence of medical indications for hospitalization, a patient with injuries of musculoskeletal system shall be consulted on further follow-up and treatment in outpatient conditions at the place of attachment. 3) Medical care on traumatological and orthopedic profile in primary health care organizations shall be provided by surgeons, doctors of traumatology and orthopedics. 4) Availability of traumatology and orthopedics rooms, trauma centers and carrying out: examination and assessment of the severity of the patient's condition, his/her traumatological and orthopedic status, additional laboratory and instrumental tests to clarify the diagnosis and treatment (anesthesia, primary surgical treatment of wounds, closed repositioning of bone fragments, immobilization). 5) implementation of expertise of temporary incapacity for work 6) availability of medical consultative board and referral of patients with persistent signs of	significant

	musculoskeletal system and musculoskeletal system dysfunction to a medical and social assessment commission;	
113	Availability of documentation on compliance with the requirements of neurological care at the outpatient and polyclinic level 1) Neurological diagnostic assistance to patients with neurological diseases is provided upon referral from a primary care physician or other specialized professional within the framework of the guaranteed volume of free medical care. In the absence of a referral from a primary care physician or other specialized professional, or in the case of referrals at the patient's initiative, consultative diagnostic assistance is provided on a paid basis. 2) The primary care physician or other specialized professional carries out further follow-up of the patient after receiving a consultative diagnostic report in accordance with the recommendations of the neurologist who provided consultative diagnostic assistance	significant
	Availability of documentation of compliance with nephrology care, which includes: 1) examination by a doctor, identification of signs of kidney damage and clinical and diagnostic tests according to CP to determine the stage, etiology and degree of disease activity; 2) referral of the patient for consultative-diagnostic assistance with registration of an extract from the medical card of an outpatient patient in the form № 097/y, with data entry into the medical information system (hereinafter referred to as the MIS); 3) formation of risk groups for the development, prevention of progression and development of complications of CKD depending on the stage and nosologic forms, as well as registration and dynamic monitoring of patients with kidney	

		diseases are carried out by primary health care specialists taking into account the recommendations of nephrologists according to CP; 4) selection and referral for hospitalization in the MO for specialized medical care and high-tech medical care, taking into account the recommendations of nephrologists and MDGs according to CP; 5) dynamic monitoring of patients with kidney damage of various genesis, including in the postoperative (post transplantation) period, including monitoring of disease activity, control and correction of immunosuppressive therapy; 6) medical rehabilitation of patients with nephrological diseases, CKD and AKI, including those receiving dialysis therapy and those who have undergone surgery after kidney transplantation (including monitoring the concentration of immunosuppressive therapy drugs, prevention and timely detection of infectious complications); 7) organization and monitoring of provision of patients with kidney diseases (including patients on RRT) with medicines for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions)" 8) carrying out an expert examination of temporary incapacity for work 9) referral for medical and social assessment to determine and establish disability 10) registration and regular entry of data of patients with CKD of 1-5 stages, AKI of all stages according to the international classification of AKI by RIFLE: Risk, Injury, Failure, Lost, End Stage Renal Disease into the IS of the MO with indication of the stage of CKD for monitoring, timely initiation of RRT and ensuring continuity of the patients' route. In case of inaccessibility or	
114		gross	

	unavailability of the IS, patients are registered in the Electronic CKD Registry. Registration of patients with CKD of stages 1 to 3a shall be carried out annually by general practitioners (family physicians), district general practitioners, pediatricians at the PHC level Registration of patients with CKD of stages 3b-5 shall be carried out by nephrologists of the polyclinic, Cabinet, nephrology center.	
115	Availability of documentation on compliance with the requirements of neurosurgical care in outpatient settings 1) Primary health care physician shall: -when patients present with complaints and symptoms of neurosurgical diseases and injuries of the central and peripheral nervous system, prescribe general clinical and radiological examinations (as indicated) and refer them to the neurosurgeon of the health care organization providing medical care at the secondary level to clarify the diagnosis and receive consultative and diagnostic assistance. The referral shall be made in electronic form in medical information systems ; - carry out dynamic follow-up of patients with established diagnosis of neurosurgical diseases according to CP and recommendations of the neurosurgeon; - refers for hospitalization when indicated. 2) Neurosurgical care in outpatient conditions at the secondary level is provided in the form of consultative and diagnostic care and includes: 1) examination by a neurosurgeon; 2) laboratory and instrumental examination of the patient in order to make a diagnosis of neurosurgical diseases and injuries of the central and peripheral nervous system, differential diagnosis;	significant

	3) selection and prescription of treatment for the detected disease according to CP; 4) referral for hospitalization on emergency indications to provide specialized medical care, including with the use of HTMU in inpatient settings; 5) referral for planned hospitalization for the provision of specialized medical care, including with the use of HTMU in hospital-replacing and inpatient settings; 6) expert evaluation of temporary incapacity for work, issuance of a temporary incapacity for work certificate or certificate	
116	Availability of documentation on compliance with the requirements of neurological care at the outpatient and polyclinic level 1) Neurological diagnostic assistance to patients with neurological diseases shall be provided upon referral from a primary care physician or other specialized professional within the framework of the guaranteed volume of free medical care. In the absence of a referral from a primary care physician or other specialized professional, or in the case of referrals at the patient's initiative, consultative diagnostic assistance is provided on a paid basis. 2) The primary care physician or other specialized professional shall carry out further follow-up of the patient after receiving a consultative-diagnostic report in accordance with the recommendations of the neurologist who provided consultative diagnostic assistance.	significant
117	Reasoned registration of the notification on the expert opinion of medical and social assessment, form № 031/y (availability of data for a comprehensive assessment of the state of the organism and the degree of restriction of vital activity)	gross
Requirements for subjects (objects) providing cardiologic, cardiac surgical care		

118	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis	Gross
119	Availability of medical documentation on compliance of treatment and diagnostic measures with the recommendations of clinical protocols	Significant
120	Availability of a written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures	significant
121	Availability of supporting documentation (emergency medical team call card form № 085/y, register of admissions and refusals of hospitalization, Medical card of inpatient form № 001/y) that the stay of the CEMS or EMS team when organizing primary health care in the emergency room of the hospital does not exceed 10 minutes (time for transferring the patient to the doctor of the emergency room) from the moment of its arrival in the hospital, except for cases of emergency medical care in emergency situations . After transferring the EMS team or EMS department when organizing primary health care of a patient to the receiving department of the hospital, the nurse conducts the distribution of incoming patients (triage according to triage system) into groups, based on the priority of emergency medical care. Triage according to triage system (hereinafter referred to as triage) shall be conducted continuously and successively. Upon completion of the assessment, patients are marked with the color of one of the triage categories, in the form of a special-colored tag or colored tape. There are 3 groups of patients according to triage:	Gross

	first group (red zone) - patients whose condition poses an immediate threat to life or who have a high risk of deterioration and require emergency medical care; second group (yellow zone) - patients whose condition poses a potential threat to health or may progress with the development of a situation requiring emergency medical care; third group (green zone) - patients whose condition does not pose an immediate threat to life and health and does not require hospitalization Presence of a record in the medical documentation on determination of the patient by groups of triages according to the triage system.	
122	Availability of documentation on ensuring hospitalization of a severe patient in need of constant monitoring of vital functions for medical reasons, by decision of the concilium and notification of the heads of health care organizations with subsequent transfer to another medical organization according to the profile of the disease for further examination and treatment after stabilization of the condition	significant
123	A medical report with a written justification of refusal in the absence of indications for hospitalization in a health care organization is issued to the patient by the doctor of the reception department. A nurse of the emergency room sends the active to the primary health care organization at the patient's place of attachment	significant
124	Availability of supporting documentation on indications for hospitalization: The need to provide pre-hospital, qualified, specialized medical care, including the use of high-tech medical services, with round-the-clock medical supervision of patients: 1) on a planned basis - by referral of primary health care specialists or other health care organization:	significant

	2) on emergency indications (including weekends and public holidays) - regardless of the availability of a referral	
125	Availability of examination of severe patients by the head of the department on the day of hospitalization, and daily thereafter. Patients in a moderately severe condition are examined at least once a week. The results of the patient's examination are recorded in the medical card with recommendations on further tactics of patient management with obligatory identification of the medical worker making the entries	significant
126	Availability of supporting documentation on the establishment of the main diagnosis in emergency conditions within 24 (twenty-four) hours from the moment of the patient's admission to a 24-hour hospital on the basis of clinical and anamnestic examination data, results of instrumental and laboratory methods of research with entry in the medical card of an inpatient in form № 001/y, in stable patients - availability of the established clinical diagnosis in conjunction with the head of the department no later than three calendar days from the date of hospitalization	significant
127	Availability of supporting documentation of planned hospitalization in the presence of indicators: - daily electrocardiogram monitoring ; - ergometric study (stress tests, spiroergometry) based on treadmill and/or cycle ergometer; daily blood pressure monitoring;	significant
	Availability of documentation on urgent (round-the-clock, including weekends and holidays) procedures, in particular: - laboratory tests necessary to assess the functional status of organs and systems in the pre- and postoperative period; - electrocardiogram and its analysis;	

128	- echocardiography; - gastroduodenoscopy; - bronchoscopy; - ultrasound examination of the blood vessels; - cardiac catheterization with angiocardiography; - micro-ultrafiltration and dialysis; - albumin dialysis (using molecular adsorbent recirculating system); - extracorporeal membrane oxygenation; - intra-aortic counterpulsation; - pacemaker implantation; - X-ray endovascular treatment methods.	significant
129	Availability of documentation on hospitalization to the catheterization laboratory, bypassing the admission department, intensive care unit (ward) if the patient is diagnosed with acute coronary syndrome with segment elevation, acute myocardial infarction	significant
130	Availability of documentation on ensuring daily examination by the attending physician of patients in the hospital except for weekends and holidays. When examining and prescribing additional diagnostic and therapeutic manipulations by the doctor on duty, appropriate entries are made in the medical record. In case of deterioration of the patient's condition, the doctor on duty shall notify the head of the department and (or) the attending physician, agree on changes in the process of diagnosis and treatment, and make an entry in the medical card (paper and (or) electronic) option. A record shall be entered into the electronic version of the medical card no later than 24 hours after a change in the patient's condition. In case of emergency, the frequency of entries depends on the dynamics of the severity of the condition. The records of the hospital doctor reflect specific changes in the patient's condition and the need for correction of prescriptions, justification of the prescribed examination and	significant

	treatment, evaluation and interpretation of the results obtained and the effectiveness of treatment. Frequency of examination for emergency conditions shall be at least every 3 hours, indicating the time of emergency care by hours and minutes.	
131	Availability of documentation on the assessment of the complexity of surgical interventions for congenital heart disease using the Aristotle Basic Scale and the effectiveness of operations in the cardiac surgical unit	significant
132	Availability of documentation on compliance of medical care provision to patients with acute coronary syndrome and (or) acute myocardial infarction by levels of regionalization: 1) at the first level, provision of medical care by emergency medical care organizations, primary medical and sanitary care organizations, as well as organizations providing inpatient care without the possibility of percutaneous coronary interventions to patients with acute coronary syndrome or acute myocardial infarction; 2) at the second level - organizations providing inpatient care with the possibility of percutaneous coronary interventions without a cardiac surgery department; 3) at the third level - organizations providing inpatient care and republican medical organizations with a cardiac surgical department.	significant
133	Availability of supporting documentation of compliance for planned hospitalization: 1) availability of a referral for hospitalization in the hospital and a coupon for planned hospitalization; 2) hospitalization of the patient in accordance with the established date of planned hospitalization in the referral; 3) availability of clinical and diagnostic (laboratory, instrumental and functional) examinations and	significant

	consultations of specialized professionals according to the diagnosis	
134	Availability of a conclusion of consultations or the concilium in case of difficulty in identifying the diagnosis, ineffectiveness of the current treatment, as well as in other indications	significant
135	Availability of supporting documentation during hospitalization at the inpatient level: 1) initial examination of the patient by a physician to determine the patient's condition and establish a preliminary diagnosis; 2) therapeutic and diagnostic non-invasive testing methods to reduce the risk of invasive tests; 3) selecting and prescribing treatment; 4) consultations with other specialists, if necessary	significant
136	Ensuring that a discharge summary is issued to the patient upon discharge, indicating the full clinical diagnosis, the scope of diagnostic tests, therapeutic measures and recommendations for further follow-up and treatment. Discharge data shall be entered into the information systems on a day-to-day basis, indicating the actual time of discharge	significant
137	Availability of documentation of adherence to discharge criteria, specifically: 1) generally accepted treatment outcomes (recovery, improvement, no change, death, transferred to another medical organization); 2) a written sick leave certificate by the patient or his/her legal representative when there is no immediate danger to the patient's life or to others; 3) cases of violation of the internal order of the health care organization, as well as obstruction of the treatment and diagnostic process, infringement of the rights of other patients to receive proper medical	significant

	care (in the absence of an immediate threat to his/her life), about which a record is made in the medical card.	
138	Availability of an agreement for provision of paid medical services in health care organizations. Availability of documents establishing the fact of co-payment	gross
139	Documentation of compliance with blood component transfusion requirements and in case of complications: Before transfusion of blood components, the recipient is examined for markers of hemotransmissible infections HIV, hepatitis B and C, and after the end of treatment, the discharge epicrisis indicates the need for repeated examination for HIV and hepatitis B and C at the place of residence. The examination of recipients for HIV infection as part of the guaranteed volume of free medical care is carried out in State health-care organizations carrying out activities in the field of HIV prevention Information concerning transfusion and obstetric anamnesis is entered in the patient's medical card before transfusion therapy is started: presence of previous transfusions, when and for what reason; whether there were any post-transfusion complications, pregnancies that ended in the birth of children with hemolytic disease of the newborn. In case of development of complications during the biological test, during transfusion or after it, a detailed record(s) is made describing the recipient's condition, vital function monitoring data, treatment methods and their effectiveness. Immediate laboratory control of the recipient's blood and urine is performed.	gross
	Presence of examination of persons on clinical indications for HIV	

	infection upon detection of the following diseases, syndromes and symptoms: 1) enlargement of two or more lymph nodes with duration of more than 1 month, persistent, generalized lymphadenopathy; 2) fever of unclear etiology (persistent or recurrent for a duration of more than 1 month); 3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained loss of 10% of weight or more; 4) chronic diarrhea for 14 days or more (in children), unexplained chronic diarrhea lasting more than a month; 5) seborrheic dermatitis, pruritic papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) zona ignea; 9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis, isosporosis, extrapulmonary histoplasmosis, strongyloidiasis, actinomycosis); 10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, except for tuberculosis of peripheral lymph nodes; 11) hairy leukoplakia of the oral cavity, linear erythema of the gums; 12) severe prolonged recurrent pneumonia and chronic bronchitis not amenable to conventional therapy (two or more times during the year), asymptomatic and clinically expressed lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent and bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis,		

140	meningoencephalitis, bone and joint infections, purulent myositis, Salmonella septicemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) pneumocystis pneumonia; 15) infections caused by herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of the disease) lesions of the skin and mucous membranes, including eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unclear etiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the esophagus, bronchi, trachea, lungs, mucous membranes of the oral cavity and nose; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unclear etiology; 26) protracted recurrent pyoderma, not amenable to conventional therapy; 27) severe chronic inflammatory diseases of the female genitalia of unclear etiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis after 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhea, genital herpes, viral papillomatosis and others) with an established diagnosis; 31) viral hepatitis B and C, with confirmed diagnosis; 32) extensive plumose condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum;	gross

	34) primary dementia in previously healthy individuals; 35) patients with hemophilia and other diseases who systematically receive transfusion of blood and its components; 36) generalized cytomegalovirus infection.	
	Availability of medical documentation on compliance with the following requirements for the examination of temporary incapacity for work, issuance of a sheet and certificate of temporary incapacity for work (form №001/y "Medical card of inpatient", form 052/y " Medical card of outpatient", stubs of patients' certificates of temporary incapacity for work, form № 025/y Register for Recording Conclusions of Medical Consultative Board, form № 029/y "Book of Registration of certificates of temporary incapacity for work", form № 037/y " Certificate №_____ on temporary incapacity of a student, college or vocational school pupil, sickness, quarantine and other reasons for absence of a child attending school or pre-school organization (underline as necessary) ", form № 038/y "Certificate №_____ on temporary incapacity" and other): 1) availability of examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient) justifying the need for temporary release from work; 2) issuance of a sheet and certificate of temporary incapacity for work on the day of discharge of persons under inpatient treatment (including day care centers, rehabilitation centers) for the entire period of inpatient treatment; 3) closing of the certificate of temporary incapacity for work by the date of discharge from the hospital if the ability to work has been fully restored;	

141	4) prolongation of the certificate of temporary incapacity for work and the certificate of temporary incapacity for work for a period of time, taking into account the time necessary for the person to visit a medical worker of the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Persons who received treatment outside the region of residence, the time required to arrive at their place of permanent residence (but not more than four calendar days) is taken into account; 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and certificate of temporary incapacity for work to persons suffering from mental illness in the event of untimely application to a medical organization for the past days upon the conclusion of the medical advisory board of a psychoneurological dispensary or a medical officer (psychiatrist) in conjunction with the head of the medical organization; 7) issuance of a sheet and a certificate of temporary incapacity for work to persons referred by court decision for forensic medical or forensic psychiatric examination and recognized as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work to a person who combines training with work.	significant
142	Compliance with the following requirements in the organization and conduct of the medical consultative board: 1) availability of the order of the head of the medical organization: - on the establishment of the medical consultative board; - on the	significant

	composition, number of members (at least three doctors), - the work and schedule of the medical consultative board 2) availability of the conclusion of the medical consultative board	
143	Availability of supporting documentation on the indications for hospitalization in day hospital at outpatient and polyclinic health care organizations and in hospital at home: 1) exacerbation of chronic diseases that do not require round-the-clock medical supervision; 2) active planned rehabilitation of a group of patients with chronic diseases subject to dynamic monitoring; 3) treatment of the patient on the next day after the course of inpatient treatment on medical grounds; 4) second and third stage medical rehabilitation courses; 5) palliative care; 6) orphan diseases in children associated with a high risk of infectious complications and requiring isolation during seasonal viral diseases to receive regular substitute enzyme and antibacterial therapy. The indications for hospitalization in a day hospital at a 24-hour hospital are: 1) carrying out operations and interventions with special preoperative preparation and resuscitation support; 2) performance of complex diagnostic tests that require special preliminary preparation and are not available in outpatient and polyclinic health care organizations; 3) monitoring of patients whose treatment involves transfusion of blood products, intravenous infusions of blood substitutes, specific hyposensitizing therapy, injections of potent drugs, intra-articular injections of drugs; 4) treatment on the next day after inpatient treatment if there are	significant

	indications for early discharge after surgical treatment; 5) palliative care; 6) chemotherapy, radiation therapy, correction of pathological conditions arising after specialized treatment of cancer patients	
144	Availability of a recovery and rehabilitation department	significant
145	Availability of a cardiology room in the structure of organizations providing outpatient care to the population (district, city, region, republic) and organizations providing in-patient care	significant
146	If it is impossible to establish the diagnosis of CDV in a primary health care organization, referral of the patient for consultation in a clinical diagnostic center for the provision of diagnostic assistance, with a consultation, if necessary, with the involvement of specialized professionals, including consultants from medical organizations at the republican level.	significant
147	Availability of supporting documentation of consultative diagnostic assistance provided to a patient with CDV by a specialized professional referred by a PHC specialist or another specialized professional	significant
148	availability of an opinion on execution of documents for referral for medical and social assessment in the presence of high blood pressure (crisis course), arrhythmia of various genesis, increased frequency of angina attacks and increasing symptoms of heart failure, issuance and prolongation of a sheet or certificate of temporary incapacity for work, and in case of permanent disability (condition after myocardial infarction, aorto-coronary bypass surgery, congestive heart failure)	significant
149	Availability of supporting documentation on treatment and diagnostic measures, drug provision, organization of therapeutic nutrition and appropriate care of the patient	significant

	from the moment of admission to the health care organization.	
150	Availability of supporting documentation on the use of opportunities for consultation with specialized republican organizations, via telemedicine network in case of difficulty in verifying the diagnosis of the child, determining the tactics of management. If necessary, the child shall be transferred to specialized republican organizations.	significant
151	Provision of supportive care (support adequate feeding, maintenance of water balance, pain control, fever management, oxygen therapy)	significant
152	Availability of medical documentation on the provision of the following treatment and diagnostic measures within the framework of primary health care: 1) diagnostic - examination by a PHC specialist, laboratory and instrumental non-invasive research methods; 2) therapeutic, including emergency and urgent medical care, therapeutic manipulations; 3) providing patients with circulatory diseases with prescriptions for medicines and medical devices for free and (or) preferential outpatient provision; 4) preventive - medical examinations , screening preventive medical examinations of target population groups with subsequent health improvement and dynamic monitoring	significant
153	Availability of supporting documentation on the use of less painful, equally effective alternative treatments when available, to avoid unnecessarily painful procedures	significant
	Availability of documentation on compliance with the requirements of anesthesiology and resuscitation care : 1) provision of specialized medical care to patients in emergency and planned procedures, including high-tech medical services;	

154	2) determination of the method of anesthesia, implementation of medical preoperative preparation and implementation of different methods of anesthesia for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring of patients' condition in the postanesthetic period in the post anesthesia care units until recovery of consciousness and stabilization of the function of vital organs; 4) assessment of the degree of dysfunction of vital organs and systems and implementation of an expanded set of resuscitation and intensive care measures in various critical situations, including methods of extracorporeal detoxification, hyperbaric oxygenation, electrocardiostimulation; 5) intensive monitoring (express control of the state of life support systems, as well as metabolism with the use of laboratory and functional diagnostics methods, respiratory and circulatory monitoring), full and targeted correction of disorders; 6) carrying out resuscitation measures to patients (if indicated) in other departments; 7) determination of indications for further treatment of patients in the Anesthesiology, resuscitation and intensive treatment department, as well as transfer of patients from the Anesthesiology, resuscitation and intensive treatment department to specialized departments after stabilization of the function of vital organs with recommendations for treatment and examination for the next 24 hours; 8) consulting doctors of other departments on issues of practical anesthesiology and resuscitation; 9) analyze the efficiency of the department and the quality of medical care, develop and implement measures to improve the quality of medical care and reduce the mortality rate	significant

	Compliance with the following actions when conducting post-mortem examination: 1) conducting post-mortem examination of corpses after the doctors have ascertained biological death, after providing the medical card of an inpatient or medical card of an outpatient with a written order from the chief physician or his deputy for the medical (treatment) part of the health care organization to send for pathoanatomical autopsy; 2) registration of post-mortem examination results in the form of pathoanatomical diagnosis (pathoanatomical diagnosis includes: main disease, complication of the main disease, concomitant disease, combined main disease); 3) transfer of the medical card of an inpatient or medical card of an outpatient with the pathoanatomical diagnosis entered into it to the medical archive of the health care organization no later than ten working days after the post-mortem examination; 4) conducting clinical and pathoanatomical analysis in cases of death of patients in health care organizations; 5) post-mortem examination in cases of suspected acute infectious, oncologic diseases, pediatric pathology, lethal outcome due to medical manipulations in order to establish the cause of death and clarify the diagnosis of a fatal disease; 6) organization by the chief physician and head of the pathoanatomical department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathoanatomical bureau, centralized pathoanatomical bureau and pathoanatomical department of medical records of inpatients for all deceased patients		

155	for the previous day not later than 10 a.m. of the day following the establishment of the fact of death; 8) registration of: - medical certificate of death (preliminary, final) by a doctor specializing in “pathological anatomy (adult, pediatric)” on the day of post-mortem examination; - medical certificate of perinatal death (preliminary, final) by a doctor specializing in “pathological anatomy (adult, pediatric)” on the day of post-mortem examination; 9) registration of the autopsy results in the form of a post-mortem examination report; 10) written notification to the forensic investigative authorities to address the issue of transferring the corpse for forensic medical examination in case of detection of signs of death through violence and termination of post-mortem examination of the corpse; 11) written notification to the doctor specializing in “pathological anatomy (adult, pediatric)” in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service, immediately after their detection; 12) performing a post-mortem examination of the placenta: - In case of stillbirth; - in all neonatal diseases detected at the time of birth; - in cases suspected of hemolytic disease of the newborn; - in cases of early departure of waters and dirty waters; - in cases of maternal illness with fever in the last trimester of pregnancy; - in case of obvious anomalies in the development or attachment of the placenta; - suspected congenital anomalies of the fetus; - cases of pre-eclampsia, eclampsia	gross

	13) compulsory registration of a fetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) establishment of post-mortem examination, depending on the complexity, into the following categories: - first category; - second category; - third category; - fourth category; 15) establishment by a doctor specializing in "pathological anatomy (adult, pediatric)" of the category of post-mortem examination and the reason for the divergence of diagnoses when the final clinical and pathoanatomical diagnoses diverge 16) availability of detailed analysis with determination of the profile and categories of iatrogenesis in all cases of iatrogenic pathology identified as a result of post-mortem examination	
156	Availability of a written application of the spouse, close relatives or legal representatives of the deceased or a written will issued by the person during his/her lifetime to release the corpse without post-mortem examination, if there is no suspicion of death through violence	significant
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed according to the following criteria: absence of history taking; completeness of history taking; availability of data on past, chronic and hereditary diseases, hemotransfusions, tolerance of medicines, allergological status; development of complications due to tactical errors made during treatment	

	and diagnostic measures due to poor history taking; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; conducting diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in the clinical protocols; conducting diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalization, investigations conducted at the pre-hospital stage are taken into account), which are evaluated according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, comorbidities affecting the outcome are not recognized; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed.	

157	Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical service (assistance) is assessed; 4) timeliness and quality of consultations of specialized professionals, which shall be assessed according to the following criteria: Lack of consultation, which led to misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take into account the consultant's opinion when making the diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical service (assistance); 5) volume, quality and validity of treatment measures, which are assessed by the following criteria: absence of treatment in the presence of indications prescription of treatment in the absence of indications; prescribing ineffective therapeutic measures without taking into account the peculiarities of the course of the disease, concomitant diseases and complications;	significant

	implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is assessed according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical service (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, volume and quality of medical care provided	
	The patient has been examined by a doctor in the emergency room of an	

158	inpatient hospital with the completion of an inpatient card, if the patient or his/her legal representative has given written consent to the provision of medical care to the patient	significant
159	Provision by a cardiologist (cardiac surgeon) of a consultative-diagnostic report in the form № 075/y, indicating the results of the conducted examination and treatment, as well as the further treatment of the patient with medical diseases to the primary care physician who referred the patient for consultative services when providing consultative diagnostic assistance	significant
160	In the presence of abnormalities in blood pressure (crisis course), arrhythmias of various genesis, increased frequency of angina attacks and increasing symptoms of heart failure, the cardiologist of the Ministry of Health issues and extends a sheet or certificate of temporary disability, and in case of persistent disability (condition after myocardial infarction, aorto-coronary bypass surgery, congestive heart failure) gives an opinion on drawing up documents for referral for medical and social expert assessment (hereinafter referred to as the MSA)	significant
161	Availability of documentation on emergency hospitalization of a patient with circulatory diseases to the intensive care unit (ward), bypassing the emergency room in case of life-threatening diseases	significant
162	Availability of documentation on hospitalization of a patient diagnosed with acute coronary syndrome (hereinafter - ACS) with segment elevation, acute myocardial infarction (hereinafter - AMI) to the catheterization laboratory, bypassing the admission department, intensive care unit (ward).	significant
	Availability of documentation on the provision of cardiologic (cardiac	

163	surgery) care in inpatient settings, which includes: 1) initial examination of the patient by a doctor in order to determine the patient's condition and establish a preliminary diagnosis; 2) therapeutic and diagnostic examinations to determine the patient's treatment tactics, as well as to reduce the risk of invasive methods of investigation and treatment; 3) selection and prescription of treatment; 4) consultations with specialized professionals.	significant
164	Availability of documentation on the immediate transfer of a patient undergoing treatment in the MO without the possibility of IV therapy when indications for urgent interventional or cardiac surgery are identified, by ambulance, including medical aviation to the MO with the possibility of IV therapy in a 24-hour mode.	significant
165	Availability of supporting documentation on the performance of surgical interventions in cardiac surgery according to the principle of regionalization with regard to the level of complexity: 1) distribution of cardiac surgical operations for adults by categories of complexity: The level of regionalization of cardiac surgical care for adults is carried out according to the principle of regionalization; if the target values of key indicators for regionalization of cardiac surgical care (according to the level of complexity of the patient category) are achieved, during three evaluation periods, the MO performs surgical interventions of the level of complexity provided for in Annex 1 to this Order; 2) assessment of the complexity of surgical interventions for congenital heart defects is carried out according to the Aristotle Basic Scale.	significant

	If several operations are performed on one child, only one operation with the highest score on the Aristotle Basic Scale shall be taken into account. To objectivize the quality of work of the pediatric cardiac surgery department, such a parameter as the efficiency of operations is used, calculated by the equation: (average value of complexity on the Aristotle Basic Scale) x (30-day postoperative survival rate)/100 = (Efficiency of operations): determining the level of regionalization of cardiac surgical care for the pediatric population; if the target values of key indicators of regionalization of cardiac surgical care for the pediatric population (according to the level of complexity of the patient category) are achieved, the MO performs surgical interventions according to the level of complexity within three evaluation periods.	
Requirements for subjects (objects), providing the hemodialysis care		
166	Availability of written voluntary consent of the patient or his/her legal representative in case of invasive interventions and therapeutic and diagnostic activities	significant
167	Availability of a conclusion on the compliance of a healthcare entity to provide high-tech medical services	gross
168	Availability of supporting documentation on compliance of treatment and diagnostic measures with the recommendations of clinical protocols	significant
169	Availability of supporting documentation of eligibility for selection and initiation of renal replacement therapy, specifically: Indices (glomerular filtration rate); - presence of hyperhydration, acidosis; - potassium level; - assessment of the patient's nutritional status)	gross
	Availability of supporting documentation of compliance with	

170	the indication for emergency extrarenal blood purification in patients with acute renal failure: - Absence of urine; - hyperkalemia; - hyperhydration.	gross
171	Availability of supporting documentation that the hemodialysis machine complies with quality certificates, with sufficient life and capacity as stipulated by the country of manufacture	gross
172	Availability of supporting documentation on compliance with the algorithm of hemodialysis procedure: - Preparation of artificial kidney apparatus for work: testing and checking of AKA apparatuses with control of ionic composition of dialyzing solution on ionometer; - preparation of the workplace of the dialysis room nurse: laying out sterile layouts, preparation of fistula needles, dialyzer, solutions for filling the lines and dialyzer; - assembly of the extracorporeal circuit (blood pipelines, dialyzer) with installation on the artificial kidney apparatus; - filling and flushing of the extracorporeal circuit with physiologic solution with anticoagulant; - preparation of the patient: weighing on electronic scales with registration of interdialysis weight gain in the dialysis card, treatment of the skin surface with disinfectants at the site of puncture of vascular access; - connection of the patient to the artificial kidney apparatus; - setting the blood flow rate on the artificial kidney apparatus; - control of blood pressure, heart rate and pulse rhythmicity at least once an hour, with hourly registration of the results in the dialysis card; - control of correctness of ultrafiltration volume (at the end of dialysis), with registration of results in the dialysis card;	gross

	- control of the position of fistula needles in the arteriovenous fistula (constantly); - control of venous and arterial pressure sensors readings (constantly); - control of anticoagulation (constantly visually); -control of blood ionic composition during the procedure (as indicated); - at the end of the procedure time: stopping the blood pump, removal of fistula needles from vascular access, control of bleeding stoppage from puncture sites, final stop of bleeding, fixation (bandaging) of the fistula limb with sterile dressing material; - control weighing of the patient on electronic scales with registration of the results in the dialysis card; - cold rinsing of the device, hot disinfection; - transportation of used consumables for disposal.	
173	Availability of supporting documentation on the provision of drugs and supplies according to the dialysis protocol	significant
174	Availability of water treatment system and compliance with requirements for hemodialysis fluid preparation, quality of hemodialysis solutions and blood purification system	significant
175	Availability of an agreement for provision of paid medical services in health care organizations. Availability of documents establishing the fact of co-payment	gross
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed according to the following criteria: absence of history taking; completeness of history taking;	

availability of data on past, chronic and hereditary diseases, hemotransfusions, drug tolerance, allergological status;

development of complications as a result of tactical errors made in the course of treatment and diagnostic measures due to poor anamnesis collection;

2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria:

absence of diagnostic measures;

incorrect conclusion or lack of conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics;

conducting diagnostic tests stipulated by clinical protocols;

performance of diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in clinical protocols;

conducting diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment;

3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of tests (in case of planned hospitalization, tests performed at the pre-hospital stage are also taken into account), which are evaluated according to the following criteria:

the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases;

the leading pathological syndrome determining the severity of the course of the disease has not been identified, concomitant diseases and complications have not been recognized;

the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the

	highlighted complications, comorbidities affecting the outcome are not recognized; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical service (assistance) is assessed; 4) timeliness and quality of consultations of specialized professionals, which are assessed according to the following criteria:	
176	absence of consultation that led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical service (assistance); 5) volume, quality and validity of treatment measures, which are assessed by the following criteria: absence of treatment in the presence of indications;	significant

prescription of treatment in the absence of indications;

prescription of ineffective treatment measures without taking into account the peculiarities of the course of the disease, concomitant diseases and complications;

performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy;

unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition;

6) absence or development of complications after medical interventions, all complications that occurred are evaluated, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures;

7) the achieved result, which is evaluated according to the following criteria:

achievement of the expected clinical effect in compliance with the technology of medical service (assistance);

absence of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic tests;

absence of expected clinical effect due to ineffective therapeutic, preventive measures without taking into account the specifics of the course of the disease, comorbidities, complications, prescription of drugs without proven clinical efficacy;

the presence of polypragmasy, which caused the development of undesirable consequences;

8) quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical

	documentation intended for recording data on the state of health of patients, reflecting the nature, volume and quality of medical care provided	
177	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis	Gross
178	Availability of supporting documentation on record keeping and accounting records	minor
Requirements for subjects (objects), providing dental care		
179	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis	Gross
180	Availability of supporting documentation on compliance with the following requirements in the organization of dental care: 1) involvement of doctors of related specialties to provide consultative assistance in the presence of concomitant pathology in patients with dental diseases (on medical indications); 2) referral of patients with dental diseases to maxillofacial departments of multidisciplinary hospitals in cases requiring specialized medical care and high-tech medical services with round-the-clock medical supervision; 3) provision of dental medical care to the patient after obtaining his/her informed consent according to the approved form of written voluntary consent of the patient in case of invasive interventions; 4) compliance with the indications for emergency hospitalization: - acute or exacerbation of chronic odontogenic and nonodontogenic inflammatory diseases of the maxillofacial region;	gross

	- traumas of the maxillofacial region; - bleeding of the maxillofacial region ; 5) observing the indications for planned hospitalization of a patient with dental diseases: - clarification of the diagnosis in unclear and difficult to diagnose and treat cases and selection of the necessary treatment regimen; - treatment of chronic diseases of the oral cavity and maxillofacial region in the stage of exacerbation; - surgical treatment of benign tumors and tumor-like diseases; - treatment of traumas and purulent-inflammatory diseases of the maxillofacial region; - surgical treatment of defects and deformities of the maxillofacial region; - surgical treatment of congenital pathologies of the maxillofacial region.	
181	Availability of a contract for provision of paid services in health care organizations.	gross
182	Availability of medical documentation confirming compliance with clinical and diagnostic tests by level of dental care provision	significant
183	Availability of form № 058/y “ Medical card of a dental patient (including sanitation)” per each patient	minor
184	Availability of supporting documentation on compliance of treatment and diagnostic measures with the recommendations of clinical protocols. In the absence of clinical protocols, according to international standards and guidelines based on evidence-based medicine.	significant
185	Availability of supporting documentation on record-keeping by specialized professionals working in health care organizations providing dental care	significant
	Availability of completed documentation with information on the provision of dental care (	

186	electronic medical records, accompanying materials on the patient's health status and diagnosis), including in the MIS for each tooth in the chart of examination of primary teeth and the chart of examination of permanent teeth	significant
187	Availability of documentation on determining the patient's allergy history before dental interventions requiring local (local) anesthesia and , if indicated, referral of the patient to primary health care organizations or medical organizations for laboratory testing to identify drug allergies	gross
188	Availability of supporting documentation on the provision of dental care to children in outpatient settings in the form of consultative and diagnostic assistance by referral and self-referral, includes: 1) examination by a dentist; 2) referral for laboratory, functional, instrumental, visual methods of research (X-ray, computer tomography, magnetic resonance tomography, ultrasound) for the purpose of diagnosis and differential diagnosis, as indicated; 3) provision of dental care for the identified disease according to clinical protocols; 4) referral for hospitalization on emergency indications and planned hospitalization to provide specialized medical care, including with the use of HTMS, in hospital-replacing and inpatient conditions.	significant
189	Availability of an informed consent of parents or representatives in case of dental interventions for children associated with the risk of painful sensations, manipulations are carried out according to the indications with the use of anesthesia (local, sedation, general)	significant
	Availability of supporting documentation for the provision of dental care to adults in outpatient settings in the form of consultative and diagnostic care by self-referral and referral, which includes:	

190	1) examination by a dentist; 2) referral on indications for laboratory, functional, instrumental, visual methods of research (X-ray, computer tomography, magnetic resonance tomography, ultrasound) for the purpose of diagnosis and differential diagnosis; 3) provision of dental care for the identified disease according to clinical protocols. 4) referral for hospitalization on emergency indications and planned hospitalization to provide specialized medical care in hospital-replacing and inpatient conditions	significant
191	Availability of supporting documentation on the provision of dental care in inpatient settings by oral and maxillofacial surgeons and includes prevention, diagnosis, treatment of diseases and conditions requiring the use of special medical methods and technologies, as well as medical rehabilitation	significant
192	Availability of supporting documentation on the conduct of a concilium or the use of remote medical services in the differential diagnosis of complex, unclear cases to verify the diagnosis	significant
193	Children aged from 0 to 17 years inclusive and pregnant women are subject to dynamic observation and dental examinations	significant
194	Availability of supporting documentation on the provision of preventive measures for pregnant women and adults, which include control over the hygienic condition of the oral cavity, instruction on brushing teeth, selection of means and items of oral hygiene, professional oral hygiene, sanitation of the oral cavity (with the use of modern materials and technologies), informational and explanatory work on risk factors for dental diseases, conducted along the route of the primary preventive examination of pregnant women and adults	significant

195	Compliance with the following requirements in the organization and conduct of the medical consultative board: 1) availability of the order of the head of the medical organization: - on the establishment of a medical advisory commission; - on the composition, number of members (at least three doctors), - the work and schedule of the medical consultative board 2) availability of the conclusion of the medical consultative board	significant
	Availability of medical documentation on compliance with the following requirements for the examination of temporary incapacity for work, issuance of a sheet and certificate of temporary incapacity for work (Form № 001/y “Medical Card of Inpatient”, form 052/y “ Medical Card of Outpatient”, stubs of sheets on temporary incapacity of patients, form № 025/y “Register for Recording Conclusions of Medical Consultative Board”, form № 029/y "Book of Registration of certificates of temporary incapacity for work”, form № 037/y “Certificate №_____ ____ on temporary incapacity of a student, college or vocational school pupil, sickness, quarantine and other reasons for absence of a child attending school or pre-school organization (underline as necessary) ", form № 038/y "Certificate №____ __ on temporary incapacity" etc.): 1) availability of examination of the person and recording of data on his/ her state of health in the medical card of an outpatient (inpatient) patient justifying the need for temporary release from work; 2) issuance of a temporary disability certificate and certificate of temporary disability on the day of discharge of persons under inpatient treatment (including day hospitals, rehabilitation centers) for the entire period of inpatient treatment; 3) closing the temporary disability certificate and certificate of	

196	temporary disability on the date of discharge from the hospital if the person's ability to work has been fully restored; 4) prolongation to persons who continue to be temporarily incapacitated for a period of time, taking into account the time required for his/her visit to a medical worker of a polyclinic or calling a medical worker at home (but not more than one calendar day). Persons who received treatment outside the region of residence, the time required to arrive at their place of permanent residence is taken into account (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sick leave certificate and a certificate of temporary incapacity for work to persons suffering from mental illness in the event of untimely application to a medical organization for the past days upon the conclusion of the medical advisory board of a psychoneurological dispensary or a medical officer (psychiatrist) in conjunction with the head of the medical organization; 7) issuance of a sick leave certificate and a certificate of temporary incapacity for work to persons sent by court decision for forensic medical or forensic psychiatric examination and recognized as incapable of work from the day of admission to the examination; 8) issuance of a sick leave certificate and a certificate of temporary incapacity for work simultaneously to a person combining study and work.	significant
197	Availability of written voluntary consent of the patient or his/her legal representative in case of invasive	significant

	interventions and therapeutic and diagnostic activities	
198	Availability of supporting documentation on compliance with the requirements of anesthesiology and resuscitation care: 1) provision of specialized medical care to patients in emergency and planned procedures, including high-tech medical services; 2) determination of the method of anesthesia, implementation of medical preoperative preparation and implementation of different methods of anesthesia for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring of patients' condition in the postanesthetic period in the “ waking up” rooms until recovery of consciousness and stabilization of the function of vital organs; 4) assessment of the degree of dysfunction of vital organs and systems and implementation of an expanded set of resuscitation and intensive care measures in various critical situations, including methods of extracorporeal detoxification, hyperbaric oxygenation, electrocardiostimulation; 5) intensive monitoring (express control of the state of life support systems, as well as metabolism with the use of laboratory and functional diagnostics methods, respiratory and circulatory monitoring), full and targeted correction of disorders; 6) resuscitation measures for patients (if indicated) in other departments; 7) determination of indications for further treatment of patients in Anesthesiology, resuscitation and intensive treatment department, as well as transfer of patients from Anesthesiology, resuscitation and intensive treatment department to specialized departments after stabilization of the function of vital organs with recommendations on treatment and examination for the next 24 hours;	significant

	8) consulting doctors of other departments on issues of practical anesthesiology and resuscitation; 9) analyzing the efficiency of the department and the quality of medical care, developing and implementing measures to improve the quality of medical care	
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed according to the following criteria: absence of history taking; completeness of history taking; availability of data on past, chronic and hereditary diseases, hemotransfusions, drug tolerance, allergological status; development of complications as a result of tactical errors made in the course of treatment and diagnostic measures due to poor history taking; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics.; conducting diagnostic tests stipulated by clinical protocols; performance of diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in clinical protocols; conducting diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of tests (in case of planned	

199	hospitalization, tests performed at the pre-hospital stage are also taken into account), which are evaluated according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, comorbidities affecting the outcome are not recognized; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical service (assistance) is assessed; 4) timeliness and quality of consultations of specialized specialists, which are assessed according to the following criteria: absence of consultation that led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease;	significant

consultant's opinion was erroneous and affected the outcome of the disease.

Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical service (assistance) provision;

5) volume, quality and validity of treatment measures, which are assessed by the following criteria:

absence of treatment in the presence of indications;

prescription of treatment in the absence of indications;

prescription of ineffective treatment measures without taking into account the peculiarities of the course of the disease, concomitant diseases and complications;

performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy;

unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition;

6) absence or development of complications after medical interventions, all complications that occurred are evaluated, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures;

7) the achieved result, which is evaluated according to the following criteria:

achievement of the expected clinical effect in compliance with the technology of medical service (assistance);

absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis

	collection and diagnostic examinations absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of medicines without proven clinical efficacy; presence of polypragmasy, which caused the development of undesirable consequences; 8) quality of medical documentation, which is assessed by the availability, completeness and quality of records in primary medical documentation, intended for recording data on the state of health of patients, reflecting the nature, volume and quality of medical care provided	

Requirements for persons/entities (facilities) rendering phthisiatric care		
Provision of anti-tuberculosis care at the outpatient and polyclinic level		
200	Presence of supporting documentation on rendering medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free of charge basis	Gross violation
	There is supporting documentation that PHC practitioners have undertaken the following activities: 1) information and awareness-raising work on prevention and early detection of tuberculosis; 2) scheduling (forming lists of persons to be examined, drawing up a schedule), organising and performing fluorographic examinations and documenting the findings in the medical records; 3) scheduling (compiling lists of persons to be examined, drawing up a schedule), organising and conducting tuberculin diagnostics of children and adolescents, documenting the findings in medical records, and conducting follow-up examinations of tuberculin-positive children);	

201	4) referral for examination of persons suspected of tuberculosis based on the diagnostic algorithm of examination; 5) referral of persons with positive results of fluorographic examination, children and adolescents with first-time positive and hyperergic tuberculin test, with increase of tuberculin sensitivity by 6 mm or more, children with adverse reactions and complications to tuberculosis vaccination to a phthisiatrician; 6) planning, organisation and implementation of tuberculosis vaccination; 7) Tuberculous infection treatment (hereinafter referred to as -TI) under the prescription of a phthisiatrist, including in video-observed mode; 8) screening of contact persons; 9) outpatient direct-controlled or video-observed treatment of tuberculosis patients; 10) diagnosis and treatment of adverse reactions to TB drugs as prescribed by a phthisiatrist; 11) diagnosis and treatment of concomitant diseases; 12) maintenance of medical records of tuberculosis patients on outpatient treatment, including multidrug-resistant and extensively drug-resistant tuberculosis; 13) regular entry of data into the National Register of tuberculosis patients within the scope of their competence	Gross violation
202	Existence of supporting documentation on patient screening for suspected tuberculosis in health facilities delivering primary health care under the scheme	Gross violation
203	Presence of supporting documentation on the detection of tuberculosis by fluorography among the target population: those at high risk of the disease and subject to mandatory annual fluorography screening	Major violation
	Existence of supporting documentation on the arrangement	

204	of directly observed treatment rooms (hereinafter referred to as “DOT”) in primary health care facilities to provide outpatient treatment. The patient shall receive and takes medicine in the DOT room under the supervision of the responsible health care provider. Once every 10 days, patients on directly supervised treatment shall be examined by a primary care physician/phthisiologist of the outpatient clinic, more frequently if specified. Patients residing in rural areas shall be seen by a phthisiatrician once a month	Major violation
205	Evaluation of the clinical condition of a patient receiving anti-tuberculosis treatment for the presence of adverse reactions and events shall be made daily by the attending physician or phthisiatrician , a health care provider of the directly observed treatment room. A health care provider who has revealed adverse reactions and events to a medicinal product shall fill in a report card and make an entry in the patient's medical records. Primary data on adverse reactions and events shall be reported by the responsible person of the healthcare facility to the state expert organisation in the sphere of circulation of medicines and medical devices. The responsible person in charge of pharmacovigilance shall be in charge of the registration of report cards. Each case of adverse reactions and phenomena shall be discussed at a session of the centralised medical advisory committee to determine the cause-and-effect relationship with the medication taken.	Gross violation
206	Presence of records of anti-tuberculosis medicines movement at the outpatient level in the ATP logbook	Major violation
207	Interviewing the patient (parents or guardians of children) prior to treatment about the need for a full course of chemotherapy, followed by signing an informed consent form	Major violation

208	Presence of supporting documentation on registration and dispensary monitoring of tuberculosis patients shall be performed in PHC facilities at the place of actual residence, work, study or military service, irrespective of residence registration	Major violation
209	Presence of supporting documentation on compliance with the following requirements in the organisation and conduct of the medical advisory board: 1) existence of an order of the head of the health care facility: - on the establishment of a central medical advisory board; - on the composition of the board (at least three doctors); - on the work and schedule of the central medical advisory commission . 2) presence of the conclusion of the central medical advisory board presence of a medical and social expert commission and referral of patients with persistent signs of respiratory system dysfunction to a medical and social expert commission;	Major violation
210	Existence of supporting documentation on the appropriateness of the levels of medical rehabilitation rendered to patients: 1) primary level - primary health care providers that have a rehabilitation room/unit, day hospital and offer medical rehabilitation to patients whose condition is evaluated from 1 to 2 points using the Rehabilitation Routing Scale (hereinafter referred to as RRS);	Major violation
Delivering tuberculosis care at the inpatient level		
211	Existence of supporting documentation on rendering health care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
	Assignment of patients to wards based on laboratory data and drug	

212	sensitivity at the time of admission and during treatment. Treatment of patients with bacteriological excretion with unknown drug sensitivity in single rooms or boxes until the results of the drug sensitivity test are available	Major violation
213	Presence of daily examination by a physician-phthisiatrician of inpatients. When examining and prescribing additional diagnostic and treatment manipulations by the doctor on duty, appropriate entries shall be made in the medical record. When the patient's condition worsens, the doctor on duty shall notify the head of the department and (or) the attending physician, agree to make changes in the process of diagnosis and treatment, and make an entry in the medical record (paper and (or) electronic) option. An entry shall be made in the electronic version of the medical record within 24 hours of a change in the patient's condition. In emergency conditions, the frequency of records depends on the dynamics of the severity of the condition. Inpatient records shall reflect specific changes in the patient's condition and the need to correct prescriptions, justification of the prescribed examination and treatment, evaluation and interpretation of the findings and the efficiency of the treatment provided. The frequency of examinations for emergency conditions shall be at least every 3 hours, with details of the time of emergency treatment by hours and minutes	Major violation
214	Presence of supporting documentation on the organisation of a consilium in complex situations to verify the diagnosis and determine treatment tactics with the participation of specialists at regional and national levels in person or remotely through telemedicine	Gross violation

215	Availability of records of anti-tuberculosis medicines movement at the inpatient level in the ATM logbook	Major violation
216	Existence of supporting documentation that the criteria for discharging a tuberculosis patient from hospital have been met: 1) no bacteriological excretion and no need for round-the-clock medical supervision; 2) two negative microscopy results taken sequentially at an interval of at least 10 calendar days in patients with initial bacteriological excretion; 3) generally accepted outcomes of inpatient treatment (recovery, improvement, no change, deterioration, death and transferred to another health care facility); 4) at the patient's (his/her legal representative's) written request until the completion of the course of treatment, if there is no immediate danger to the patient's life or to others.	Major violation
217	Presence of written voluntary consent of the patient or his/her legal representative in case of invasive interventions and therapeutic and diagnostic measures	Major violation
218	Severe patients shall be examined by the head of the ward on the day of admission and daily thereafter. Patients in a moderately severe condition shall be examined at least once a week. The findings of the patient's examination are recorded in the medical record with recommendations on further tactics of patient management with the obligatory identification of the medical worker making the entries	Major violation
219	Having an identified clinical diagnosis jointly with the head of department no later than three calendar days from the day of the hospitalisation of the patient by a health care facility	Major violation
220	Consultations or consiliums in case of difficulty in identifying the diagnosis, inefficiency of the current	Gross violation

	treatment, as well as other indications	
221	A discharge summary is issued to the patient upon discharge, specifying the full clinical diagnosis, the scope of diagnostic tests, therapeutic measures and recommendations for further follow-up and treatment. Discharge data are entered into the information systems on a day-to-day basis, indicating the actual time of discharge.	Minor violation
222	Existence of supporting documentation of compliance with anaesthetic and resuscitation care: 1) rendering specialised medical care to patients in emergency and planned procedures, including high-tech medical services; 2) determination of the method of anaesthesia, medical preoperative preparation and different methods of anaesthesia for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring of patients in the post-neurocostal period in waking rooms until consciousness is restored and the function of vital organs stabilises; 4) Evaluating the degree of dysfunction of vital organs and systems and performing an expanded range of resuscitation and intensive care measures in various critical situations, including extracorporeal detoxification, hyperbaric oxygenation, and electrocardiostimulation methods; 5) intensive observation (express control of the state of life support systems and metabolism with the use of laboratory and functional diagnostics methods, respiratory and circulatory monitoring), full and targeted correction of disorders; 6) resuscitation of patients (if required) in other wards; 7) establishing criteria for further treatment of patients in Anaesthesiology, Reanimation and Intensive Care Units (hereinafter referred to as ARIC), as well as	Major violation

	transfer of patients from ARIC to specialised wards after stabilisation of the function of vital organs along with recommendations on treatment and examination for the next 24 hours; 8) consultation with doctors of other wards on issues of practical anaesthesiology and resuscitation; 9) analysing the efficiency of the work of the ward and the quality of medical care delivered, developing and implementing measures to improve the quality of medical care and reduce mortality rates	
223	Evidence of compliance with transfusion requirements for blood components and in case of complications: Prior to transfusion of blood components, the recipient is tested for markers of haemotransmissible infections HIV, hepatitis B and C, and after the end of treatment, the discharge epicrisis specifies the need for repeated screening for HIV and hepatitis B and C at the place of residence. Recipients are examined for HIV infection as part of the guaranteed volume of free medical care in state health care facilities engaged in HIV prevention activities. Details regarding the transfusion history are entered in the patient's medical record prior to the start of transfusion therapy: presence of previous transfusions, when and due to what there were post-transfusion complications, pregnancies that ended in birth of children with haemolytic disease of the newborn. In the event of complications developing during the biological test, during or after transfusion, detailed record(s) are made describing the recipient's condition, vital function monitoring data, treatment methods and their efficacy. Immediate laboratory monitoring of the recipient's blood and urine is performed.	Gross violation

	Examination of persons on clinical indications for HIV infection when the following diseases, syndromes and symptoms are detected: 1) enlargement of two or more lymph nodes for more than 1-month, persistent, generalised lymphadenopathy; 2) fever of unclear aetiology (persistent or recurrent for more than 1 month); 3) unexplained severe cachexia or severe nutritional deficiencies that do not respond well to standard treatment (in children), unexplained loss of 10% of weight or more; 4) chronic diarrhoea for 14 days or more (in children), unexplained chronic diarrhoea lasting more than a month; 5) seborrhoeic dermatitis, pruritic papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) shingles; 9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis, isosporosis, extrapulmonary histoplasmosis, strongyloidosis, actinomycosis); 10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, apart from tuberculosis of peripheral lymph nodes; 11) hairy leukoplakia of the oral cavity, linear gingival erythema; 12) severe prolonged recurrent pneumonia and chronic bronchitis not amenable to conventional therapy (two or more times during the year), asymptomatic and clinically expressed lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent and bacterial diseases of internal organs (pneumonia, pleural		

224	empyema, meningitis, meningoencephalitis, bone and joint infections, purulent myositis, Salmonella septicaemia (excluding Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) pneumocystis pneumonia; 15) infections caused by herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of the disease) lesions of the skin and mucous membranes, including eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unclear etiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the oesophagus, bronchi, trachea, lungs, oral and nasal mucous membranes; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unclear etiology; 26) prolonged recurrent pyoderma not amenable to conventional therapy; 27) severe chronic inflammatory diseases of the female genital sphere of unclear etiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis after 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhoea, genital herpes, viral papillomatosis and others) with a diagnosis established; 31) viral hepatitis B and C, with confirmed diagnosis; 32) extensive plumose condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum;	Gross violation

	34) primary dementia in previously healthy persons; 35) patients with haemophilia and other diseases who systematically receive transfusion of blood and its components; 36) generalised cytomegalovirus infection	
225	Presence of medical documentation on observance of the following requirements for the examination of temporary incapacity for work, issuance of temporary incapacity for work and certificates of temporary incapacity for work (Form № 001/y “Medical Record of Inpatient Patient ”, Form 052/y “Medical Record of Outpatient Patient”, stubs of temporary incapacity for work sheets of patients, form № 025/y “Log for Recording of Reports of Medical Advisory Board”, form № 029/y “ Book of Registration of Sheets on Temporary Disability”, form № 037/ y “Certificate №_____ on Temporary Disability of a Student, College Student, Vocational School Student, on Illness, Quarantine and Other Reasons for the Absence of a Child Attending School, Pre-School Institution (underline as appropriate) ”, form № 038/y “Certificate №_____ on Temporary Disability” and others): 1) examination of the person and recording of data on his/her state of health in the medical record of an outpatient (inpatient) patient justifying the need for temporary release from work; 2) issuance of a sheet and certificate of temporary incapacity for work on the day of discharge of persons under inpatient treatment (including day care centers, rehabilitation centers) for the entire period of inpatient treatment; 3) closing of the sheet and certificate of temporary incapacity for work by the date of discharge from hospital if the persons' ability to work has been fully restored;	Major violation

	4) prolongation to persons who continue to be temporarily incapacitated for a period of time, based on the time required for his/her visit to a health care provider at the outpatient clinic or home visit (but not more than one calendar day)., the time required to arrive at their place of permanent residence is considered (but not more than four calendar days) for persons who have received treatment outside the region of residence; 5) issuance of a certificate of temporary disability for injuries sustained while under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary disability; 6) issuance of a sheet and certificate of temporary incapacity for work to persons suffering from mental illness if they do not apply to a health care facility in a timely manner for the past days by the conclusion of the health-consulting commission of a psychoneurological dispensary or a medical worker (psychiatrist) in conjunction with the head of the health care facility; 7) issuance of a sheet and a certificate of temporary incapacity for work to persons referred by court ruling for forensic medical or forensic psychiatric examination and recognized as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work to a person who combines training with work.	
	Existence of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation based on the following criteria: 1) quality of history taking, evaluated by the following criteria: absence of anamnesis collection; full history taking;	

data on past, chronic and hereditary diseases, hemotransfusions, drug tolerance, allergic status;

development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor history taking;

2) completeness and validity of diagnostic tests, evaluated by the following criteria:

absence of diagnostic measures;

incorrect conclusion or absence of a conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics;

performance of diagnostic tests stipulated by clinical protocols;

performance of diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in the clinical protocols;

diagnostic tests that are uninformative for making a correct diagnosis and resulted in unjustified increase of treatment time and cost of treatment;

3) accuracy, promptness and validity of the clinical diagnosis, based on the findings of investigations (in case of planned hospitalization, investigations conducted at the pre-hospital stage are also considered), which are evaluated against the following criteria:

the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases;

the leading pathological syndrome describing the severity of the course of the disease has not been identified , comorbidities and complications have not been recognised;

the diagnosis is correct but incomplete, the leading pathological syndrome is not distinguished with the highlighted complications, comorbidities affecting the outcome are not recognised;

the diagnosis of the main disease is correct, but comorbidities affecting

226	the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The effect of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated); 4) promptness and quality of consultations with profile specialists, which are evaluated by the following criteria: lack of consultation, which led to misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to include the consultant's opinion in the diagnosis partially influenced the outcome of the disease; the consultation is timely, the consultant's opinion is taken into consideration when making the diagnosis, failure to implement the consultant's treatment recommendations partially influenced the outcome of the disease; the consultant's opinion was erroneous and affected the outcome of the disease. Presence of supporting documentation on evaluation of objectivity of reasons for late consultation and impact of late diagnosis on subsequent stages of health services (care) provision); 5) volume, quality and validity of treatment measures, which are estimated based on the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of low-effective treatment measures without regard to the specifics of the course of the	Major violation

	disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without accounting for the functional state of organs and systems, prescription of drugs without proven clinical efficacy; необоснованное отклонение от требований клинических протоколов, наличие полипрагмазии, приведшее to the development of a new pathologic syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is evaluated based on the following criteria: achievement of the expected clinical effect in compliance with the technology of health care services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor history collection and diagnostic tests; absence of expected clinical effect due to inefficient therapeutic and preventive measures without regard to the peculiarities of the disease course, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; presence of polypragmasy, which caused the development of undesirable consequences; 8) quality of medical documentation, which is estimated by the availability , completeness and quality of records in the primary medical documentation intended for recording data on the health status of patients, reflecting the nature, scope and quality of medical care provided.	

	Presence of documentation of adherence to the following when performing pathologic autopsies: 1) conducting a pathological anatomical autopsy of cadavers after physicians have ascertained biological death, upon submission of the medical record of an inpatient patient or the medical record of an outpatient patient with a written order from the chief physician or his/her deputy for the medical (treatment) part of the health care facility to send for a pathological anatomical autopsy; 2) registration of the findings of the pathologoanatomical autopsy in the form of a pathologoanatomical diagnosis (pathologoanatomical diagnosis includes: the main disease, complication of the main disease, concomitant disease, combined main disease); 3) transfer of the medical record of an inpatient patient or the medical record of an outpatient patient with the pathological anatomical diagnosis entered into it to the medical archive of the health care facility no later than ten working days after the pathological anatomical autopsy; 4) clinical and pathological anatomical examination in cases of death of patients in health care facilities; 5) pathologoanatomical autopsy in cases of suspected acute infectious, oncological diseases, pathology of childhood, lethal outcome due to medical manipulations in order to establish the cause of death and clarify the diagnosis of fatal disease; 6) arrangement by the chief physician and head of the pathology department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathology bureau, centralized pathology bureau and pathology department of medical records of inpatients for all deceased	

227	patients for the previous day not later than 10 a.m. of the day following the establishment of the fact of death; 8) drawing up: - a medical certificate of death (preliminary, final) by a doctor in the specialty of “athological anatomy (adult, pediatric)” on the day of the pathological anatomical autopsy; - a medical certificate of perinatal death (preliminary, final) by a doctor in the specialty of “pathological anatomy (adult, pediatric)” on the day of the pathological anatomical autopsy; 9) processing the results of the autopsy in the form of a protocol of pathological anatomical examination ; 10) written notification to the forensic investigative agencies to address the issue of transferring the corpse for forensic medical examination in case of detection of signs of violent death and termination of the pathological anatomical examination of the corpse; 11) written notification of a medical doctor majoring in Pathological Anatomy (Adult, Paediatric)” in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the State Sanitary and Epidemiological Service, immediately after their detection; 12) performing pathological and anatomical examination of the placenta: - in case of stillbirth; - in all diseases of newborns diagnosed at the time of birth; - in cases suspected of haemolytic disease of the newborn; - in cases of early discharge and dirty waters; - in cases of maternal illness with fever in the last trimester of pregnancy;	Gross violation

	- if there is an obvious abnormality in the development or attachment of the placenta; - suspected congenital anomalies of the foetus; - cases of pre-eclampsia, eclampsia 13) compulsory registration of a foetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) establishment of pathological anatomical autopsy, depending on the complexity, into the following categories: - first category; - second category; - third category - fourth category; 15) identification by a medical doctor majoring in "Pathological Anatomy (Adult, Paediatric)" of the category of the pathological anatomy autopsy and the reason for the divergence of diagnoses when the final clinical and pathological anatomical diagnoses diverge 16) extensive analysis with identification of the iatrogenic profile and categories in all cases of iatrogenic pathology identified as a result of pathological anatomical autopsy.	
228	A written application from the spouse, close relatives or lawful guardians of the deceased or a written will given by the person during his or her lifetime to release the corpse without a pathological anatomical autopsy, if there is no suspicion of violent death	Major violation
229	Presence of an agreement for rendering paid medical services by health care providers. Availability of documents establishing the fact of co-payment	Gross violation
	Existence of supporting documentation on conformity of levels of medical rehabilitation delivery to patients: 1) secondary level - health care providers that have specialised	

230	departments and (or) centres in their structure, performing medical rehabilitation in outpatient, inpatient substitution and inpatient settings, providing medical rehabilitation to patients whose condition is estimated from 2 to 4 points on the Rehabilitation Routing Scale (RRS); 2) tertiary level - specialised health care facilities with wards and (or) centres offering medical rehabilitation, including with the use of high-tech services, in outpatient, inpatient substitution and inpatient settings, to patients whose condition is estimated from 2 to 4 points as per the RRS	Major violation
231	A medical worker's entry in the medical record with the subsequent collection of biological materials to determine the content of a psychoactive substance and recording the results in the medical record when signs of psychoactive substance use are detected during a request for medical assistance in a health care facility without issuing a medical examination report to establish the fact of psychoactive substance use and state of intoxication.	Minor violation
232	Availability of supporting documentation on consistency of treatment and diagnostic measures with the recommendations of clinical protocols.	Major violation
Requirements for entities (facilities) rendering oncological care		
233	Existence of supporting documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free-of-charge basis	Gross violation
	Existence of a multidisciplinary team to ensure an individualised approach to the delivery of medical care to patients with malignant neoplasms. MDG includes a head (a doctor of health care management or a doctor majoring in Oncology), physicians majoring in the following specialties: Oncology; Paediatric Oncology and	

234	Haematology; Radiation Oncology, Chemotherapeutic Oncology, Radiology, Nuclear Medicine, Mammology, Oncological Surgery, Ultrasound Diagnostics by profile of the main specialty, Endoscopy by Profile of the Main Specialty, Pathological Anatomy, Cytopathology, Hospice and Palliative Care, a paramedical worker to record the minutes of the meeting. Profile experts of relevant specialties and specialisations, as well as psycho-social specialists are involved in complex clinical cases.	Gross violation
235	Presence of supporting documentation of review at the MDG sessions: 1) all primary patients with verified diagnosis of MN (malignant neoplasm). In case of diagnosis of MN after planned surgical treatment, the MDG meeting is held in the ward , based on the results of the histological report received; 2) patients with suspected MN, the diagnosis of which is difficult; 3) patients with MN recurrence; 4) patients who need to change the treatment tactics due to complications, contraindications, progression of the process; in case of obtaining additional data in the course of treatment; 5) patients in case of impossibility to fulfil the recommendations of the previous MDG session due to complications, progression, contraindications, patient's refusal; 6) patients who need referral for diagnosis and treatment in tertiary institutions and abroad; 7) patients in need of targeted and immunopreventive drugs.	Gross violation
	Presence of supporting documentation on the organisation by PHC experts of: 1) a set of measures for prevention and early detection of precancerous and oncological diseases, including information and awareness-raising	

236	work among the attending population on issues of cancer alertness; 2) screening studies of target groups of the adult population for early detection of MN and behavioural factors; 3) questioning and examination of patients in examination and pre-medical rooms for early detection of precancerous and oncological diseases; 4) examination by a general practitioner (hereinafter referred to as GP) for the purpose of assessing the patient's condition and referral to a medical oncologist, mammologist, specialised experts in case of suspected malignant neoplasm and (or) progression of the process in case of suspected malignant neoplasm and (or) progression of the oncological process by a general practitioner of a primary health care provider, a medical specialist of a consultative and diagnostic care organisation; 5) forming groups of people at risk of developing cancer for their subsequent rehabilitation with the participation of relevant experts, monitoring behavioural risk factors and teaching skills to reduce identified MN risk factors are implemented to monitor groups of high cancer risk in primary health care and consultative and diagnostic care medical institutions; 6) field visits of mobile teams to improve the level of diagnostics of MN, including GPs, oncologists and relevant experts, using mobile medical complexes; 7) dynamic follow-up of patients with oncological, chronic and pre-tumour diseases depending on the clinical group; 8) palliative care and medical rehabilitation of patients with MN based on clinical protocols.	Major violation
	Existence of supporting documentation on the provision of CDC, which includes:	

237	1) clinical check-up to determine the patient's condition and establish a diagnosis; 2) follow-up examination of persons with suspected MN in order to verify the diagnosis; 3) laboratory and instrumental examination of the patient; selection and referral for hospitalisation of oncological patients to receive specialised medical care, including high-tech medical services; 4) management and treatment of the patient based on the recommendations of the MDG; 5) providing outpatient antitumour therapy.	Major violation
238	There is supporting documentation that the GP has referred the patient to an oncologist or cancer care co-ordinator if a tumour disease is diagnosed or suspected. From the moment the referral is made, the oncologist or cancer care co-ordinator will examine the patient within seven working days and perform the necessary tests and refer the patient to an oncology care provider to confirm the diagnosis and determine the subsequent management and treatment. Since the moment of establishing a preliminary diagnosis of MN or suspicion of disease recurrence, the oncologist arranges the collection of cytological, histological material (biopsy, surgical material), preservation, labelling and referral for morphological examination of the material, as well as referral for diagnostic tests required to establish the diagnosis, prevalence of the oncological process and to identify the stage of the disease, disease recurrence.	Major violation
	Presence of supporting documentation on observance of requirements when rendering oncological care in the form of outpatient and polyclinic care: Formation of groups of persons at risk of developing oncological diseases;	

239	examination by a physician to determine the patient's condition and establish a diagnosis; laboratory and instrumental examination of the patient in order to establish a diagnosis; dynamic monitoring of oncological patients; selection and referral for hospitalisation of oncological patients to receive specialised medical care, including high-tech medical services; follow-up examination of persons with suspected MN in order to verify the diagnosis; determining the patient's management and treatment tactics; providing outpatient anti-tumour therapy	Major violation
240	Presence of supporting documentation on immunohistochemical studies and molecular genetic studies to evaluate molecular and biological features of tumours in order to individualise treatment of patients, as well as to confirm (verify) the diagnosis of MN . IHC studies are performed at the level of pathomorphological laboratories of oncological care providers at the secondary level and reference centres at the tertiary level and are performed following clinical protocols. An extract from the medical record of an outpatient or inpatient patient, MDG report, histological report are enclosed to the material for MDG studies (paraffin blocks and microdrugs). Materials for IHC studies are delivered by mail, courier service, personally by the patient and (or) his/her relatives. The timeframe for conducting IHC tests does not exceed fourteen working days from the date of receipt of the material. The report of the IHC examination with indication of the date, examination number, name of the performer is entered into the medical information system and transferred to the entity that sent the	Major violation

	material for examination by means of information interaction or by mail. Reference centre consults complex diagnostic cases, expert examination of IHC studies using the possibilities of telemedicine consultation (remote medical services). Expertise of IHC studies performed in pathomorphological laboratories is performed by reference centres at least once a year. Storage of paraffin blocks, glass specimens and conclusions in the archive of pathomorphological laboratories is conducted for fifteen years, in the archive of reference centres - for twenty-five years.	
241	Presence of confirming documentation of international teleconsultations of tumour biosamples via the telepathology system to clarify the diagnosis in complex clinical cases. The timeframe for teleconsultations does not exceed thirty working days.	Gross violation
	There is confirmatory documentation that the entire period of examination of patients with suspected MN in outpatient clinics with cancer precautionary markers within the following examination timeframes is reflected in the MIS: 1) in case of suspicion or detection of tumour disease, the expert of the examination room assigns the “ Cancer Caution 1” marker and refers the patient to the GP within three working days; 2) the GP jointly with a specialised medical expert conducts a follow-up examination and refers the patient to an oncologist or cancer care co-ordinator within five working days and sets a “Cancer Caution 2” marker; 3) upon issuing a referral, within ten working days, the oncologist or cancer care co-ordinator performs an examination and the necessary tests, based on the results of which he/she refers the patient to an institution offering oncological care to confirm and establish the diagnosis,	

242	determine the subsequent management and treatment tactics with the establishment of the marker “Oncology Caution 3”; 4) specialist consultations and examination of patients with suspected MN in outpatient settings are performed within the ‘green’ corridor - outside the general queue and restrictions, within eighteen working days; 5) doctor-oncologist of the secondary level organisation conducts diagnostic tests needed to confirm and establish the final diagnosis, prevalence of the process. 6) in-depth examination of patients in the clinical group for the purpose of verifying the diagnosis is performed within fifteen working days from the moment of application to the institution rendering oncological care, for the purpose of specifying treatment tactics and personalisation of therapy - within thirty working days; 7) the entire itinerary of a primary cancer patient and the timing of examinations in line with oncology alert markers are monitored in the situation centre of the institution coordinating oncological care in the region.	Gross violation
243	Presence of supporting documentation that a patient with MN receives specialised treatment no later than thirty calendar days after the diagnosis is established and the patient is placed under dynamic monitoring.	
	There are supporting documents on dynamic follow-up of clinical groups of patients with suspected MN and confirmed diagnosis of MN: 1) group Ia - patients with suspected MN; 2) group Ib - patients with pre-tumour diseases; 3) group II - patients with MN to be treated with special treatment (surgical treatment, chemotherapy, radiation therapy, immune cell therapy);	

244	4) group IIa - patients with early forms of MN subject to radical treatment; 5) group III - patients after radical treatment of malignant tumour (almost healthy individuals); 6) group IV - patients with advanced forms of MN, subject to palliative or symptomatic treatment. Following the findings of in-depth examination of a patient of clinical group Ia, primary care physicians remove the suspicion of MN or transfer the patient to the appropriate clinical groups: 1) if a pre-tumour disease is revealed , the patient is transferred to clinical group Ib; 2) if the diagnosis of MN is confirmed (verified), the patient is taken for dynamic follow-up in clinical group II; 3) patients with advanced forms of MN, not amenable to special treatment, are transferred to the IV clinical group. Patients of clinical group Ib should be dynamically monitored and recuperated by PHC and CDC experts in institutions rendering medical care in outpatient conditions at the place of their attachment, performed on monitoring of groups of high cancer risk in health care facilities monitoring of groups of high cancer risk in health care facilities of primary health care and consultative-diagnostic care. The II clinical group includes all primary patients with MN who are eligible for special treatment, regardless of the stage of the disease, including patients with stage 4 MN, if there are indications for special treatment. Patients are transferred from the II clinical group to the III group after completion of the full course of special treatment, if there are diagnostically confirmed results of radical cure, as well as the absence of progression and relapse of MN.	Major violation

	Medical dynamic monitoring of patients of clinical group III is performed: 1) during the first year of the disease - once every three months; 2) during the second year of the disease - once every six months; 3) from the third year - once a year. Patients in clinical group II are followed up by secondary level experts in line with periodic clinical protocols, at least once every three months. Patients from clinical group III are transferred to clinical group II in case of progression and relapse of MN. The IV clinical group includes patients with advanced forms of MN, with aggravating concomitant pathology that does not allow special treatment, subject to palliative or symptomatic treatment. Patients are transferred from clinical group II to group IV in case of disease progression on the background of treatment. Patients in clinical group III are transferred from clinical group III to IV in case of disease progression over the period of dynamic observation and worsening of the condition that does not allow special treatment. Patients of clinical group IV who need palliative and symptomatic treatment are observed in the primary health care facility at the place of registration. Patients of clinical group IV are not removed from the oncological register.	
	Patients with MN are subject to lifelong follow-up in an institution rendering medical care in outpatient conditions at the place of registration - primary level (III clinical group) and institutions rendering oncological care at the secondary level (II clinical group) at the place of residence and registration. In case of change of place of residence and change of institution of registration within the country,	

245	region, the patient is not removed from the dynamic monitoring, but is dislocated to the new place of registration or residence, with the documents sent to the primary and secondary level institutions. A patient with MN is deregistered in cases of: 1) moving to another country with the issuance of a detailed extract from the outpatient medical record; 2) follow-up in an institution offering oncological care with a diagnosis of “Skin Basalioma”, “ Trophoblastic Disease” for more than five years after cure, in the absence of relapses; 3) death based on a medical certificate of death.	Major violation
246	Upon establishing a diagnosis of MN for the first time, a form № 034/y “ Notification” is filled out for each patient, which is sent within three working days to the institution rendering oncological care at the secondary level at the place of the patient's permanent residence for registration in the Electronic Register of Oncological Patients and Registration, specifying the circumstances of the diagnosis (patient's self-referral to a primary health care facility, CDC - primary level, patient's self-referral to an institution offering oncological care at secondary and tertiary levels, diagnosis established during screening examination, diagnosis established during preventive examination)	Major violation
247	Each patient with a first-time diagnosis of stage IV MN and visually accessible localisations of stage III disease should have a protocol completed in case a patient is diagnosed with an advanced form of malignant neoplasm (clinical group V). The PHC, CDC entity to which a patient with a detected advanced MN is assigned must conduct a mandatory case review of all detected advanced cases. The	Gross violation

	materials of the case review are sent to the entity coordinating oncological care in the region within ten working days from the receipt of the report on the neglected MN case. Information on case reviews of neglected cases is presented on a monthly basis by the entity coordinating oncological care in the region to the designated health care authority to the chief specialist (freelance oncologist).	
248	Presence of mandatory confidential medical screening for HIV infection of persons based on clinical and epidemiological grounds, including sexual partners of pregnant women, persons who applied voluntarily and anonymously.	Major violation
249	Presence of supporting documentation on observance of indicators for hospitalisation in a day hospital at outpatient and polyclinic health care facilities and inpatient care at home: 1) exacerbation of chronic diseases that do not require round-the-clock medical supervision; 2) active planned recuperation of a group of patients with chronic diseases subject to dynamic monitoring; 3) treatment of a patient on the next day after inpatient treatment for medical reasons; 4) providing courses of medical rehabilitation of the second and third stages; 5) palliative care; 6) orphan diseases in children with a high risk of infectious complications and requiring isolation during seasonal viral diseases to receive regular enzyme and antibacterial replacement therapy. Adherence to the requirements for day hospitalisation in a 24-hour hospital: 1) conducting surgeries and interventions with special pre-surgical preparation and resuscitation support;	Major violation

	2) conducting complex diagnostic tests that require special preliminary preparation and are not available in outpatient and polyclinic health care facilities; 3) monitoring of patients whose treatment involves transfusion of blood products, intravenous infusions of blood substitutes, specific hyposensitising therapy, injections of potent drugs, intra-articular injections of drugs; 4) treatment on the next day after inpatient treatment if there are evidences for early discharge after surgical treatment; 5) palliative care; 6) chemotherapy, radiation therapy, correction of pathological conditions arising after specialised treatment of oncological patients	
	Presence of medical documentation on observance of the following requirements during the examination of temporary incapacity for work, issuance of a sheet and a certificate of temporary incapacity for work (form № 001/y “Medical Records of an Inpatient Patient”, form № 052/y “Medical Records of an Outpatient Patient”, stubs of certificates of temporary incapacity for work of patients, form № 025/y “Log for Recording Opinions of Medical Advisory Board”, form № 029/y “ Book of Registration of Certificates of Temporary Incapacity for Work”, form № 037/y “Certificate №_____ ____ on Temporary Disability of a Student, Pupil of a College, Vocational School, Sickness, Quarantine and Other Reasons for Absence of a Child Attending School, Preschool Institution (underline as appropriate)”, form № 038/y “Certificate №_____ on Temporary Disability” and others. 1) presence of examination of the person and recording of data on his/ her state of health in the medical record of an outpatient (inpatient) patient justifying the need for temporary release from work;	

250	2) issuance of a temporary disability certificate on the day of discharge of persons under inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing the temporary disability certificate and certificate of temporary incapacity for work on the date of discharge from the hospital if the person's ability to work is fully restored; 4) prolongation to persons who continue to be temporarily incapacitated for a period of time a sheet and certificate of temporary incapacity for work, with due regard to the time required for his/her visit to a health worker of a polyclinic or a call of a health worker at home (but not more than one calendar day). Persons who received treatment outside the region of residence shall be considered for the time required to arrive at the place of his/her permanent residence (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as for acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and certificate of temporary incapacity for work to persons suffering from mental illnesses in the event of failure to apply to a healthcare facility in a timely manner for the past few days upon the conclusion of the medical advisory board of a psychoneurological dispensary or a medical officer (psychiatrist) jointly with the head of the healthcare facility; 7) issuance of a sheet and a certificate of temporary incapacity for work to persons sent by court decision for forensic medical or forensic psychiatric examination and recognised as incapable of work from the day of admission to the examination;	Major violation	

	8) issuance of a sheet and a certificate of temporary incapacity for work to a person who combines training with work.	
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, evaluated based on the following criteria: absence of anamnesis collection; completeness of anamnesis collection; presence of data on past, chronic and hereditary diseases, haemotransfusions, acceptability of medicines, allergological status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor anamnesis collection; 2) completeness and validity of diagnostic tests, which are evaluated against the following criteria: absence of diagnostic measures; inaccurate report or lack of a report based on the findings of diagnostic tests, resulting in incorrect diagnosis and errors in treatment tactics; performing diagnostic tests stipulated by clinical protocols; performing diagnostic tests with high , unjustified risk to the patient's health, justification of diagnostic tests not included in clinical protocols; conducting diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment/S; 3) accuracy, timeliness and validity of the clinical diagnosis, with due consideration of the findings of the tests performed (in case of planned hospitalisation, the tests performed at the pre-hospital stage are also included), which are estimated by the following criteria:	

251	the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome causing the severity of the course of the disease is not distinguished, comorbidities and complications are not recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not identified in the complications identified, comorbidities affecting the outcome are not recognised; the diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated); 4) promptness and quality of consultations with relevant experts, which are estimated based on the following criteria: lack of counselling, which led to misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into consideration when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; the consultant's opinion is erroneous and affected the outcome of the disease.	Major violation

	Presence of evidence on the evaluation of the objectivity of the reasons for late consultation and the impact of late diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which are evaluated based on the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without regard to the peculiarities of the course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy that led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is estimated by the following criteria: achievement of the expected clinical effect in adherence to the technology of health care services (care); lack of clinical effect of therapeutic and prophylactic measures due to poor anamnesis and diagnostic studies; lack of expected clinical effect due to ineffective therapeutic and preventive measures without regard to the peculiarities of the course of the disease, comorbidities,	

	complications, prescription of drugs without proven clinical efficiency; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is estimated by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of health care provided.	
Delivery of oncological care at the inpatient level		
252	Presence of confirming documentation regarding rendering medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
253	Presence of confirming documentation on dilution of antitumour drugs in the rooms of centralised dilution of cytostatic drugs (hereinafter - RCDC) to ensure safety of medical personnel from toxic effects of antitumour drugs and rational use of drugs. Applications for dilution of anticancer drugs for each patient should be presented by the physician of the clinical unit jointly with the responsible expert of the RCDC. Antitumour medicines are diluted upon request. Diluted medicinal products are packed in disposable sterile containers and labelled. The second copy of the application is fastened to the container. Diluted anticancer medicinal products are received and transported by the clinical unit nurse. The medicines are transported in containers. Before administering the anticancer medicinal product, the clinical unit nurse compares the patient's data, requisition and labelling on the vials and (or) syringes.	Major violation
	Presence of supporting documentation that radiation therapy	

254	is performed based on the principle of “single physician - radiation therapist (radiation oncologist)”, providing for clinical management of the patient, pre-radiation preparation and radiation treatment by a single physician - radiation therapist (radiation oncologist). Pre-radiation preparation procedures are performed on special X-ray machines (simulators, computer tomographs), where data of the irradiation site and surrounding organs and tissues are obtained. These machines also transmit to computerised planning systems the following topographical features of the irradiation site: dimensions, weight, orientation and additional information required for subsequent dosimetric calculations. A radiation therapy physics service or a team of medical physicists and radiation therapy equipment maintenance engineers is established to ensure continuity of operation and quality control of radiation therapy equipment, verification of radiation plans using phantom measurements in the case of complex radiation therapy equipment.	Major violation
255	Presence of supporting documentation that anti-tumour therapy, radiation and radionuclide therapy, palliative care in cases that do not require constant medical supervision are delivered to patients with MN under inpatient substitution conditions in institutions rendering oncological care at secondary and tertiary levels in chemotherapy, radiation therapy, palliative care, medical rehabilitation wards. Medical care in hospital substitution conditions is rendered by an oncological institution of secondary and tertiary levels upon referral of an oncologist with the results of laboratory and instrumental examinations and consultations of profile experts needed for the treatment of a given patient, with due regard to the recommendation of the MDG.	Major violation

256	Hospitalisation of a severe patient in need of constant monitoring of vital functions for medical reasons, by decision of a consilium and notification of the heads of health care facilities, followed by transfer to another healthcare facility based on the profile of the disease for further examination and treatment after stabilisation of the condition	Major violation
257	Severe patients are examined by the head of the ward on the day of hospitalisation and daily thereafter. Patients in a moderately severe condition are examined at least once a week. The results of the patient's examination are recorded in the medical record with recommendations on further tactics of the patient's management with obligatory identification of the medical worker making the entries	Major violation
258	Presence of an established clinical diagnosis jointly with the head of ward no later than three calendar days from the day of the patient's hospitalisation in a health care facility	Major violation
259	Daily examination of patients in the hospital by the attending physician, excluding weekends and public holidays. Upon examination and appointment of additional diagnostic and therapeutic manipulations by the physician on duty, appropriate entries are made in the medical record. If the patient's condition worsens, the physician on duty notifies the head of the ward and (or) the attending physician, agrees to make changes in the process of diagnosis and treatment, and makes an entry in the medical record (paper and (or) electronic) option. An entry is made in the electronic version of the medical record within 24 hours of a change in the patient's condition. In case of emergency, the frequency of entries depends on the dynamics of the severity of the condition. The records of the hospital physician reflect specific changes in the	Major violation

	patient's condition and the need to correct prescriptions, justification of the prescribed examination and treatment, evaluation and interpretation of the results obtained and the effectiveness of the treatment. Frequency of examination for emergency conditions at least every 3 hours, specifying the time of emergency care by hours and minutes.	
260	Consultations or consiliums in case of difficulty in identifying the diagnosis, inefficiency of the current treatment, as well as other indications	Gross violation
	Presence of examination of persons on clinical indications for HIV infection upon detection of the following diseases, syndromes and symptoms: 1) enlargement of two or more lymph nodes with duration of more than 1 month, persistent, generalised lymphadenopathy; 2) fever of unclear etiology (persistent or recurrent for more than 1 month); 3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained loss of 10% of weight or more; 4) chronic diarrhoea for 14 days or more (in children), unexplained chronic diarrhoea for more than a month; 5) seborrhoeic dermatitis, pruritic papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) herpes zoster; 9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis, isosporosis, extrapulmonary histoplasmosis, strongyloidosis, actinomycosis);	

261	10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, excluding tuberculosis of peripheral lymph nodes; 11) hairy leukoplakia of the oral cavity, linear erythema of the gums; 12) severe prolonged recurrent pneumonia and chronic bronchitis not responding to conventional therapy (two or more times during the year), asymptomatic and clinically evident lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent and bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis, meningoencephalitis, bone and joint infections, purulent myositis, Salmonella septicemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) pneumocystis pneumonia; 15) infections caused by herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of the disease) lesions of the skin and mucous membranes, including eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unclear etiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the esophagus, bronchi, trachea, lungs, oral and nasal mucous membranes; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unclear etiology; 26) prolonged recurrent pyoderma that does not respond to conventional therapy;	Gross violation

	27) severe chronic inflammatory diseases of the female genital sphere of unclear etiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis after 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhea, genital herpes, viral papillomatosis, and others) with an established diagnosis; 31) viral hepatitis B and C, with confirmed diagnosis; 32) extensive draining condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum; 34) primary dementia in previously healthy persons; 35) patients with hemophilia and other diseases systematically receiving transfusion of blood and its components; 36) generalized cytomegalovirus infection	
262	Presence of an agreement for rendering paid medical services in health care facilities. Availability of documents establishing the fact of co-payment	Gross violation
263	Presence of confirming documentation that discharge criteria have been met, such as: 1) generally accepted treatment outcomes (recovery, improvement, no change, death, transferred to another healthcare facility); 2) a written application by the patient or his/her legal representative in the absence of immediate danger to the patient's life or to others; 3) cases of breaching the internal order of the health care facility, as well as obstruction of the treatment and diagnostic process, infringement of the rights of other patients to receive proper medical care (in the absence of an immediate threat to his /her life), about which an entry is made in the medical record.	Major violation

264	Discharge epicrisis is issued to the patient upon discharge, stating the full clinical diagnosis, the scope of diagnostic tests, therapeutic measures and recommendations for further follow-up and treatment. Discharge data are entered into information systems on a day-to-day basis, specifying the actual time of discharge.	Minor violation
265	There is supporting documentation of adherence to the requirements for transfusion of blood components and in case of complications: Prior to transfusion of blood components, the recipient is examined for markers of hemotransmissible infections HIV, hepatitis B and C, and after the end of treatment, the discharge epicrisis specifies the need for repeated screening for HIV and hepatitis B and C at the place of residence. Recipients are examined for HIV infection as part of the guaranteed scope of free medical care by state health care providers working in the field of HIV prevention Information on the transfusion and obstetric anamnesis is included in the patient's medical record prior to the start of transfusion therapy: previous transfusions, when and in relation to what; whether there were any post-transfusion complications, pregnancies resulting in birth of children with haemolytic disease of the newborn. In case of development of complications during the biological test, during transfusion or after it, a detailed record(s) is made describing the recipient's condition, vital function monitoring data, treatment methods and their efficacy. Immediate laboratory control of the recipient's blood and urine is performed.	Gross violation
	Presence of supporting documentation on the determination of the method and tactics of treatment by the MDG.	

266	MDG meetings are held in the oncology centre on a daily basis (excluding weekends and holidays). Availability of rooms for centralised dilution of cytostatic medicines (hereinafter - RCDC) to ensure safety of medical personnel from toxic effects of anticancer drugs and rational use of medicines. The work in the RCDC for the dilution of antitumour medicines is arranged in shifts. Presence and control of requests for dilution of antitumour medicines for each patient. Requirements for packaging, labelling, transportation (medicines are packed in disposable sterile containers (vials, syringes) and labelled. Medicines are transported in containers.)	Gross violation
267	Presence of confirming documentation on conformity of the provided medical care to clinical protocols	Major violation
	Presence of medical documentation on observance of the following requirements for the examination of temporary incapacity for work, issuance of certificates of temporary incapacity for work (form № 001/y “ Medical Record of Inpatient Patient” , form № 052/y “Medical Record of Outpatient Patient”, stubs of patients' certificates of temporary incapacity for work, form № 025/y “Log for Recording Medical Advisory Board Reports”, form № 029/y “Book of Registration of Certificates of Temporary Incapacity for Work”, Form № 037/y “Certificate №_____ _____ on Temporary Incapacity for Work of a Student, a Student of a College, a Vocational School, on Illness, Quarantine and Other Reasons for the Absence of a Child Attending School, Pre-School Institution (to be underlined)”, Form № 038/y “Certificate №_____ on Temporary Incapacity for Work” and others): 1) examination of the person and recording of data on his/her state of	

268	health in the medical card of an outpatient (inpatient) patient, justifying the need for temporary exemption from work; 2) issuance of a temporary disability certificate on the day of discharge of persons under inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing the temporary disability certificate and certificate of temporary incapacity for work on the date of discharge from the hospital if the person's ability to work is fully restored; 4) prolongation of the temporary disability certificate and certificate of temporary disability for a period of time, considering the time required to visit a health worker of the outpatient clinic or call a health worker at home (but not more than one calendar day). Persons who received treatment outside the region of residence shall be accounted for the time required to arrive at the place of his/her permanent residence (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as for acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and certificate of temporary incapacity for work to persons with mental illnesses in case of untimely referral to a health care facility for the past days by the conclusion of the medical advisory board of a psychoneurological dispensary or a health care worker (psychiatrist) jointly with the head of the health care facility; 7) issuance of a sheet and a certificate of temporary incapacity for work to persons sent by court decision for forensic medical or forensic psychiatric examination and	Major violation

	recognised as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work at the same time to a person who combines training with work.	
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, to be evaluated on the following criteria: absence of anamnesis collection; completeness of anamnesis collection; data on past, chronic and hereditary diseases, haemotransfusions, drug tolerance, allergological status; growth of health complications as a result of tactical errors in the course of treatment and diagnostic measures due to poor anamnesis collection; 2) completeness and justification of diagnostic tests, which are evaluated by the following criteria: absence of diagnostic measures; erroneous statement or absence of a statement based on the results of diagnostic studies, which led to erroneous diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; diagnostic tests with high, unjustified risk to the patient's health , justification of diagnostic tests not included in clinical protocols; performance of diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and cost of treatment; 3) accuracy, timeliness and validity of the clinical diagnosis, based on the results of the conducted investigations (in case of planned hospitalisation, investigations conducted at the pre-hospital stage	

269	shall be taken into account), which are evaluated against the following criteria: the diagnosis is missing, incomplete or erroneous, does not correspond to the international classification of diseases; the leading pathological syndrome defining the severity of the course of the disease is not highlighted, comorbidities and complications are not recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the indicated complications, comorbidities affecting the outcome are not recognised; diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for erroneous and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the expertise. The impact of erroneous and (or) untimely diagnosis on the subsequent stages of medical services (care) is estimated; 4) timeliness and quality of consultations of relevant experts, which are estimated against the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to consider the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; consultation was timely, the consultant's opinion was considered when making the diagnosis, failure to implement the consultant's	Major violation	

	treatment recommendations partially influenced the outcome of the disease; the consultant's opinion is erroneous and affected the outcome of the disease. Presence of confirming documentation on the evaluation of the objectivity of the reasons for late consultation and the impact of late diagnosis on the subsequent stages of health services (care); 5) volume, quality and validity of treatment measures, which are estimated under the following criteria: no treatment when there is an indication; prescribing treatment in the absence of indications; prescription of inefficient therapeutic measures without considering the specifics of the course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or progression of complications after medical interventions, all complications encountered, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is estimated against the following criteria: achievement of the expected clinical effect while observing the technology of rendering medical services (assistance);	

	lack of clinical effect of therapeutic and preventive measures due to poor history assessment and diagnostic tests; absence of expected clinical effect due to inefficient therapeutic and preventive measures without regard to the specifics of the course of the disease, comorbidities, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) quality of medical documentation, which is estimated by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care delivered	
	Presence of confirming documentation of observance of the following actions when performing pathological autopsies: 1) conducting pathological anatomical autopsy of corpses after the doctors have ascertained biological death, upon submission of the medical record of an inpatient patient or the medical record of an outpatient patient with a written order from the chief physician or his/her deputy for medical (treatment) part of the health care facility to send for a pathological anatomical autopsy; 2) registration of the results of the pathological anatomical autopsy in the form of a pathological anatomical diagnosis (pathological anatomical diagnosis includes: the main disease, complication of the main disease, concomitant disease, combined main disease); 3) transfer of the medical record of an inpatient or medical record of an outpatient with the pathological anatomical diagnosis entered into it to the medical archive of the health care facility no later than ten	

	working days after the pathological anatomical autopsy; 4) conducting clinical and pathological anatomical examination in cases of death of patients in health care facilities; 5) pathological anatomical autopsy in cases of suspected acute infectious diseases, oncological diseases, pathology of childhood, lethal outcome due to medical manipulations for the purpose of establishing the cause of death and clarifying the diagnosis of fatal disease; 6) arrangement by the chief physician and head of the pathology department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathological anatomy bureau, centralised pathological anatomy bureau and pathological anatomy department the medical records of inpatients for all deceased patients for the previous 24 hours no later than 10 a.m. of the day following the establishment of the fact of death; 8) drawing up: - medical certificate of death (preliminary, final) by a physician majoring in 'pathological anatomy (adult, paediatric)' on the day of the pathological anatomical autopsy; - medical certificate of perinatal death (preliminary, final) by a physician specialising in ' pathological anatomy (adult, child)' on the day of the pathological anatomical autopsy; 9) recording the results of the autopsy in the form of a protocol of pathological anatomical examination ; 10) written notification to the judicial and investigative authorities to address the issue of transferring the corpse for forensic medical examination if signs of violent death	
270		Gross violation

	are found, and termination of the pathological anatomical examination of the corpse; 11) written notification of a physician majoring in 'pathological anatomy (adult, paediatric)' in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service, immediately after their detection; 12) performing pathological and anatomical examination of the placenta: - in case of stillbirth; - in case of all diseases of newborns detected at the time of birth; - for cases suspected of haemolytic disease in newborns; - in case of early discharge and dirty waters; - maternal illness with fever in the last trimester of pregnancy; - if there is an obvious abnormality in the development or attachment of the placenta; - suspected congenital anomalies of the foetus; - in cases of pre-eclampsia, and eclampsia 13) compulsory registration of a foetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) the establishment of pathological anatomical autopsies depending on their complexity into the following categories: - first category; - second category; - third category; - fourth category; 15) establishment of the category of pathological anatomy (adult, paediatric) by a physician specialising in 'pathological anatomy (adult, paediatric)' and the reason for the divergence of	

	diagnoses when the final clinical and pathological anatomical diagnoses diverge 16) detailed analysis with the definition of the profile and categories of iatrogenic pathology in all cases of iatrogenic pathology revealed as a result of pathological anatomical autopsy	
271	Presence of a written application from the spouse, close relatives or lawful guardians of the deceased or a written will given by the person during his/her lifetime to release the corpse without a pathological anatomical autopsy, in the absence of suspicion of violent death	Major violation
272	Presence of supporting documentation on rendering oncological care at home: 1) when a PHC or CDC (primary level) health worker is called by a patient under dynamic monitoring (clinical groups Ib, III) when it is impossible to consult face-to-face in the institution; 2) when a mobile brigade is called to visit patients with MN outside the exacerbation of the disease with limited mobility and in need of palliative care, including with the use of remote medical services; 3) in the form of active patronage of patients with MN in severe condition with restricted movement discharged from the hospital or transfer of assets from the ambulance station; 4) when providing treatment at home (hospital at home), to patients with clinical group IV.	Major violation
Requirements for persons (facilities) offering medical and social assistance in the field of mental health care		
Requirements for actors (facilities) offering medical and social care in the field of mental health at the outpatient and polyclinic level		
273	Presence of supporting documentation on rendering health care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
	Presence of confirming documentation on observance of the	

274	criteria for dynamic observation of persons with MBD: 1 group of dynamic psychiatric observation - persons who are prone by their mental state to socially dangerous actions, including those who have a risk of committing violent acts of a sexual nature against minors, as well as those who have perpetrated particularly dangerous acts in a state of insanity, and who have been ordered by a court to undergo forced medical measures in the form of outpatient mandatory treatment; 2 group of dynamic psychiatric observation - Persons with MBD who have a disability due to mental illness, excluding MBD specified in the diagnostic headings F8 and F9; persons diagnosed with F20 ‘ Schizophrenia’ within one year after diagnosis (in this case, if recognised as a person with a disability, he/she continues to be observed in the 2nd group of dynamic psychiatric observation); 2A - persons with frequent and pronounced exacerbations of psychotic symptoms, decompensations, in need of psychopharmacotherapy within the framework of free outpatient treatment, including persons with MBD specified in the diagnostic headings F8 and F9. 2B - persons with stabilised conditions, with moderately progressive course of the process and spontaneous remissions; dynamic narcological observation group - Persons prone to socially dangerous actions due to clinical manifestations of MBD caused by substance abuse. Dynamic narcological observation group 1) MBD due to substance abuse in persons sent by court order to forced treatment units; 2) MBD due to substance use in persons who, following a	Major violation

	court-ordered forensic narcological expertise report, have been assigned treatment; 3) MBD due to substance use in persons sent from places of deprivation of liberty where forced medical measures have been applied; 4) MBD due to substance use, after psychotic disorder due to substance use in inpatient care; 5) MBD due to substance use in persons prone to socially dangerous behaviour; 6) MBD due to substance use in persons who have voluntarily consented to dynamic monitoring. Persons referred to in sub-paragraphs 1) - 5) are taken for dynamic monitoring by the decision of the medical advisory board. Observing the periodicity and frequency of observation of persons with mental, behavioural disorders (diseases): 1 group of dynamic psychiatric observation - at least once a month 2 group of dynamic psychiatric observation: 2A - at least once every three months , 2B - at least once every six months; group of dynamic narcological observation - at least six times a year , depending on the individual characteristics of the personality and the course of the disease	
275	Presence of confirming documentation on observance of the requirement to supply medicines to persons with MBD under dynamic monitoring Persons with MBD who are under dynamic monitoring are supplied with medicines	Major violation
	Presence of confirming documentation of adherence to the requirements for deregistration and transfer to another group of dynamic monitoring: Termination of dynamic follow-up of persons with MBD and deregistration is done in the following cases:	

276	1) absence of criteria, taking on dynamic observation of persons with MBD, not less than 12 months, with the indication in the EIS - ‘recovery, persistent improvement’; 2) change of place of residence with travelling outside the serviced territory; 3) absence of reliable data on the location for 12 months, confirmed by a report of the district police inspector and patronage of the district nurse at least once every two months, with the indication in the EIS – “absence of data”; 4) death on the grounds of a medical certificate of death in the form № 045/y and (or) confirmed by data in the register of the attached population, with the indication in the EIS – “death”; 5) persons sentenced to imprisonment for more than 1 year are removed from dynamic monitoring after receiving a response to the request from the Committee on Legal Statistics and Special Records of the General Prosecutor's Office of the Republic of Kazakhstan; 6) persons diagnosed with F20 “ Schizophrenia”, recorded in the 2nd group of dynamic psychiatric observation: in case of failure to establish a disability group within 12 months from the moment of dynamic observation. Criteria for transferring a person with MBD to another group: absence of criteria for taking a person with MBD on dynamic observation for at least 12 months	Major violation
	Presence of confirming documentation on the implementation of the following activities during dynamic monitoring of a person with MBD by a psychiatric doctor: 1) informing the patient of the need for dynamic monitoring, the list, scope, frequency of examinations, laboratory and instrumental tests, and the period of monitoring;	

277	2) establishing dynamic monitoring in case of written consent of the person with MBD to be placed on dynamic monitoring; 3) referral to a session of the medical advisory board (hereinafter - MAB) to resolve the issue of establishing dynamic monitoring without his/her consent or his/her lawful guardian in the case of refusal of a person with MBD or his/her lawful guardian to voluntarily take up dynamic monitoring; upon taking a person with MBD under dynamic observation, conducting an initial examination of the patient, establishing the group of dynamic observation, the frequency of examinations, the need for special social services in the field of health care, drawing up an individual treatment plan, individual rehabilitation programme and other measures with due regard to an individual approach, and entering data into electronic information systems (hereinafter referred to as EIS) as per the form of health care records 5) conducting periodic examinations and analysing the results of diagnostic tests, conclusions and recommendations of relevant experts ; 6) monitoring and control of the efficiency of treatment, rehabilitation (habilitation) measures, making adjustments if needed; 7) drawing up documents and referrals for medical and social expert evaluation, medical and social rehabilitation, inpatient substitution, inpatient treatment, including mandatory treatment in the presence of relevant indications; 8) referral for consultation of relevant health care experts, required laboratory and instrumental examinations, examination by a psychologist, consultation by a social worker and other specialists; 9) visits to the person with MBD at the place of his/her residence;	Major violation

	10) continuity in the levels, conditions and types of medical and social assistance rendered	
278	Presence of an individual treatment plan and rehabilitation programme for persons after discharge from a facility rendering health care in the field of mental health, excluding those discharged by court order as early recovered. In the case of maintenance treatment, a psychiatrist (narcologist) draws up an individual treatment plan and an individual rehabilitation programme for persons with MBD. The individual treatment plan and individual rehabilitation programme include: 1) diagnostic techniques: analysis of the content of PS in biological fluids and body tissues, HIV testing, experimental-psychological diagnostics, determination of quality of life and social functioning, clinical and biochemical diagnostics, neurophysiological diagnostics; 2) medication therapy: psychopharmacotherapy, symptomatic therapy, therapy of comorbid pathology, antagonistic therapy using opioid receptor blockers; 3) counselling techniques: health, psychological and social counselling for psychoactive substance-dependent and co-dependent persons; 4) training techniques: motivational trainings for the continuation of supportive antiseizure therapy, for the formation of adaptation skills and stress resistance, for the formation of psychological resistance to re-involvement in PS dependence; 5) psychotherapeutic techniques: individual and group psychotherapy for substance-dependent persons, individual express psychotherapy for PS-dependent persons in a state of breakdown.	Major violation
	Presence of confirming documentation of the	

279	implementation of PHC by a physician, upon suspicion or identification of a person with a MBD, excluding MBD requiring emergency and urgent medical and social care: 1) patient identification; 2) diagnostic measures as per clinical protocols; 3) establishes a diagnosis and treats MBD under the 10th revision of the International Classification of Diseases (hereinafter referred to as ICD-10), which are within the competence of the PHC physician. If a person is suspected of having a diagnosis of MBD according to ICD-10 that is not within the competence of the PHC physician, the PHC physician refers the person to a MHU (mental health unit) or PMHC by territorial registration; 4) in case of diagnoses of borderline substance use disorders falling within the competence of a PHC physician for the first time in the current year - sending information on the patient with passport data (surname, name, patronymic (if any), individual identification number (hereinafter - IIN), address of residence), diagnosis and date of diagnosis, to be entered into the electronic information system (hereinafter - EIS) not later than 5 working days from the date of diagnosis; 5) undertaking activities when revealing a person at risk of committing suicide who applied on his/her own or when examining a minor referred by psychologists; 6) filling out primary medical documentation; 7) reconciliation with the doctor of the MHU or PMHC on newly entered patients in the EIS on registration of persons with MBD, monthly, not later than the 5th day of the month following the reporting period.	Major violation
	Implementation of the following activities by a mental health clinician	

280	of a MHU or PMHC when a person with PPR is suspected or identified, excluding MBD requiring emergency and urgent medical and social care: 1) patient identification; 2) diagnostic measures based on clinical protocols; 3) prescription of treatment following clinical protocols (if required); 4) verification in the EIS for registration of persons with MBD on the availability of data on the applicant. In case of initial diagnosis of the MBD information is entered into the EIS, including it in the statistical group, in case of previously established diagnosis of the MBD and absence of information in the mentioned EIS information is entered, and in case of availability of information it is supplemented with information; 5) decision on dynamic follow-up, as well as termination of dynamic follow-up; 6) issuing a referral to a medical advisory board (hereinafter - MAB); 7) preparation of medical documentation in respect of a person with MBD in need of medical and social expert appraisal (hereinafter referred to as MSE); 8) preparation of documents for persons with drug use disorders caused by substance use for referral for compulsory treatment; 9) entering details of a person with a drug use disorder into the EIS no later than 3 working days after receiving a notification from a primary health care physician; 10) dynamic follow-up of persons in dynamic follow-up groups based on territorial registration; 11) referring persons with suspected or diagnosed MBD for examination and (or) treatment to the territorial Mental Health Centre or RSPCMH (if indicated); 12) referring persons with MBD to institutions rendering medical and	Major violation

	social rehabilitation in the field of mental health; 13) maintenance of primary medical documentation; 14) entering data into the EIS on registration of persons with MBD; 15) reconciles with the PHC physician on the newly entered and registered persons in the EIS and provides this information to the head of the territorial PMHC.	
281	There is confirming documentation regarding the implementation of the following activities by the psychiatric physician of the MHU or PMHC when a person who was previously on dynamic follow-up with a MBD applies and is deregistered from the EIS with a reason for deregistration other than " convalescence, persistent improvement": 1) patient identification; 2) diagnostic measures based on clinical protocols; 3) decision on dynamic observation, as well as termination of dynamic observation; 4) in the absence of criteria for dynamic observation, issuing a referral to the MAB to decide whether to withdraw from dynamic observation, stating the grounds for the withdrawal in the EIS.	Major violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, which is evaluated based on the following criteria: lack of anamnesis; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, haemotransfusions, tolerance to drugs, allergological status; development of complications as a result of tactical errors made during	

	treatment and diagnostic measures due to poor quality anamnesis collection; 2) completeness and validity of diagnostic tests, which are evaluated against the following criteria: absence of diagnostic measures; erroneous opinion or lack of opinion on the results of diagnostic investigations, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; performing diagnostic tests with high , unjustified risk for the patient's health condition, justification of diagnostic tests not included in the clinical protocols; performing diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified extension of treatment time and increased cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, based on the results of the conducted investigations (in case of planned hospitalisation, the investigations conducted at the pre-hospital stage are taken into account), which are estimated based on the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome defining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not distinguished with the highlighted complications, comorbidities affecting the outcome are not recognised; the diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed.	

282	Objective reasons for erroneous and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the results of the expertise. The impact of erroneous and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated; 4) timeliness and quality of consultations of relevant experts, which are estimated against the following criteria: absence of consultation, which led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely counselling, failure to take the consultant's opinion into account when making the diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendations partially influenced the outcome of the disease; consultant's opinion was wrong and affected the outcome of the disease. Presence of supporting documentation on the evaluation of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which are estimated by the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of inefficient treatment measures without regard to the	Major violation

specifics of the course of the disease, concomitant diseases and complications;

performance of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of medicines without proven clinical efficacy;

unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition;

6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated;

7) the achieved result, which is estimated based on the following criteria:

achievement of the expected clinical effect in observance of the technology of medical services (assistance);

absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic examinations;

lack of expected clinical effect due to ineffective therapeutic and preventive measures without considering the specifics of the course of the disease, comorbidities, complications, prescription of drugs without proven clinical efficacy;

the presence of polypragmasy, which caused the development of undesirable consequences;

8) the quality of medical documentation, which is estimated by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature,

	scope and quality of medical care rendered.	
Requirements for entities (facilities) delivering health and social care in the field of mental health in inpatient settings with 24-hour medical supervision		
283	Presence of confirming documentation on rendering medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free of charge basis	Gross violation
284	There are grounds for hospitalisation in inpatient clinical units. The grounds for hospitalisation in inpatient clinical departments are: 1) referral by a psychiatric physician ; 2) judgement, decision, determination of judicial and investigative bodies; 3) referral by a military medical board; 4) a written statement of the person himself/herself, if there is evidence; 5) an enforceable court decision on forced treatment of persons with MBD caused by substance use; 6) a court decision on the application of coercive measures of medical nature envisaged by Article 93 of the Criminal Code of the Republic of Kazakhstan, which has entered into legal force.	Major violation
285	Comprehensiveness of the measures implemented during planned hospitalisation in inpatient clinical wards of RSPCMH, MHC. During planned hospitalisation in inpatient clinical wards of RSPCMH , MHC the head or a psychiatrist (narcologist) of the clinical ward, admission and diagnostic department undertakes the following activities: 1) identification of the patient; 2) checks the availability of available medical and other documentation, if required, directs the patient to undergo regulated and (or) additional examinations; 3) verifies the existence of an enforced court decision on hospitalisation, if any;	Major violation

	4) evaluates the mental and somatic condition, findings of laboratory and diagnostic tests, establishes the need for emergency care at the level of the admissions and diagnostic department and (or) the presence of indications and contraindications for hospitalisation; 5) determines a preliminary diagnosis, specifies the scope of differential diagnosis, observation regime, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols of diagnosis and treatment; 6) fill in primary medical documentation.	
286	Comprehensiveness of the measures undertaken during hospitalisation in the inpatient clinical ward of RSPCMH, MHC for emergency indications. During hospitalisation in the inpatient clinical ward of RSPCMH, MHC for emergency indications, the head or a psychiatrist (narcologist) of the clinical ward or admission-diagnostic ward, or a physician on duty performs the following activities: 1) identification of the patient; 2) assesses mental and somatic condition, findings of laboratory and diagnostic tests and defines the need for emergency care at the level of the admissions and diagnostic ward and (or) the presence of indications and contraindications for hospitalisation; 3) establishes a preliminary diagnosis, determines the scope of differential diagnosis, observation regime, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols of diagnosis and treatment; 4) fill in primary medical documentation	Major violation
	Comprehensiveness of the activities undertaken during routine hospitalisation in PFSIS. When planned hospitalisation in PFSIS, the physician on duty undertakes the following activities:	

287	1) verifies the availability and consistency of the available documentation: an enforceable court judgement; an identity document. 2) identifies the patient; 3) evaluates the mental and somatic condition, results of laboratory and diagnostic tests, determines the need for emergency care at the level of the reception and diagnostic department and (or) the presence of indications and contraindications for hospitalisation; 4) specifies the ward, establishes the observation regime, therapeutic nutrition and other therapeutic and diagnostic measures based on clinical protocols of diagnosis and treatment; 5) fills in primary medical documentation	Major violation
288	Comprehensiveness of the activities undertaken after admission of a person with MBD to the inpatient clinical unit. Upon admission of a person with MBD to an inpatient clinical unit, the following activities are performed: 1) identification of the patient; 2) verification of the availability and consistency of available medical and other documentation; 3) evaluation of mental and somatic condition, findings of laboratory-diagnostic tests, establishment of preliminary diagnosis, determination of the scope of differential diagnostics, observation regime, therapeutic nutrition and other therapeutic-diagnostic measures according to clinical protocols of diagnostics and treatment; 4) filling in primary medical documentation of treatment;	Major violation
	Comprehensiveness of interventions following the person's admission to the PFSIS inpatient clinical unit Once a person has been hospitalized to the PFSIS inpatient clinical unit,	

289	the following activities are undertaken: 1) patient identification; 2) verification of presence and consistency of available medical and other documentation; 3) evaluation of mental and somatic condition, laboratory and diagnostic tests results, establishment of preliminary diagnosis, determination of the scope of differential diagnostics, observation regime, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols of diagnostics and treatment; 4) filling in primary medical documentation	Major violation
	Adherence to observation regimes. In clinical inpatient departments of RSPCMH, MHC and multidisciplinary city (regional) hospitals the following types of observation are assumed: 1) general observation regime - round-the-clock observation without restriction of movement in the department. The general regime for patients is established when: absence of danger to themselves and others; the ability to observe personal hygiene without external help; 2) partial hospitalisation regime - the possibility of staying in the ward during the day or at night, with due regard to the need for adaptation in out-of-hospital conditions, as well as the possibility of performing work activities against the background of ongoing treatment and control of symptoms of MBD for the purpose of re-socialisation. The regime of partial hospitalisation is established by the decision of a medical board (hereinafter referred to as the medical board) consisting of two physicians in the following cases: absence of danger for oneself and others; the ability to maintain personal hygiene without assistance;	

290	stabilisation of the mental state requiring daily, but not round-the-clock observation and control; 3) therapeutic leave regime - the possibility of staying outside the ward from several hours to several days for the purpose of gradual adaptation to non-hospital conditions, solution of domestic and social issues, as well as evaluation of the achieved therapeutic effect. The therapeutic leave regime is established by the decision of the MB consisting of two physicians and is granted in the following conditions: absence of danger for oneself and others; the ability to observe personal hygiene without assistance; stabilisation of the mental state, which does not require daily observation. 4) enhanced observation regime - round-the-clock observation and restriction of movement outside the ward. Intensified observation regime is established for patients with: acute MBD, which do not pose a danger to themselves and others; the ability to observe personal hygiene without external help; absence of a psychiatric or somatic disorder requiring a different regime of observation and detention; 5) strict observation regime - round-the-clock continuous observation in the observation ward, constant accompaniment by health care personnel in the ward and outside it. Strict regime for patients is established for patients in case of: immediate danger to themselves and others; helplessness, i.e. incapacity to independently fulfil their vital needs, in the absence of proper care; possible serious harm to health if the person is left unsupervised. The following types of observation are envisaged in clinical inpatient PFSIS wards:	Major violation

	1) general observation regime - round-the-clock observation with movement in the ward as per the daily schedule, possibility to participate in occupational therapy outside the ward; 2) enhanced observation regime - round-the-clock observation and restriction of movement within the ward; 3) strict observation regime - round-the-clock continuous observation in the observation ward, constant accompaniment by health care personnel in the ward and outside the ward.	
291	Presence of confirming documentation that the criteria for forced hospitalisation in an inpatient hospital have been met: Forced hospitalisation is admissible by a court decision. Forced hospitalisation of a person before a court decision is allowed only in cases pursuant to the law. For each case of forced hospitalisation without a court decision, the administration of an institution rendering mental health care to persons with a mental or behavioural disorder (illness) sends a written notification to the prosecutor within forty-eight hours of the person's admission to the hospital, and also informs the spouse, close relatives and/or legal representatives, if there is information on them. A person's stay in a forced inpatient hospital remains in force only for the duration of the grounds for which hospitalisation was undertaken. During the first six months of forced hospitalisation, a person hospitalised in an inpatient facility should be examined at least once a month by a commission of psychiatrists to decide whether to extend the hospitalisation. Extension of hospitalisation beyond six months is made by court decision based on an application by an institution rendering mental health care to persons with mental or behavioural	Major violation

	disorders (diseases) on the need to extend the period of compulsory hospitalisation and treatment, to which the opinion of a board of psychiatrists is enclosed.	
292	There is confirming documentation that the conditions of discharge have been met. The patient is discharged from inpatient clinical wards upon recovery of the patient or improvement of his/her mental condition, when no further inpatient treatment is required, as well as upon completion of examination, expertise, security measures, coercive measures of medical nature, which were the grounds for admission to the hospital. The patient staying in inpatient clinical wards voluntarily is discharged upon his/her personal application, application of his/her lawful guardian or upon the decision of his/her attending physician. The patient who has been subjected to forced medical and security measures by court order is discharged only upon a court order that has entered into force. A patient hospitalised in an inpatient clinical ward voluntarily may be refused discharge if the MAB establishes grounds for compulsory hospitalisation	Major violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, which is evaluated based on the following criteria: absence of anamnesis collection; comprehensiveness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status;	

development of complications due to tactical errors in the course of therapeutic and diagnostic measures due to poor quality of anamnesis collection;

2) comprehensiveness and validity of diagnostic tests, which are evaluated based on the following criteria:

absence of diagnostic measures;

erroneous opinion or lack of opinion based on the results of diagnostic tests, which led to erroneous diagnosis and errors in treatment tactics;

performance of diagnostic tests stipulated by clinical protocols;

conducting diagnostic tests with a high, unjustified risk to the patient's health, justification of diagnostic tests not included in clinical protocols;

diagnostic tests that are not informative for a correct diagnosis and resulted in an unjustified extension of treatment time and increased cost of treatment;

3) accuracy, timeliness and validity of the clinical diagnosis, with due consideration of the results of the conducted examinations (in case of planned hospitalisation, the examinations conducted at the pre-hospital stage are also considered), which are evaluated against the following criteria:

the diagnosis is absent, incomplete or erroneous, does not correspond to the international classification of diseases;

the leading pathological syndrome defining the severity of the course of the disease is not highlighted, comorbidities and complications are not recognised;

the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the identified complications, comorbidities affecting the outcome are not recognised;

the diagnosis of the main disease is correct, but comorbidities affecting

293	the outcome of treatment are not diagnosed. Objective reasons for erroneous and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the examination results. The impact of erroneous and (or) untimely diagnosis on the subsequent stages of health care services (care) is evaluated; 4) timeliness and quality of consultations of relevant experts, which are evaluated against the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to observe the consultant's opinion when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was noted in the diagnosis, failure to follow the consultant's treatment recommendation partially affected the outcome of the disease; the consultant's opinion was wrong and affected the outcome of the disease. Presence of confirming documentation on the evaluation of the objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of health care services (assistance); 5) volume, quality and reasonableness of treatment measures, which are evaluated based on the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of inefficient treatment measures without consideration of	Major violation

	the specifics of the course of the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred are evaluated, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures; 7) the achieved result, which is evaluated against the following criteria: achievement of the expected clinical effect with observance of the technology of rendering health care services (care); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to inefficient therapeutic and preventive measures without due consideration of the specifics of the course of the disease, concomitant diseases, complications, prescription of medicines without proven clinical efficacy; the presence of polypragmasy that caused the adverse effects; 8) the quality of medical documentation, which is evaluated by the availability, comprehensiveness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature,	

	scope and quality of medical care provided	
Requirements for entities (facilities) delivering health and social care in the field of mental health in inpatient substitute conditions that do not require 24-hour medical supervision and treatment and include medical supervision and treatment during the day with the provision of a bed place		
294	Presence of confirming documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
295	Indications for inpatient substitution treatment for persons with MBD The indications for inpatient substitution treatment for persons with MBD are: 1) the need for active therapy of persons with MBD, including those caused by substance use, which does not require 24-hour supervision; 2) the need for gradual adaptation to a normal life environment, after receiving treatment in a 24-hour hospital; 3) conducting examinations and evaluations that do not require round-the-clock inpatient observation Hospitalisation in an entity rendering care in inpatient substitution conditions is provided in a planned manner.	Major violation
296	Implementation of the following activities during day hospitalisation: 1) identification of the patient; 2) verification of availability and consistency of available medical and other documentation; 3) evaluation of mental and somatic condition, as well as the results of laboratory and diagnostic tests, determination of indications and contraindications for hospitalisation; 4) establishing a preliminary diagnosis, determining the scope of differential diagnosis, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols of diagnosis and treatment; 5) filing of primary medical records.	Major violation

297	Requirements for the duration of treatment and time of stay in the day hospital. The duration of treatment in the day hospital should not exceed 30 calendar days. If a patient's condition worsens and requires round-the-clock medical supervision and treatment, he/she is hospitalised in an appropriate inpatient ward. The daily stay in the day hospital is at least 6 hours. Two meals a day are included in the day care centre, considering the time of psychotropic medication intake	Major violation
298	Observing the requirements for discharge from the day care hospital. Discharge is made upon recovery of the patient or improvement of his/her mental state, when transfer to outpatient treatment is possible, as well as upon completion of examination, expertise, which were the grounds for admission to the day care centre. On the day of the patient's discharge from the facility offering inpatient substitute care, an epicrisis is drawn up, a copy of which is sent to the PMHC, the MHU at the patient's place of residence for inclusion in the outpatient's medical record.	Major violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, which is measured by the following criteria: absence of anamnesis collection; comprehensiveness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status; development of complications due to tactical errors in the course of therapeutic and diagnostic measures	

	due to poor quality of anamnesis collection; 2) comprehensiveness and validity of diagnostic tests, which are estimated based on the following criteria: absence of diagnostic measures; erroneous conclusion or absence of a conclusion based on the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; conducting diagnostic tests with a high, unjustified risk to the patient's health, justification of diagnostic tests not included in clinical protocols; diagnostic tests that are not informative for making a correct diagnosis and resulted in an unjustified extension of treatment time and increased cost of treatment; 3) accuracy, timeliness and validity of the clinical diagnosis, with due consideration of the results of the conducted examinations (in case of planned hospitalisation, the examinations conducted at the pre-hospital stage shall be taken into account), which is evaluated based on the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not identified with the identified complications, comorbidities affecting the outcome are not recognised; the diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed.	

299	Objective reasons for erroneous and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the expertise. The impact of erroneous and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated; 4) timeliness and quality of consultations of relevant experts, which are evaluated based on the following criteria: absence of consultation, which led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to consider the consultant's opinion in making the diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion is considered when making the diagnosis, failure to implement the consultant's treatment recommendation partially influenced the outcome of the disease; consultant's opinion is erroneous and affected the outcome of the disease. Presence of confirming documentation on the evaluation of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: absence of treatment in the presence of indications; prescribing treatment in the absence of indications; prescribing inefficient therapeutic measures without due consideration of the specifics of the course of the disease, concomitant diseases and complications;	Major violation

	implementation of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of medicines without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or progression of complications after medical interventions, all complications encountered, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is evaluated against the following criteria: achievement of the expected clinical effect in adherence to the technology of medical services (care); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic examinations; lack of expected clinical effect due to ineffective therapeutic and preventive measures without regard to the specifics of the course of the disease, comorbidities, complications, prescription of medicines without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is estimated by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care provided.	
Requirements for entities (facilities) delivering health and social care to persons with mental, behavioural disorders (diseases) in the form of emergency health and social care		

300	Emergency specialised psychiatric care is rendered by specialised teams organised as part of the organisation delivering emergency health and social care or MHC.	Major violation
Requirements for actors(facilities) offering health and social rehabilitation in the field of mental health		
301	Presence of confirming documentation on the delivery of health care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
302	Presence of confirming documentation on fulfilment of the requirements for health and social rehabilitation in outpatient or inpatient substitute conditions. When rendering medical and social rehabilitation in outpatient or hospital-substitute conditions, the daily stay should be at least six (6) hours, excluding weekends and public holidays, with two meals a day, considering the time of taking psychotropic drugs. In the medical and social rehabilitation unit, the patient is offered the required medication therapy and necessary examinations. Medical and social rehabilitation of patients with MBD is performed in keeping with an individual programme for the rehabilitation of patients with MBD	Major violation
303	Presence of confirming documentation on adherence to the requirements for medical and social rehabilitation in inpatient settings. During hospitalisation for medical and social rehabilitation, the following activities are undertaken: 1) identification of the patient; 2) verification of the availability and compliance of existing medical documentation and referral for regulated and (or) additional examinations; 3) development of an individual rehabilitation programme for a patient with MBD;	Major violation

	4) primary medical documentation is filled out. Identification of general contraindications for hospitalisation for medical and social rehabilitation: 1) acute conditions that require strict or intensified observation regime; 2) presence of concomitant diseases requiring treatment in hospitals of other profiles; 3) infectious diseases in the period of epidemiological danger	
304	Presence of proving documentation on the implementation of the activities of the multidisciplinary group. Medical and social rehabilitation of adults with MBD is implemented by a multidisciplinary group: 1) a supervisor (a physician health manager or a psychiatrist); 2) a psychiatrist; 3) a psychologist; 4) social worker or social work specialist; 5) labour instructor or specialist in occupational therapy, sports; 6) an average healthcare worker. The composition of the multidisciplinary group is enlarged when the list and (or) volume of services is increased	Gross violation
305	Requirements for the duration of medical and social rehabilitation. The duration of medical and social rehabilitation of adult patients with MBD should not exceed 3 (three) months. The duration of medical and social rehabilitation for children with MBD should not exceed 3 (three) months. The duration of medical and social rehabilitation for adults with substance use disorders does not exceed nine (9) months. The duration of medical and social rehabilitation for children with substance use disorders does not exceed nine (9) months.	Major violation
Requirements for entities (facilities) rendering health examinations to establish the fact of psychoactive substance use and intoxication status		

306	Presence of confirming documentation on the delivery of healthcare included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
307	Presence of confirmatory documentation on observance of the requirements for identification of the person referred or coming for health examination. Prior to healthcare examination, a medical worker identifies the person referred or coming for healthcare examination by familiarising himself /herself with his/her identity documents or electronic documents from the digital document service. Should the documents of the person being examined be missing, the opinion of the medical examination to establish the fact of psychoactive substance use and state of intoxication (hereinafter referred to as the 'Opinion') specifies his/her special features with a mandatory indication of obtaining passport data from the words of the referring person or the person being examined . The absence of identity documents or electronic documents from the digital document service is not the basis for refusal in the examination. Establishing the identity of the person referred for medical examination does not fall within the competence of a medical worker.	Major violation
308	Presence of confirming documentation on observance of the requirements for performing the examination of foreign citizens and underage citizens of the Republic of Kazakhstan. Foreign citizens permanently residing and temporarily staying on the territory of the Republic of Kazakhstan, as well as stateless persons who are intoxicated in a public place, at work , or driving a vehicle, should undergo physical examination on general grounds.	Major violation

	Medical examination of underage citizens of the Republic of Kazakhstan is performed in the presence of their lawful guardians.	
309	Presence of supporting documentation on observance of the requirements for health examination of persons brought in in a seriously unconscious state. In a specialised health care facility, when a person is brought in in a severe, unconscious state due to the use of PS, a twofold (30-60 minutes apart) quantitative test for the presence of PS in body fluids (blood, urine, saliva) is done to determine the state associated with the use of PS). In a specialised healthcare facility, at the time of medical care, a record is made in the patient's medical record of the presence (absence) of intoxication or substance use based on the results of clinical examination and laboratory testing of biological samples, and no opinion is drawn up.	Major violation
310	Presence of confirming documentation on observance of the requirements to the conditions for laboratory examination or rapid testing of biological media. Laboratory examination or express testing of biological media (blood or urine if alcohol intoxication is suspected, urine if narcotic or toxicomanic intoxication is suspected) is conducted in the following cases: 1) impossibility of full examination due to the severity of the condition of the person being examined; 2) in the presence of doubts of the health care worker in the complex evaluation of the state of intoxication (mental, behavioural, vegetative and somatoneurological disorders); 3) if the person being examined disagrees with the results of the Report; 4) repeated examination; 5) when the fact of substance use is established and there are no signs of intoxication (mental, behavioural,	Major violation

	vegetative and somato-neurological disorders); 6) in the event of a road traffic accident or commission of an offence with the presence of injured persons; 7) when more than 3 (three) hours have passed from the moment of committing a road traffic accident or an offence without victims	
311	Presence of confirming documentation on observance of the requirements for laboratory examination or rapid testing of biological media. The nature and sequence of biological samples is determined by the health care provider conducting the examination, depending on the specifics of the clinical condition of the person being examined. Sealing and labelling of selected biological samples for laboratory examination is performed in the presence of the examinee and the person who sent and (or) delivered the examinee. If the person being examined is unable to objectively evaluate the events, this procedure is performed in the presence of witnesses (disinterested persons)	Major violation
312	Presence of confirming documentation on observance of the requirements for the quantitative breath alcohol test. A quantitative breath alcohol test is performed during medical examination to establish the fact of alcohol consumption and the state of alcohol intoxication. The exhaled air is tested for alcohol using technical means of measurement officially registered in the Republic of Kazakhstan. If it is not possible to conduct the examination in full due to mental and (or) somato-neurological disorders, or the person's refusal to be examined, the Report specifies the reasons for the impossibility to conduct the examination in full	Major violation

313	Presence of confirming documentation of fulfilment of the requirements for issuing a refusal of health examination Should the person refuse to undergo medical examination, the health care worker completes paragraph 1 of the Report and signs signatures of witnesses (disinterested persons). The presence of witnesses (disinterested persons) in case the person being examined is unable to estimate the events taking place or refuses to undergo medical examination is ensured by the persons on whose initiative the examination is conducted.	Major violation
314	Presence of confirmatory documentation on observance of the requirements for establishing the condition of the person being examined. When drawing up the Report and completing the full examination and the person's consent to the examination, the healthcare professional establishes one of the following conditions based on available clinical and (if required) laboratory data or rapid test results confirming the type of psychoactive substance that caused intoxication: 1) sober; 2) the fact of substance use, signs of intoxication are not revealed; 3) alcohol intoxication (light, medium, heavy degree); 4) intoxication (narcotic, toxicomanic) caused by the use of PS (narcotics - opioids, cannabioids, cocaine; sedatives, sleeping pills; psychostimulants; hallucinogens; volatile solvents).	Major violation
	Presence of supporting documentation on adherence to the requirements for drawing up the Report of Medical Examination. The Report is prepared in 3 (three) copies, certified by the signature of the healthcare professional and the seal of the healthcare facility where the medical examination was conducted. One copy is issued to the	

315	person who delivered the person being examined or to the person who came to the examination on his/her own, the second copy remains in the health care facility and is kept in the archive for 5 (five) years, the third copy is issued to the person delivered to the medical examination . In the absence of an accompanying person, a copy of the Report is sent by mail or to the specified e-mail address upon an official written request of the person who sent for medical examination. The findings of the medical examination are reported to the person being examined immediately in the presence of the person who sent and (or) delivered him/her. In cases when the Report is issued after receiving the results of laboratory tests, a copy of the Report is given no later than 5 working days from the day of receiving the results of laboratory tests. Should the person being examined or the official who delivered him/her disagree with the results of medical examination, a repeated medical examination is conducted.	Major violation
316	Presence of confirming documentation on observance of the requirements for repeated medical examination. The repeated medical examination is conducted not later than 2 (two) hours after the initial examination.	Major violation
Requirements for actors (facilities) offering temporary adaptation and detoxification services		
317	Presence of confirming documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
	There is confirming documentation on observance of the requirements for the operation of the temporary adaptation and detoxification centre: A person with suspected alcohol intoxication is delivered to the TADC by internal affairs officers.	

318	Upon delivery, internal affairs officers: 1) assist medical personnel in examining the person, placing him/her in the TADC; 2) seize firearms, cold weapons, explosives, poisonous and toxic substances, other items prohibited in circulation in the Republic of Kazakhstan.	Major violation
319	Establishing the identity of the delivered person by the internal affairs officers and reporting it to the health care personnel of the TADC. Lack of identity documents does not serve as a reason for refusal to place the person in a TADC.	Major violation
320	Registration of a person delivered with suspected alcohol intoxication in the logbook of admissions and refusals of hospitalisation in the approved form After registering the person, a psychiatrist (narcologist) conducts a medical examination to determine whether there are indications and contraindications for admission to the TADC.	Major violation
321	The findings of the medical examination are recorded in a report on the medical examination conducted at the TADC (hereinafter - the report) as per the approved form The report outlines the clinical condition with the following conclusions: subject to placement in a TADC; refused to be placed in a TADC. The report is prepared in two copies, signed by a psychiatrist (narcologist). One copy of the report is given to the internal affairs officer who delivered the person, and the second copy is kept at the TADC. The report is enclosed to the card of the patient staying in the temporary adaptation and detoxification centre.	Major violation
	Registration of personal belongings, documents, money and other valuables by health care personnel in the patient's document and personal	

322	belongings registration log pursuant to the form prior to the patient's admission to the TADC. Clothes of patients admitted to the TADC are kept in individual wardrobes. Documents, money, other valuables are kept in metal cabinets (safes) in appropriate containers. The wardrobe and individual containers have the same serial number.	Major violation
323	Availability of the record of the patient placed in the TADC (hereinafter referred to as the patient's record) If there are medical indications, treatment is prescribed. The doctor's prescriptions are recorded in the patient's card. The frequency of medical examinations depends on the patient's condition.	Major violation
324	The patient is discharged by a psychiatrist (narcologist) on a planned basis if the patient's condition has improved and does not require further observation and treatment at the TADC within twenty-four (24) hours of admission. When the patient is discharged, a relevant entry is made in the patient's card and in the log of admissions and refusals to hospitalisation.	Major violation
325	Written confirmation from the patient that upon receipt of his/her documents and personal belongings, all documents and personal belongings have been received as recorded in the log book of patients' documents and personal belongings, excluding items that are illegal to keep.	Major violation
Requirements for actors (facilities) offering medical examinations and sex reassignment for persons with gender identity disorder		
326	Presence of confirming documentation on the delivery of healthcare included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
	Presence of confirming documentation on observance of the requirement for medical examination	

327	of persons with gender identity disorder for sex reassignment: A person with gender identity disorder, who is at least twenty-one years of age, legally capable, excluding a person with mental, behavioural disorders (diseases) (hereinafter referred to as MBD), who wishes to undergo sex reassignment (hereinafter referred to as the person being examined), applies in writing to an entity rendering medical assistance in the field of mental health (hereinafter referred to as the medical entity). A psychiatrist examines and studies the documents available to the person being examined in order to determine the MBD that are contraindications for sex reassignment.	Major violation
328	Referral by a psychiatrist of the person being examined, if there are doubts about his or her mental state, to a healthcare facility for an inpatient examination	Major violation
329	Referral of the person to be examined by a psychiatrist, in the absence of MBD, being contraindications for sex reassignment, to the polyclinic at the place of residence, for medical examination Following the medical examination, a psychiatrist sends the person to be examined by a medical board approved by the head of the medical institution.	Major violation
Requirements for entities (facilities) providing laboratory services		
330	Presence of supporting documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
331	Presence of written voluntary consent of the patient or his/her lawful guardian for invasive interventions and therapeutic and diagnostic measures	Major violation

332	The presence of a biosafety expert in the laboratory staff (if the laboratory staff is more than twenty full-time units)	Major violation
333	Availability of portable test strip analysers in primary health care facilities	Major violation
334	Presence at the inpatient level in health care facilities as part of the consultative and diagnostic laboratory (hereinafter - CDL) of an additional unit or a separate express-laboratory in intensive care units to perform emergency and urgent laboratory tests within a minimum time from sample collection to reporting the result (within 15-60 minutes). General clinical and biochemical tests, including rapid tests are performed for emergency evaluation of the pathological condition of patients. The express laboratory performs laboratory diagnostics in various emergency conditions (during surgical interventions, anaesthesia care, management of patients in intensive care units) on a 24-hour basis. In the absence of an express laboratory in healthcare facilities rendering inpatient care in the evening and at night, as well as on Sundays and public holidays, the work in the CDL is ensured by a duty team consisting of physicians and laboratory technicians	Major violation
335	Running quality management processes for clinical laboratory tests based on the principle of staging, which includes the pre-analytical, analytical and post-analytical stages of a laboratory test	Major violation
336	Use of equipment, diagnostic reagent kits, test systems and complete consumables certified and registered in the Republic of Kazakhstan to perform tests	Major violation
337	Availability of laboratory information system	Major violation
338	Conducting intra-laboratory quality control of the tests	Major violation

339	Observance of triple packaging and temperature regime when transporting biomaterial, including by road, air and railway transport.	Major violation
340	Presence of supporting documentation of observance of the algorithm of analytical quality control in laboratory diagnostics	Major violation
341	Presence of an agreement for rendering paid medical services in health care facilities. Presence of documents establishing the fact of co-payment	Gross violation
342	Availability of supporting documentation on the competence and quality of laboratory diagnostics	Major violation
343	Documenting the performance of laboratory diagnostics	Major violation
Requirements for entities (facilities) delivering emergency medical aid and medical aid in the form of medical aviation		
General requirements		
344	Presence of confirming documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
345	Presence of supporting documentation on conformity of treatment and diagnostic measures with the recommendations of clinical protocols	Major violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) the total number of identified violations, their structure, possible causes and ways of elimination; 4) the number of identified violations that caused deterioration of health status; The Service conducts expert examination: in emergency health care providers, expert examination of the quality of medical services (assistance) of at least 10% of calls	

346	serviced in a quarter, including all cases of: visits to the patient after refusal of hospitalisation by a health care facility rendering inpatient care; refusal of medical assistance specifying the possible consequences , with a record in medical documents , including in electronic form, signed by the patient or his/her lawful representative, as well as by a healthcare worker; refusal of the patient or his/her lawful representative to sign a refusal of medical assistance, with a corresponding record in medical documents, including in electronic form, signed by a healthcare worker; repeated calls to the same patient for the same disease within 24 hours from the moment of the first call to the same patient for the same disease ; The findings of internal expertise, including their comparison with the results of external expertise, are brought up and discussed at the sessions of the Service, intra-hospital commissions, at doctors' conferences with subsequent adoption of organisational decisions in order to improve the level of knowledge of healthcare workers and to develop optimal approaches to the treatment and diagnostic process, which are formalised in a protocol. Based on the results of the internal expert review, the Service submits monthly proposals to the head of the healthcare facility to eliminate the identified causes and conditions for the reduction in the quality of medical services (care) provided).	Major violation
For emergency ambulance service		
347	Equipping sanitation vehicles with radio communication and navigation system	Gross violation
	Availability in the ambulance service of regions, cities of national importance and the capital city of an automated control system for receiving and processing calls and systems enabling monitoring of ambulance vehicles by means of	

348	navigation systems, as well as a system of computer recording of dialogues with subscribers and an automatic identifier of the telephone number from which the call is received. Dialogue recordings are stored for at least 2 years.	Gross violation
349	Presence of regional call-centres (call-centres) within regional emergency medical aid stations and emergency medical aid stations of cities of national importance and the capital city	Gross violation
350	Observance of a five-minute processing time of an ambulance call from the moment it is received by the dispatcher, during which time the call is triaged by urgency category.	Major violation
351	Adherence to the time of arrival of the brigade to the patient's location from the moment of receiving the call from the dispatcher as per the list of urgency categories of emergency medical calls (from 10 minutes to 60 minutes)	Major violation
352	The dispatcher of the emergency health care service (EHCS) correctly identifies calls by urgency category as per: 1) call of 1 (first) urgency category - patient's condition posing an immediate threat to life, requiring immediate medical assistance; 2) call of 2 (second) category of urgency - patient's condition posing a potential threat to life without medical assistance; 3) call of the 3rd (third) category of urgency - the patient's condition posing a potential threat to health without medical assistance; 4) call of the 4th (fourth) category of urgency - patient's condition caused by an acute illness or exacerbation of a chronic disease, without sudden and pronounced disorders of organs and systems, in the absence of an immediate and potential threat to the patient's life and health.	Major violation
	A paramedic or a physician of an EMS or team makes one of the following decisions when organising	

353	primary health care, based on the results of examination data, instrumental diagnostics, patient's condition dynamics against the background of or after treatment measures, in line with the preliminary diagnosis reflecting the causes of the condition: - transporting the patient to a healthcare facility rendering inpatient care (hereinafter - inpatient facility); - the patient is left at the place of call ; - the patient is left at home (at the place of residence)	Gross violation
354	Medical recommendations are offered for further referral to a primary health care facility (at the place of residence or registration in case a patient who does not need hospitalisation is left at the place of call or at home, by a team from an EMC or an EHCS unit at a primary health care facility)	Major violation
355	Presence of a patient signalling sheet in case a patient is ill and needs a home visit by a precinct physician	Major violation
356	Availability of recording of the following data when a call is received by the dispatch service of the ambulance station: 1) surname, first name, patronymic (if any), age and gender of the patient ; 2) data on the patient's condition and circumstances of the accident, injury or disease; 3) address and telephone number, as well as approximate data on travelling to the patient's location.	Major violation
357	Observance of the time of arrival of paramedic and specialised (medical) teams to the patient's location from the moment of receiving a call from the dispatcher of the ambulance station, with due regard to the category of urgency: 1) 1 category of urgency - up to ten minutes; 2) 2nd category of urgency - up to fifteen minutes;	Major violation

	3) 3 category of urgency - up to thirty minutes; 4) 4th category of urgency - up to sixty minutes	
358	The dispatcher of the EHCS is informed of the patient's delivery in case a decision is made by the team of the EMC or the EHCS department to transport the patient to the hospital .	Major violation
359	Availability of a minimum list of medical devices for ambulance station transport by classes A, B and C	Major violation
For medical assistance in the form of medical aviation		
360	Presence of an assignment for sanitary flight as per form № 090/y	Major violation
361	Supporting documentation that the mobile medical aviation team, while transporting the patient(s), routinely evaluates and treats the patient(s) following appropriate clinical protocols for diagnosis and treatment .	Major violation
362	Presence of grounds for granting medical assistance in the form of medical aviation (an excerpt from the medical record of a patient in need of medical assistance in the form of medical aviation; a request from the coordinating physician of the medical aviation department to the dispatcher of the Coordinating Entity; in emergency cases, a verbal order from a competent authority with written confirmation; a call from the emergency medical services and other emergency services)	Gross violation
363	Dispatcher of the Coordinating Entity has agreed on the membership of the mobile medical aviation brigade and the involved qualified specialist(s) from the regional healthcare facilities with their informed consent.	Major violation
364	Presence in the Coordinating Entity of a schedule of qualified specialists for medical assistance in the form of medical aviation approved by health care entities and medical education institutions	Gross violation

365	Presence of informed consent of the patient (s) for medical assistance in the form of medical aviation during his/her transportation. In respect of minors and citizens recognised by a court as incapable, consent is granted by their lawful guardians. Medical assistance to unconscious patients is decided by a decision of a consilium or by a physician of a healthcare facility in the region, or by a mobile medical aviation team, or by a qualified specialist, with a free-form notification to the officials of the healthcare facility.	Gross violation
Requirements for actors (facilities) engaged in HIV prevention activities		
366	Availability of supporting documentation on the delivery of healthcare included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
367	Examination by express testing method with registration in the register of HIV tests by express testing method. If the result of the rapid test is positive, HIV testing is performed upon informed consent of the tested person and in the availability of an identity document pursuant to the procedure for diagnosing HIV infection in adults and children over 18 months of age.	Major violation
368	Availability of written notification by the health care facility, which revealed during medical examination the fact of HIV infection in the examined person of the result obtained, of the necessity to observe precautionary measures aimed at protecting one's own health and the health of others, as well as warning of administrative and criminal liability for evasion from treatment and infection of other persons, with the patient signing a confidential interview sheet with a person infected with HIV as per form № 095/y	Major violation

369	Presence of supporting documentation on adherence to the deadlines for issuing negative results . The person being tested obtains a negative result at the place of blood collection upon presentation of an identity document or an electronic document from the digital document service within 3 (three) working days from the moment of receipt of the blood sample for testing in the laboratory.	Major violation
370	Presence of supporting documentation on adherence to the deadlines for sending serum samples to the RSHF. If two positive results are obtained, a serum sample of at least 1 (one) ml should be sent to the RSHF laboratory for confirmatory testing within three working days of the last treatment.	Major violation
371	Presence of supporting documentation of fulfilment of re-examination deadlines in case of doubtful results. If the results of the tests are contradictory, the result is considered doubtful. After 14 (fourteen) calendar days, blood collection and HIV testing is repeated as per the first stage of diagnostics of HIV infection in adults (RSHF passes the information on doubtful result of HIV infection to the territorial state health care facility, engaged in HIV prevention activities, for a repeat HIV test). Additional tests using other serological tests are conducted after 14 (fourteen) calendar days if a second doubtful result for HIV infection is obtained. A negative result is issued for two negative results out of three conducted tests. A positive result is issued based on two positive results out of three conducted tests. In case of examination of pregnant women, additional molecular biological tests are used (quantitative determination of HIV ribonucleic acid with a test	Major violation

	sensitivity of no more than 50 copies /ml or determination of proviral HIV deoxyribonucleic acid).	
372	Pre-test and post-test counselling is available. Pre-test counselling is offered by means of visual aids, which are displayed in waiting areas. Pre-test counselling includes: 1) information on the benefits of HIV screening, modes of transmission and the meaning of HIV-positive and HIV-negative test results; 2) explanation of available services in case of HIV-positive diagnosis, including explanation of free antiretroviral therapy; 3) a brief description of methods of prevention and screening of the partner in case of a positive HIV test result; 4) guarantee of confidentiality of the test results. Availability of post-test counselling for those examined. Post-test counselling includes: 1) informing the patient of the test result and the significance of the result; 2) informing on possible seronegative window (in case of uncertain or negative result) and the need for repeated HIV testing; 3) explaining the possibilities of reducing the risk of infection through behavioural changes; 4) informing on possibilities of additional medical care for key populations, psycho-social support; 5) psychological assistance and support.	Major violation
373	Health care facility engaged in HIV prevention activities sends an emergency notification in form № 034/y to the territorial public authority in the field of sanitary and epidemiological well-being for each case of HIV infection presumably related to the delivery of medical care (intra-hospital one)	Gross violation

374	Presence of the Confidential Interview Sheet with a person infected with HIV, Form № 095/y, that includes: his/her consent to enter personal data into electronic information resources. In case of refusal to enter personal data into the ES system, data is entered, specifying immune blocking number (hereinafter - IB), date of IB, initials, date of birth, data of epidemiological anamnesis	Major violation
375	Monitoring and evaluation of the coverage of key populations and people living with HIV infection is performed by maintaining a database of individual client records and relevant forms of accounting and reporting documentation by experts from health care facilities involved in HIV prevention activities	Major violation
376	Transfer by the health care workers diagnosed with HIV-infection to another job that does not involve violation of the integrity of skin or mucous membranes.	Gross violation
377	Availability of supporting documentation on the diagnosis and treatment of STIs. STI diagnosis and treatment is performed in friendly rooms based on clinical protocols for STI diagnosis and treatment	Major violation
378	Availability of equipped transport for mobile confidence-building centres	Major violation
379	Availability of confirmatory documentation of implementation of pre-exposure and post-exposure prophylaxis in the population and key populations	Major violation
	Surveillance of contact persons within the established timeframes. Contact persons are monitored in a health care facility that is active in the field of HIV prevention. The duration of contact person surveillance is established for: 1) children born from HIV-infected mothers - eighteen months; 2) health care workers in case of emergency - three months;	

380	4) recipients of donor biomaterial - three months; 5) sexual partners of HIV-infected persons and contact persons for joint drug administration - till the negative HIV test result is obtained 3 months after the end of the contact; in case of continuing contact, contact persons are examined for HIV infection 2 times a year; 6) persons from a nosocomial centre - three months after discharge from a healthcare facility; if more than three months have elapsed since discharge , contact persons are examined once, and if the result is negative, surveillance is discontinued.	Gross violation
381	Dynamic monitoring and ensuring antiretroviral therapy of HIV-infected persons. The findings of laboratory testing of contact persons are recorded in the outpatient card of the HIV-infected person on dispensary registration (discordant couples). The HIV-infected person presents data on changes in marital status, surname, first name, patronymic (if available), data on new contact persons for examination and monitoring, which are entered into the electronic tracking database. Anti retroviral therapy to reduce the risk of HIV transmission from the moment of diagnosis is offered following the recommendations of clinical protocols for diagnosis and treatment of HIV infection in adults and children, with the involvement of outreach workers and social workers.	Gross violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, to be evaluated by the following criteria: absence of anamnesis collection; completeness of history taking;	

availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status;

progression of complications as a result of tactical errors made in the course of treatment and diagnostic measures due to poor anamnesis collection.;

2) comprehensiveness and validity of diagnostic tests, to be evaluated against the following criteria:

absence of diagnostic measures;

erroneous conclusion or absence of a conclusion based on the results of diagnostic tests, which led to erroneous diagnosis and errors in treatment tactics;

performance of diagnostic tests stipulated by clinical protocols;

performing diagnostic tests with high , unjustified risks to the patient's health, justification of diagnostic tests not included in clinical protocols;

diagnostic tests that are not informative for establishing a correct diagnosis and resulted in an unjustified extension of treatment time and increased cost of treatment;

3) correctness, timeliness and validity of the clinical diagnosis, with due consideration of the results of the conducted examinations (in case of planned hospitalisation, the examinations conducted at the pre-hospital stage are also considered), which are estimated using the following criteria:

the diagnosis is absent, incomplete or erroneous, does not correspond to the international classification of diseases;

the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised;

the diagnosis is correct but incomplete, the leading pathological syndrome is not defined with the highlighted complications,

	comorbidities affecting the outcome are not recognised; the diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for erroneous and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated; 4) timeliness and quality of consultations of relevant experts, which are evaluated by the following criteria:	
382	lack of counselling resulting in misinterpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to include the consultant's opinion in the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was noted in the diagnosis, failure to follow the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on the evaluation of objectivity of the grounds for untimely consultation and the impact of untimely diagnosis on the subsequent stages of health services (care); 5) volume, quality and validity of treatment measures, which are evaluated against the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications;	Major violation

prescribing inefficient therapeutic measures without regard to the specifics of the course of the disease, concomitant diseases and complications;

performance of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of medicines without proven clinical efficacy;

unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition;

6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated;

7) the achieved result to be evaluated by the following criteria:

achievement of the expected clinical effect with observance of the technology of rendering healthcare services (aid);

absence of clinical effect of therapeutic and preventive measures due to poor history taking and diagnostic tests;

absence of expected clinical effect due to ineffective therapeutic and preventive measures without accounting for the specifics of the course of the disease, comorbidities, complications, prescription of medicines without proven clinical efficacy;

the presence of polypragmasy, which caused the progression of undesirable consequences;

8) the quality of medical documentation, to be estimated by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature,

	scope and quality of medical care rendered.	
Requirements for actors (facilities) engaged in activities in the field of blood services		
383	Presence of supporting documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
384	Evidence of adherence by the blood service institution to the requirements for the stepwise labelling of blood and blood components. Ensuring the traceability of each blood product from the donor to the finished product and its use	Gross violation
385	Presence of supporting documentation on meeting the requirements for laboratory testing of recipient blood samples for the presence of markers of haemotransmissible infections before and after transfusion by qualitative immunoserological and molecular-biological methods on automatic closed-type analysers.	Gross violation
386	Registration in the electronic information database after donation of blood and its components of all data on donation of blood and its components, including the type of reaction and the amount of medical care provided, in case of side effects of donation, correspondence of documents on transfer to the primary fractionation unit with the accompanying documentation of the collected blood and its components	Major violation
387	Availability of a blood and blood component donor questionnaire and an information sheet given to the donor, which he/she fills in independently or with the participation of a medical registrar	Major violation
388	Presence of confirmatory documentation of adherence to the requirements for performing immunohaematology studies for irregular anti-erythrocyte antibodies in liquid-phase systems on plane and	Major violation

	in vitro, reading the result of agglutination reaction with obligatory microscopy.	
389	Presence of confirming documentation of adherence to the requirements for incoming and daily in-laboratory quality control of reagents to confirm their activity and specificity. Input control includes: 1) purchased materials (blood collection containers, reagents, test systems, disinfectants, instruments and other materials), the nomenclature thereof is approved by the first head of the blood service facility; 2) units of donor blood and its components (when accepted for production)	Major violation
390	Placement of blood collected in travelling conditions in thermocontainers labelled “Untested Haemoproducts, not to be Handed Out” and delivered at 22±2°C for 18 -24 hours to the blood service centre.	Major violation
391	Use of reagents with monoclonal antibodies and equipment registered by the public authority in the sphere of circulation of medicines and medical devices for immunohaematological studies of blood samples of potential recipients	Major violation
392	Presence of supporting documentation on fulfilment of requirements for transfusion of blood , its components	Major violation
393	Presence of supporting documentation on observance of the requirements of compulsory medical examination of the donor before donation of blood and its components within the framework of the guaranteed volume of free medical care	Major violation
394	Consistency with donor medical clearance, safety and quality requirements in the manufacture of blood products for medical use	Major violation
395	Presence of confirming documentation on observing the requirements of external quality evaluation of measurement quality of	Major violation

	laboratory tests in reference laboratories	
396	Adherence to incoming and daily in-laboratory quality control of reagents to confirm reagent activity, and specificity.	Major violation
397	Presence of a blood and blood components donor questionnaire available to the donor, which he/she fills in on his/her own or with the assistance of a medical registrar.	Major violation
398	The following are subject to input control: 1) purchased materials (blood collection containers, reagents, test systems, disinfectants, instruments and other materials), the nomenclature thereof is approved by the first head of the blood service centre centre;	Major violation
399	Conformity with donor medical clearance, safety and quality requirements in the manufacture of blood products for medical use	Major violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection that is evaluated by the following criteria: absence of anamnesis collection; completeness of history taking; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status; development of complications due to tactical errors in the course of therapeutic and diagnostic measures due to poor quality of anamnesis collection; 2) comprehensiveness and validity of diagnostic tests estimated by the following criteria: absence of diagnostic measures; erroneous conclusion or absence of a conclusion based on the results of diagnostic tests, which led to	

	erroneous diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; conducting diagnostic tests with a high, unjustified risk to the patient's health, justification of diagnostic tests not included in clinical protocols; performing diagnostic tests that are not informative for making a correct diagnosis and resulted in an unjustified extension of treatment time and increased cost of treatment; 3) accuracy, timeliness and validity of the clinical diagnosis based on the results of tests performed (in case of planned hospitalisation, tests performed at the pre-hospital stage are also taken into account), evaluated by the following criteria: the diagnosis is absent, incomplete or erroneous, does not correspond to the international classification of diseases; the leading pathological syndrome defining the severity of the course of the disease is not identified, comorbidities and complications are not recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not identified in the complications identified, comorbidities affecting the outcome are not recognised; diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective factors of erroneous and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the results of the expertise. The impact of erroneous and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated;	

400	4) timeliness and quality of consultations of relevant professionals to be evaluated by the following criteria: absence of consultation, which led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to consider the consultant's opinion in making the diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion was respected in diagnosis, failure to implement the consultant's treatment recommendation partially influenced the outcome of the disease; consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on the evaluation of objectivity of the grounds for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which are estimated by the following criteria: no treatment when indicated; prescribing treatment in the absence of indications; prescription of inefficient therapeutic measures without regard to the specifics of the course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without considering the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition;	Major violation

	6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result is estimated by the following criteria: achieving the expected clinical effect in adherence to the technology of healthcare services (aid); absence of clinical effect of therapeutic and preventive measures due to poor history taking and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without considering the specifics of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is estimated by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care delivered	
Requirements for entities (facilities) performing pathological anatomical diagnostics		
401	Presence of supporting documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
402	Observance of the requirement to register the refusal to accept biological material, stapled with a copy of the referral for analysis of biological material in the pathology	Major violation

	unit in a separate folder (“Rejected Samples”), as well as in a separate log (“Rejected Samples”).	
403	Adherence by the pathologist to the requirement for participation of the laboratory technician in the work on based on the act of excision, macroscopic examination and macroscopic description of the biological material. The medical specialist who sent the material for examination is involved when additional clinical information is required at the stage of macroscopic examination of the biological material	Major violation
404	Observance of the requirement that tissue fragments have a thickness of 5 millimetres (hereinafter - mm) and an average diameter of no more than 24 mm.	Major violation
405	Presence of microscopic description in the protocol of pathological and anatomical examination of biopsy (surgical) and autopsy material	Major violation
406	Adherence to the requirement to issue the results of pathomorphological examination with entries in the established form logs by the medical registrar or laboratory technician	Major violation
407	Presence of supporting documentation on meeting the requirement to store tissue samples in paraffin blocks in a single archive organised by the principle of end-to-end numbering	Major violation
408	Presence of supporting documentation on meeting the requirement to store tissue specimens in paraffin blocks in a specially equipped dry and cool room, using specialised archiving systems and adapted containers, as well as storage of microdrugs in specialised archiving systems.	Gross violation
409	Adherence to the requirement to place micro specimens in boxes in such a way that slides pertaining to one case are arranged in one indivisible unit	Major violation

410	Observance of the requirement for the laboratory technician to sort and prepare biological and medical waste for disposal	Major violation
411	Presence of written consent of the spouse or one of the close relatives or lawful guardian in case of pathological and anatomical diagnosis in case of unspecified immediate cause of death	Major violation
412	Adherence to the requirement for an independent (independent) expert(s) to perform a pathological anatomical autopsy of the deceased at the request of the spouse, close relatives or legal representative	Major violation
413	Adherence to the requirement to issue a medical certificate of death (preliminary, final) on the day of the pathological anatomical autopsy by a physician specialising in pathological anatomy (adult, paediatric)	Major violation
414	Adherence to the requirement to document autopsy results in the form of a pathological examination report	Major violation
415	Observance of the requirement to stop the autopsy when signs of violent death are detected during the pathological anatomical examination of the corpse, the head of the healthcare facility reports the incident in writing to the forensic and investigative authorities to address the issue of transferring the corpse for forensic medical examination. A physician specialising in pathological anatomy (adult, paediatric) undertakes measures to preserve the body, organs and tissues of the corpse for further forensic medical examination . A protocol is prepared for the performed part of the pathological anatomical examination, at the end of which the reason for further forensic medical examination is indicated. In each case of interrupted pathological autopsy, the pathologist informs in writing the head of the ward, the administration of the	Major violation

	health care facility where the death occurred immediately after the interruption of the autopsy	
416	Observance of the requirement to send an emergency notification to the public authority in the sphere of sanitary and epidemiological well-being of the population by a physician specialising in “ Pathological Anatomy (for Adults, for Children)” in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination	Major violation
417	Observance of the requirement for pathological and anatomical autopsy of all newborn children who died in healthcare facilities, including obstetric facilities (regardless of how long after birth they showed signs of life) and stillborn foetuses with a body weight of 500 grams or more at a gestational age of 22 weeks or more, including after termination of pregnancy (spontaneous, for medical and social reasons) with mandatory histological examination of the placenta and registration of a medical certificate of perinatal care.	Major violation
418	Observance of the requirement of the head of the pathological anatomy department to ensure that autopsies are performed on dead newborns and stillborns with mandatory histological examination of tissue and organ fragments and inclusion in the protocol of pathological anatomical examination.	Major violation
419	Adherence to the requirement by the heads of health care facilities and heads of pathological anatomical units of the facility for the required virological and bacteriological examination of autopsy materials of deceased newborns, stillborns and placentas, using appropriate laboratories of health care facilities or public authorities and agencies in the field of sanitary and epidemiological well-being of the population.	Major violation

420	Adherence to the requirement to issue a medical certificate of perinatal death (preliminary, final, instead of preliminary) by a physician specialising in pathological anatomy (adult, paediatric) on the day of the pathological anatomical autopsy.	Major violation
421	Adherence to the requirement by a physician specialising in " Pathological Anatomy (for Adults, for Children)" when drawing up a pathological anatomical diagnosis based on the results of a pathological anatomical autopsy: 1) the underlying disease; 2) complication of the main disease; 3) cause of death; 4) concomitant disease; 5) combined main disease: competing diseases, co-morbidities, background disease	Major violation
422	Observance of the requirements for registration and maintenance of primary medical documentation	Major violation
423	Presence of supporting documentation on observance of the requirement for accounting of pathological anatomical examination materials (biopsy, surgical and autopsy material): 1) the accounting unit of pathological anatomical examination of biological material is one object (one fragment of tissue obtained as a result of a single diagnostic or therapeutic manipulation or surgery, poured into one paraffin or frozen block), processed by one staining or reaction; 2) a registration number is assigned to each object. Each histological preparation bears a registration number identical to the registration number of the corresponding block. When it is required to perform several stains (reactions) from one block, additional alphabetic or numeric identifiers of stains (reactions) are appended to the registration number of the microdrug corresponding to the number of the block;	Major violation

	3) registration of biological material is performed in the logbook of biopsy (surgical) material receipt and issuance of morphological examination results	
424	Observance of the requirement not to submit the protocol of pathological anatomical examination to the spouse, close relatives, legal representatives or other persons for familiarisation. Spouse, close relatives or legal representatives, and in their absence other relatives, as well as at the request of law enforcement agencies and (or) the court, a public authority in the field of health care services (aid) to issue a pathological anatomical report on the cause of death and diagnosis of the disease	Major violation
425	Adherence to the requirement to issue originals or copies of pathological anatomical examination reports at the request of bodies of enquiry and preliminary examination , prosecutor, lawyer and (or) court due to investigation or court proceedings, as well as at the request of public authorities in the field of medical services (aid)	Major violation
426	Observance of requirements for cytological examinations, which include: 1) macroscopic evaluation and processing of delivered biological material obtained by various methods (exfoliation, puncture, impression, flush, biological fluids); 2) preparation and staining of microdrugs with subsequent microscopy; 3) evaluating the results of the study and establishing a cytological conclusion; 4) correlation of cytological and histological findings	Major violation
427	Presence of supporting documentation on meeting the requirement for the laboratory technician's acceptance, initial sorting and registration of biological material received in the cytology laboratory, macroscopic examination	Major violation

	, description of biological material, processing of biological material (preparation, fixation, staining, conclusion, sorting of cytological microdrugs).	
428	There is documentation of adherence to the requirement to perform microscopic examination in the first step by a laboratory technician, then by a cytologist	Major violation
429	Observance of the requirement to involve a physician (relevant expert) when it is required to obtain additional clinical information at the stage of microscopic examination of biological material, who sent the material for examination. The final microscopic examination of smears and drawing up a protocol of the results of the study is performed by a cytologist	Major violation
430	Adherence to the requirement to establish the category of pathological anatomy (adult, paediatric) by a physician specialising in pathological anatomy (adult, paediatric) and the reason for the discrepancy between the final clinical and pathological diagnoses	Gross violation
Requirements for entities (facilities) assisting in the field of nuclear medicine		
431	Presence of supporting documentation on the delivery of medical care included in the guaranteed volume of free medical care and (or) the system of mandatory social health insurance on a free-of-charge basis	Gross violation
432	Presence of supporting documentation on conformity of treatment and diagnostic measures with the recommendations of clinical protocols	Major violation
	Presence of documentation confirming the status of the Nuclear Medicine Centre (hereinafter referred to as the Centre) as a structural unit of a multidisciplinary hospital or an independent healthcare facility rendering medical care to the population of the Republic of Kazakhstan on RND and (or) RNT.	

433	The structure of the Centre, depending on the functions assigned to it, includes: Radiopharmaceutical medicinal product (RPMP) production and quality control department; RND Department; RNT Department; Department of Radiation Safety and Medical Physics; Department of Engineering and Technical Support.	Major violation
434	Presence of supporting documentation on the main tasks and areas of activity of entities rendering medical care in the field of nuclear medicine and observance of the main objectives: 1) provision of specialised medical care by profile specialists in outpatient, inpatient substitution and inpatient conditions at secondary and tertiary levels of medical care; 2) conducting radioisotope (radionuclide) research methods; 3) performing RNT with the use of RPMPs; 4) production and quality control of the manufactured RPMPs for their conformity with the requirements of pharmacopoeial articles, technical regulations and good manufacturing practices; 5) ensuring patient satisfaction with the level and quality of medical care; 6) development, mastering and introduction of modern innovative methods of RND and RNT into practice; 7) development, mastering and introduction of new RPMPs into production; 8) ensuring radiation safety of patients and production and medical personnel, exercising control over the production of RPMPs, rational application of RND and RNT techniques; 9) training in nuclear medicine residency; 10) participation in the development of normative legal acts, standards,	Major violation

	instructions, recommendations in the field of nuclear medicine; 11) rendering organisational, methodological and advisory aid to health care facilities on nuclear medicine issues; 12) consulting in the planning of nuclear medicine centres.	
435	Presence of supporting documentation on the delivery of medical care using nuclear medicine methods within the guaranteed scope of free medical care, voluntary medical insurance and on a paid basis.	Gross violation
436	Presence of supporting documentation on the delivery of specialised medical care in the field of nuclear medicine in outpatient, inpatient substitution, inpatient conditions in a planned form: in outpatient conditions that do not require round-the-clock medical supervision and treatment; in inpatient substitute conditions that do not require round-the-clock medical supervision and treatment and provide for medical supervision and treatment during the day with the provision of a bed place; in inpatient settings, ensuring round-the-clock medical observation, treatment, care and bed and board, including in cases of 'same-day' therapy, providing round-the-clock observation during the first 24 hours after the start of treatment.	Major violation
437	Presence of supporting documentation on referral of patients for PET/CT, PET/MRI, SPECT, SPECT/CT studies to the RND department by relevant experts	Major violation
438	Presence of supporting documentation on conducting radioisotope (radionuclide) studies following clinical protocols, documented procedures, the specific diagnostic method used, with mandatory compliance with radiation safety measures for the patient and personnel as indicated	Gross violation

439	A signed informed consent of the patient for radioisotope (radionuclide) examination prior to undergoing this examination, indicating the activity of the RPMP used, after which the patient is examined by a physician and a nurse.	Major violation
440	Presence of supporting documentation on the nuclear medicine specialist interpreting the results of the examination after completion of the diagnostic procedure. In complicated cases with mandatory “double-read”, double dependent reading (the image is read twice; during the second reading the result of the first reading is available), PET, PET/CT, PET/MRI, SPECT, SPECT/CT studies by nuclear medicine specialists and a final diagnostic report is issued.	Gross violation
441	Presence of supporting documentation on referral of patients to the RNT department after preliminary examination and clinical decision on the need for RNT with the participation of the head of the department or nuclear medicine physician as per the list of diseases for RNT. A referral for inpatient medical care for oncological diseases is issued by a multidisciplinary group established in health care facilities rendering oncological care; In case of non-oncological diseases, the medical advisory board of the healthcare facility prescribes whole-body scintigraphy with the diagnostic activity of the radiopharmaceutical drug “Sodium Iodide I-131” for clinical indications 185 MBq.	Gross violation
442	Presence of supporting documentation of RNT in inpatient settings in ‘active’ wards and/or beds . After receiving RPMP, the patient is a source of beta-gamma radiation, therefore, daily rounds of the doctor are conducted via audio and video communication. The radiation safety engineer (dosimetrist) registers the	Gross violation

	dose rate from patients daily via an alarm meter and a stationary dose rate measurement system.	
443	Presence of supporting documentation on delivery of the cadaver of a patient with administered RPMP of “active” wards to a specially allocated freezing chamber located in the radionuclide support unit of the RNT unit (in the radioactive waste storage facility) in case of lethal outcome. The corpse is held in the freezing chamber until an acceptable level of radioactive decay (at a distance of 1 metre from the body surface - 20 μSv/h), then the corpse is transported. For urgent pathological examination, the RNT dosimetrist calculates the duration of the autopsy procedure based on the exposure standards for Group B personnel.	Gross violation
	Presence of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation against the following criteria: 1) quality of anamnesis collection, which is evaluated by the following criteria: absence of anamnesis collection; completeness of anamnesis collection; presence of data on past, chronic and hereditary diseases, haemotransfusions, tolerance to medicines, allergological status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor anamnesis collection; 2) completeness and validity of diagnostic tests, evaluated by the following criteria: absence of diagnostic measures; erroneous opinion or lack of opinion on the results of diagnostic tests, resulting in erroneous diagnosis and errors in treatment tactics;	

performing diagnostic tests stipulated by clinical protocols;

conducting diagnostic tests with high, unjustified risk to the patient's health, justification of diagnostic tests not included in clinical protocols;

performing diagnostic tests that are uninformative for making a correct diagnosis and lead to an unjustified increase in the duration of treatment and the cost of treatment;

3) accuracy, timeliness and validity of the clinical diagnosis, based on the results of the investigations performed (in case of planned hospitalisation, studies performed at the pre-hospital stage are also included), that are measured against the following criteria:

the diagnosis is missing, incomplete or erroneous, does not correspond to the international classification of diseases;

the leading pathological syndrome determining the severity of the course of the disease is not identified, associated diseases and complications are not recognised;

the diagnosis is correct but incomplete, the leading pathological syndrome is not identified with the highlighted complications, comorbidities affecting the outcome are not recognised;

diagnosis of the underlying disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed.

Objective grounds for erroneous and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of a concomitant disease, rare complications and concomitant diseases) are reflected in the findings of the expertise. The impact of erroneous and (or) untimely diagnosis on the subsequent stages of medical services (care) is evaluated;

4) timeliness and quality of consultations of relevant experts,

444	which are estimated using the following criteria: absence of consultation, which led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to include the consultant's opinion in the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was noted in the diagnosis, failure to implement the consultant's treatment recommendation partially influenced the outcome of the disease; the consultant's opinion was erroneous and affected the outcome of the disease. There is supporting documentation on the evaluation of the objectivity of the grounds for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which are estimated by the following criteria: no treatment when indicated; prescribing treatment in the absence of indications; prescription of inefficient therapeutic measures without considering the specifics of the course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without regard to the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or progression of complications after medical interventions, all complications that occurred are considered, including	Major violation

	those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures; 7) the achieved result, to be evaluated based on the following criteria: achievement of the expected clinical effect while adhering to the technology of rendering medical services (care); lack of clinical effect of therapeutic and preventive measures due to poor history taking and diagnostic tests; lack of expected clinical effect due to inefficient therapeutic and preventive measures without regard to the specifics of the course of the disease, concomitant diseases, complications, prescription of medicines without proven clinical efficacy; the presence of polypragmasy that caused the development of undesirable consequences; 8) the quality of medical documentation, to be estimated by the availability, completion and quality of records in the primary medical documentation meant for recording data on the state of health of patients, reflecting the nature, scope and quality of the health care rendered.	
445	Availability of supporting documentation of record-keeping and accounting records	Minor violation

Note:

HIV - human immunodeficiency virus

STI - sexually transmitted infections

CDC - consultative and diagnostic care

MDG - multidisciplinary group

PS psychoactive substances

PHC - primary health care

PFSIS - a psychiatric facility of a specialised type with intensive supervision

MBD - mental, behavioural disorders

ATM - antituberculosis medicines

PMHC - primary mental health centre

RSHF - republican state health care facility engaged in the prevention of HIV infection
RSPCMH - republican scientific and practical centre for mental health
EMC - emergency medical service
EHCS - emergency health care service
CVD - cardiovascular disease
MHC - mental health centre
EIS - electronic information system
RND - radioisotope (radionuclide) diagnostics
RNT - radionuclide therapy
RPMP - radiopharmaceutical medicinal product
PET/CT - positron emission tomography combined with a computed tomography scanner
SPECT - single photon emission computed tomography scanner

Annex 3
to the Criteria for Evaluating
the Level of Risk in
the Delivery of Health Services (Care)

List of subjective criteria for establishing the degree of risk by subjective criteria in the sphere of health services (care) provision)

_____

under Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of entities (facilities) offering outpatient and polyclinic care (primary medical and sanitary care and consultative and diagnostic care)

_____

name of a homogeneous group of entities (facilities)

_____ **under control**

№ s/o	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight by significance, point (the total should not exceed 100 points), wi	Conditions /values,, xi		
				condition 1/ value	condition 2/ value	condition 3/ value
1	2	3	4	5		
For preventive control with visits						
	Failure to execute	findings of preventive control without visiting the entity (facility)		no	yes	

1	recommendations issued as a result of preventive control without visiting the entity (facility) under control	under control (final documents issued based on the findings of preventive control without visiting the entity (facility) under control).	100.0	0%	100%	
2	Annual pregnancy rate of women of fertile age with extragenital pathology for whom pregnancy is absolutely contraindicated -	results of monitoring of reports and data supplied by the entity under control	10.0	0-1.9%	between 2% and 4.0% of cases	more than 4 per cent of cases
				0%	50%	100%
3	Number of stroke deaths (ICD-10 code - I63) at home within 1 month after discharge	results of monitoring of reports and data supplied by the entity under control	25.0	0 to 4 cases	Between 5 and 9 cases	more than 10 cases
				0%	50%	100%
4	Proportion of hospitalisations of patients with complications of cardiovascular diseases (arterial hypertension, myocardial infarction, stroke)	results of monitoring of reports and data supplied by the entity under control	10.0	0-9.9%	10% -19.9% cases	more than 20 per cent of cases
				0%	50%	100%
5	Annual indicator of the proportion of patients with acute cerebral circulation disorder registered after discharge from hospital within 3 working days at the place of registration -	results of monitoring of reports and data supplied by the entity under control	10.0	0 % cases	0-9.9% cases	From 10% of cases
				0%	50%	100%

6	Proportion of deaths from circulatory system diseases out of total number of deaths, with ICD-10 diagnosis (I00-I99)	results of monitoring of reports and data supplied by the entity under control	25.0	0-10 %	10.01 –19.9% cases	more than 20 per cent of cases
				0%	50%	100%
7	Annual rate of first-time detected patients with malignant neoplasms of stage 3-4 -	results of monitoring of reports and data supplied by the entity under control	10.0	0-9.9%	More than 10%	
				0	100 %	
8	Number of child deaths from 0-5 years of age	results of monitoring of reports and data supplied by the entity under control	100.0	no	yes	
				0	1 and more	
9	Number of maternal deaths	results of monitoring of reports and data supplied by the entity under control	100.0	no	yes	
				0	1 and more	
For compliance inspections						
1	Certificate of a professional for admission to clinical practice	results of monitoring of reports and data presented by the entity under control (e-license)	50	There is a certificate	There is no certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganisation of the legal entity-licensee	results of analysis of data provided by public authorities and entities	50	yes	no	
				0%	100%	

Annex 4
to the Criteria for Evaluating
the Level of Risk in
the Delivery of Health Services (Care)

List of subjective criteria for establishing the degree of risk based on subjective criteria

in the area of quality of health care services (care)

_____

as per Article 138

_____

of the Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) offering in-patient, in-patient substitute care

_____

name of a homogeneous group of entities (facilities)_____being controlled

№ s/o	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight by significance, point (the total should not exceed 100 points), w_i	Conditions /values, x_i		
				condition 1/ value	condition 2/ value	condition 3/ value
1	2	3	4	5		
For preventive control with visits						
1	Non-fulfilment of recommendations issued following the findings of preventive control without a visit to the entity (facility) under control	findings of preventive control without visiting the entity (facility) under control (final documents issued based on the findings of preventive control without visiting the entity (facility) under control).	100.0	no	yes	
				0%	100%	
2	Postoperative mortality rate in cases of planned hospitalisation -	results of monitoring of reports and data supplied by the entity under control	25.0	0-4.9%	5-10.0% cases	more than 10 per cent of cases
				0%	50%	100%
3	Annual rate of repeat unplanned hospitalisation	results of monitoring of reports and data supplied	10.0	0-5% cases	5.01-10% cases	more than 10 per cent of cases

	s (within a month for the same illness) -	by the entity under control		0%	50%	100%
4	Annual mortality rate for planned hospitalisations	results of monitoring of reports and data supplied by the entity under control	25.0	0 cases	more than 1 case	
				0%	100%	
5	Number of child deaths from 0-5 years of age	results of monitoring of reports and data supplied by the entity under control	100.0	no	yes	
				0	1 and more	
6	Number of maternal deaths	results of monitoring of reports and data supplied by the entity under control	100.0	no	yes	
				0	1 and more	
For compliance inspections						
1	Certificate of a professional for admission to clinical practice	results of monitoring of reports and data presented by the entity under control (e-license)	50	There is a certificate	There is no certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganisation of the legal entity-licensee	results of analysis of data reported by public authorities and entities	50	yes	no	
				0%	100%	

Annex 5
to the Criteria for Evaluating
the Level of Risk in
the Delivery of Health Services (Care)

List of subjective criteria for establishing the degree of risk based on subjective criteria

in the area of quality of health care services (care)

as per Article 138

of the Entrepreneurial Code of the Republic of Kazakhstan in respect of _____

entities (facilities), obstetric and (or) inpatient facilities with maternity wards and neonatal pathology wards newborns _____

name of a homogeneous group of entities (facilities)

_____ being controlled

№ s/o	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight by significance, point (the total should not exceed 100 points), w_i	Conditions /values,, x_i		
				condition 1/ value	condition 2/ value	condition 3/ value
1	2	3	4	5		
For preventive control with visits						
1	Failure to fulfil recommendations issued as a result of preventive control without visiting the entity (facility) under control	findings of preventive control without visiting the entity (facility) under control (final documents issued based on the results of preventive control without visiting the entity (facility) under control).	100.0	no	yes	
				0%	100%	
2	Number of child deaths from 0-5 years of age	results of monitoring of reports and data supplied by the entity under control	100.0	no	yes	
				0	1 and more	
3	Number of maternal deaths	results of monitoring of reports and data supplied by the entity under control	100.0	no	yes	
				0	1 and more	
4	Annual mortality rate for planned	results of monitoring of reports and	25.0	0 cases	more than 1 case	

	hospitalisations	data supplied by the entity under control		0%	100%	
5	Ratio of emergency and planned Caesarean sections	results of monitoring of reports and data supplied by the entity under control	10.0	0-10 % cases	10.1-24.9% cases	more than 25 % of cases
				0%	50%	100%
6	Proportion of birth injury cases	results of monitoring of reports and data supplied by the entity under control	10,0	0-10 % cases	10.1-19.9% cases	more than 20 % of cases
				0%	50%	100%
7	Postoperative mortality rate in cases of planned hospitalisation -	results of monitoring of reports and data supplied by the entity under control	25.0	0-4.9%	5-9.9% cases	more than 10 % of cases
				0%	50%	100%
8	Number of cases of intrapartum fetal death in a health care facility in the absence of CHD (excluding charts with a final major, concomitant, or clarifying diagnosis with ICD-10 code Q00-Q99.9)	results of monitoring of reports and data supplied by the entity under control	25.0	0	1 case	
				0%	100%	
9	Rate of repeat unplanned admissions (within one month for the same condition) (female pelvic inflammatory disease (N70-N77)	results of monitoring of reports and data supplied by the entity under control	10.0	0-4.99 % cases	5-9.9 % cases	more than 10 per cent of cases
				0	50 %	100 %
For compliance inspections						
	Certificate of a specialist for	results of monitoring of reports and		There is a certificate	There is no certificate	

1	admission to clinical practice	data supplied by the entity under control (e-license)	50	0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganisation of the legal entity-licensee	findings of the analysis of data presented by public authorities and entities	50	yes	no	
				0%	100%	

Annex 6
to the Criteria for Evaluating
the Level of Risk in the Delivery
of Health Services (Care)

List of subjective criteria for establishing the degree of risk based on subjective criteria

in the delivery of health care services (care)

_____

pursuant to Article 138

_____

of the Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) offering cardiological, cardiosurgical and cardiosurgical care____

_____

name of a homogeneous group of entities (facilities)

_____ being controlled

№ s/o	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight by significance, point (the total should not exceed 100 points),w_i	Conditions /values, x_i		
				condition 1/ value	condition 2/ value	condition 3/ value
1	2	3	4	5		
For preventive control with visits						
	Failure to fulfil recommendati	findings of preventive control without visiting the entity (facility) being		no	yes	

1	ons issued as a result of preventive control without visiting the entity (facility) under control	controlled (final documents issued based on the findings of preventive control without visiting the entity (facility) being controlled).	100.0	0%	100%	
2	Number of stroke deaths (ICD-10 code - I63) at home within 1 month after discharge	results of monitoring of reports and information presented by the entity under control	25.0	0 to 4 cases	Between 5 and 9 cases	over 10 cases
				0%	50%	100%
3	Proportion of hospitalisations of patients with complications of cardiovascular diseases (arterial hypertension, myocardial infarction, stroke)	findings of monitoring of reports and information presented by the entity under control	10.0	0	1- 19.9% cases	more than 20 per cent of cases
				0%	50%	100%
4	Proportion of deaths from circulatory diseases out of total number of deaths, with ICD-10 diagnosis (I00-I99)	results of monitoring of reports and data supplied by the entity under control	25.0	0-10 %	10.1 – 20% cases	more than 20 per cent of cases
				0%	50%	100%
5	The rate of postoperative mortality in cases of planned hospitalisation -	findings of monitoring of reports and data supplied by the entity subject to control	25.0	0-4.9%	5-10% cases	more than 10 per cent of cases
				0%	50%	100%
6	Annual rate of repeat unplanned hospitalisation	findings of monitoring of reports and data supplied	10.0	0-5% cases	5.1-10% cases	more than 10 per cent of cases

	s (within a month for the same illness) -	by the entity subject to control		0%	50%	100%
7	Annual mortality rate for planned hospitalisations	findings of monitoring of reports and data supplied by the entity subject to control	25.0	0 cases	more than 1 case	
				0%	100%	
8	Number of child deaths from 0-5 years of age	findings of monitoring of reports and data supplied by the entity subject to control	100.0	no	yes	
				0	1 or more	
9	Number of maternal deaths	findings of monitoring of reports and data supplied by the entity subject to control	100.0	no	yes	
				0	1 or more	
For compliance inspections						
1	Specialist certificate for admission to clinical practice	findings of monitoring of reports and data supplied by the entity subject to control	50	There is a certificate	There is no certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganisation of the legal entity-licensee	findings of the analysis of data presented by public authorities and entities	50	yes	no	
				0%	100%	

Annex 7
to the Criteria for assessing
the degree of Risk assessment criteria
in the sphere of rendering medical
services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) providing haemodialysis care

_____

name of homogeneous group of entities (facilities)

_____ of control

№ r/n	Indicator of the subjective criterion	Source of information on the subjective criterion indicator	Weight by importance, point (the total should not exceed 100 points), wi	Conditions /values, xi		
				condition 1/ values	condition 2/ values	condition 3/ values
1	2	3	4	5		
For preventive control with a visit						
1	Failure to fulfil recommendations issued as a result of preventive control without visiting the subject (object) of control	results of preventive control without visiting the subject (object) of control (final documents issued based on the results of preventive control without visiting the entity (facility) of control).	100,0	no	yes	
				0%	100%	
3	Annual mortality rate during planned hospitalisation	Results of monitoring of reports and information provided by the entity of control	25,0	0 case	More than 1 case	
				0%	100,0	
For compliance verifications						
	Availability of a certificate of a specialist for	results of monitoring of reports and information		With a certificate	Without a certificate	

1	admission to clinical practice	provided by the entity of control (e-license)	50	0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganisation of the legal entity-licensee	results of analysis of information provided by state bodies and organisations	50	yes	no	
				0%	100%	

Annex 8
to the Criteria for assessing
the degree of risk in the sphere of
rendering
medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of quality of medical services (care)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of _____ entities (facilities), providing dental care

_____

name of homogeneous group of entities (facilities)

_____ of control

№ r/n	Indicator of the subjective criterion	Source of information on the subjective criterion indicator	Weight by importance, point (the total should not exceed 100 points), wi	Conditions /values, xi		
				condition 1/ values	condition 2/ values	condition 3/ values
1	2	3	4	5		
For preventive control with a visit						
	Failure to fulfil recommendations issued as a result of	results of preventive control without visiting the entities (facilities) of control (final		no	yes	

1	preventive control without visiting the entities (facilities) of control	documents issued based on the results of preventive control without visiting the entities (facilities) of control).	100,0	0%	100%	
3	Number of child deaths from 0-5 years of age	Results of monitoring of reports and information provided by the entity of control	100,0	no	yes	
				0	1 and more	
For compliance inspections						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the entity of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies and organizations	50	yes	no	
				0%	100%	

Annex 9
to the Criteria for assessing
the degree of risk in the sphere
of rendering medical services
(assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____ entities (facilities),

providing phthisiatric care _name of homogeneous group of entities (facilities) _____ of the control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
1	Failure to fulfil recommendations issued as a result of preventive control without visiting the entities (facilities) of control	results of preventive control without visiting the entities (facilities) of control (final documents issued based on the results of preventive control without visiting the entities (facilities) of control).	100,0	no	yes	
				0%	100%	
3	Annual mortality rate during planned hospitalisation	Results of monitoring of reports and information provided by the entity of control	25,0	0 cases	More than 1 case	
				0%	100,0	
4	The rate of postoperative mortality in cases of planned hospitalisation -	results of monitoring of information received from automated information systems	25,0	0-4,9%	5-9,9% of cases	More than 10% of cases
				0%	50%	100%
For compliance verifications						
1	Availability of a certificate of a specialist for admission to	results of monitoring of reports and information	50	With a certificate	Without a certificate	

	clinical practice	provided by the entity of control (e-license)		0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies and organizations	50	yes	no	
				0%	100%	

Annex 10
to the Criteria for assessing the degree of risk in the sphere of rendering medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of _____ entities (facilities), providing oncological care _name of homogeneous group entities (facilities)_____ _ of control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
	Failure to fulfil recommendations issued as a result of preventive	results of preventive control without visiting the entities (facilities) of control (final documents		no	yes	

1	control without visiting the entities (facilities) of control	issued based on the results of preventive control without visiting the entities (facilities) of control).	100,0	0%	100%	
3	Annual mortality rate during planned hospitalisation	Results of monitoring of reports and information provided by the entity of control	25,0	0 case	More than 1 case	
				0%	100,0	
4	The rate of postoperative mortality in cases of planned hospitalisation -	results of monitoring of information received from automated information systems	25,0	0-4,9%	5-9,9% of cases	More than 10% of cases
				0%	50%	100%
5	Annual rate of repeated unplanned admissions (within a month for the same illness) -	Results of monitoring of reports and information provided by the entity of control	10,0	0-5% of cases	5,1-10% of cases	More than 10% of cases
				0%	50%	100%
For compliance inspections						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the subject of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies and organizations	50	yes	no	
				0%	100%	

Annex 11

to the Criteria for assessing the degree of risk in the sphere of rendering

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of _____ entities (facilities), providing medical and social assistance in the field of mental health

_____

name of homogeneous group of entities (facilities)

_____ of control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
1	Failure to fulfil recommendations issued as a result of preventive control without visiting the entities (facilities) of control	results of preventive control without visiting the entities (facilities) of control (final documents issued based on the results of preventive control without visiting the entities (facilities) of control).	100,0	no	yes	
				0%	100%	
	Annual mortality rate during planned hospitalisation of patients			0-10 % of cases	10,1-25% of cases	More than 25% of cases

2	with mental and behavioural disorders, including substance use F00-F99 (Percentage of inpatient deaths out of the total number of patients discharged (discharged patient, died)).	results of monitoring of information received from automated information systems	25,0	0%	50%	100%
3	Presence of cases of inappropriate length of stay (3 beds/day or less) (The proportion (%) of inpatient discharges with a length of stay of 3 nights/day or less out of the total number of patients (discharged) with mental and behavioural disorders F00-F99, including those due to substance (ПАВ) use).	results of monitoring of information received from automated information systems	10,0	0-10 % of cases 0%	10,1-20% of cases 50%	More than 20 % of cases 100%
For compliance inspections						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the subject of control (e-license)	50	With a certificate 0%	Without a certificate 100%	
	The fact of re-registration of the licensee, change of its	results of analysis of		yes	no	

2	name or legal address and (or) reorganization of the legal entity-licensee	information provided by state bodies a n d organizations	50	0%	100%	

Annex 12
to the Criteria for assessing the degree
of risk in the sphere of rendering
medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of _____ entities (facilities), providing laboratory services

_____

name of homogeneous group of entities (facilities)

_____ of control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
	Failure to fulfil recommendations issued as a result of preventive control without visiting the	results of preventive control without visiting the entities (facilities) of control (final documents issued based on the results of preventive control without visiting the		no	yes	
					100%	

1	entities (facilities) of control	entities (facilities) of control).	100,0	0%		
For compliance inspections						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the facility of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies a n d organizations	50	yes	no	
				0%	100%	

Annex 13
to the Criteria for assessing the degree
of risk in the sphere of rendering
medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of _____ entities (facilities), providing ambulance medical aid, medical aid in the form of air ambulance _____

name of homogeneous group of entities (facilities)

_____ of control

				Conditions /values, xi		

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
1	Number of cases of deviations from the time of arrival in the relevant category (for organisations providing emergency medical care) over the past year	results of monitoring of reports and information provided by the entity of control	50,0	0-4 cases	5-9 cases	More than 10 cases
				0%	50%	100%
2	Number of repeat visits for the same incident within a 24-hour period in the past year	Results of monitoring of reports and information provided by the entity of control	50,0	0-4 cases	5-9 cases	More than 10 cases
				0%	50%	100%
3	Failure to fulfil recommendations issued as a result of preventive control without visiting the entity (facility) of control	results of preventive control without visiting the entity (facility) of control (final documents issued based on the results of preventive control without visiting the entity (facility) of control).	100,0	no	yes	
				0%	100%	
For compliance inspections						
1	Availability of a certificate of a specialist for	results of monitoring of reports and information provided by	50	With a certificate	Without a certificate	

	admission to clinical practice	the entity of control (e-license)		0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies and organizations	50	yes	no	
				0%	100%	

Annex 14
to the Criteria for assessing the degree of risk in the sphere of rendering medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of _____ entities (facilities), carrying out activities in the area of HIV prevention

_____

Name of homogeneous group of entities (facilities) of control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
	Failure to fulfil recommendations issued as a result of preventive control without visiting the	results of preventive control without visiting the entities (facilities) of control (final documents issued based		no	yes	

1	entities (facilities) of control	on the results of preventive control without visiting the entities (facilities) of control).	100,0	0%	100%	
For compliance inspections						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the subject of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies a n d organizations	50	yes	no	
				0%	100%	

Annex 15
to the Criteria for assessing the degree
of risk in the sphere of rendering
medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) carrying out activities in the field of blood service

_____

name of homogeneous group of entities (facilities)

_____of control

		Source of information on	Specific weight in terms of significance, point (the total	Conditions /values, xi		

№ r/n	Subjective criterion indicator	the subjective criterion indicator	should not exceed 100 points), w_i	condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
1	Failure to fulfil recommendations issued as a result of preventive control without visiting the entities (facilities) of control	results of preventive control without visiting the entities (facilities) of control (final documents issued based on the results of preventive control without visiting the entities (facilities) of control).	100,0	no	yes	
				0%	100%	
For compliance verifications						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the entity of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies a n d organizations	50	yes	no	
				0%	100%	

Annex 16
to the Criteria for assessing the degree
of risk in the sphere of rendering
medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) providing pathological anatomical diagnostics

_____

name of homogeneous group of entities (facilities)

_____ of control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
1	Failure to fulfil recommendations issued as a result of preventive control without visiting the entities (facilities) of control	results of preventive control without visiting the entities (facilities) of control (final documents issued based on the results of preventive control without visiting the entities (facilities) of control).	100,0	no	yes	
				0%	100%	
For compliance verifications						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the subject of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
	The fact of re-registration			yes	no	

2	of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies a n d organizations	50	0%	100%	

Annex 17
to the Criteria for assessing the degree of risk in the sphere of rendering medical services (assistance)

List of subjective criteria for determining the degree of risk by subjective criteria

in the sphere of medical services (assistance)

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) providing assistance in the field of nuclear medicine

_____

name of homogeneous group of entities (facilities)

_____ of control

№ r/n	Subjective criterion indicator	Source of information on the subjective criterion indicator	Specific weight in terms of significance, point (the total should not exceed 100 points), w_i	Conditions /values, xi		
				condition 1/ values	condition 1/ values	condition 1/ values
1	2	3	4	5		
For preventive control with a visit						
	Failure to fulfil recommendations issued as a result of preventive control without visiting the entities (facilities) of control	results of preventive control without visiting the entities (facilities) of control (final documents issued based on the results of preventive		no	yes	
					100%	

1		control without visiting the entities (facilities) of control).	100,0	0%		
For compliance inspections						
1	Availability of a certificate of a specialist for admission to clinical practice	results of monitoring of reports and information provided by the subject of control (e-license)	50	With a certificate	Without a certificate	
				0%	100%	
2	The fact of re-registration of the licensee, change of its name or legal address and (or) reorganization of the legal entity-licensee	results of analysis of information provided by state bodies and organizations	50	yes	no	
				0%	100%	

Annex 2
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ RK MH-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 2 – in the wording of the joint order of the Minister of Healthcare of the RK dated 29.05.2023 № 90 and the Minister of National Economy of the RK dated 29.05.2023 № 91 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

in the area of quality of health care delivery

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____ entities (facilities),

providing in-patient, in-patient substitute care

name of homogeneous group of control entities (facilities)

_____

State body that appointed the inspection/preventive control

with a visit to the entity (facility) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the entities (facilities) of control (facility) of control

_____

_____ №, date

Name of the entities (facilities) of control _____

_____

(Individual identification number), business identification number

of the entities (facilities) of control _____

—

_____

Address of residence _____

_____

_____

№	List of requirements	Complies with the requirements	Does not comply with the requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free-of-charge basis		
2	Availability of a conclusion on the compliance of the health care entity to provide high-tech medical care		

3	Presence of written voluntary consent of the patient or his/her legal representative in case of invasive interventions and therapeutic and diagnostic measures.		
4	Availability of supporting documentation (form № 085/y "emergency medical care team EMCT call card" , admission and refusal of hospitalisation log, form № 001/y "medical card of an inpatient"), that the stay of the emergency medical care team or EMCT department in the hospital's emergency room shall not exceed 10 minutes (the time for transferring the patient to the emergency room doctor) from the moment of its arrival at the hospital, except in cases of emergency medical care in emergency situations. After the transfer of the patient to the inpatient admission department by the ambulance crews or the ambulance department in the organisation of primary health care, the nurse shall distribute the incoming patients (medical triage according to the triage system) into groups, based on the priority of emergency medical care. Medical triage according to the triage system (hereinafter referred to as the medical triage) shall be carried out continuously and in succession and successive. Upon completion of the assessment, patients shall be marked with a colour of one of the triage categories in the form of a special-coloured tag or coloured tape.		

	According to the medical triage, there are 3 groups of patients: First group (red zone) - patients whose condition shall be immediately life-threatening or at high risk of deterioration and who shall require emergency medical care; second group (yellow zone) - patients whose condition poses a potential threat to health or may progress with the development of a situation requiring emergency medical care; third group (green zone) - patients whose condition shall be a potential health risk or may progress to a situation requiring emergency medical care; third group (green zone)		
5	Availability of supporting medical documentation (form № 001/y "Inpatient medical card") on hospitalisation of a severe patient in need of continuous monitoring of vital functions for medical reasons, by the decision of a Concilium and notification of the heads of healthcare organisations with subsequent transfer to another medical organisation according to the profile of the disease for further examination and treatment after stabilisation of the condition		
	Availability of supporting documentation on the medical opinion of the emergency room doctor with a written justification of the refusal in the absence of indications for hospitalisation in a health care organisation (Journal of admissions and refusals		

6	of hospitalisation from medical information systems, certificate in form № 027/y (refusals of hospitalisation)). A nurse of the admission department shall send an active referral to the PHS organisation at the patient's place of attachment		
7	Presence of records in medical documentation (Journal of patient admission and refusals of hospitalisation from the MIS, scheduled hospitalisation coupons, " Medical card of an inpatient" (form № 001/y) on indications for hospitalisation: The need to provide pre-hospital, qualified, specialised medical care, including the use of high-tech medical services, with round-the-clock medical supervision of patients: 1) on a planned basis - by referral of PHS specialists or other health care organisation: 2) on emergency indications (including weekends and public holidays) - regardless of the availability of a referral		
8	Availability of supporting medical documentation (form № 001/y "Medical card of inpatient") on the examination of heavy patients by the head of the department on the day of admission, and daily thereafter. Patients in a moderately severe condition shall be examined at least once a week. The results of the patient's examination shall be recorded in the medical		

	record with recommendations on further tactics of patient management with obligatory identification of the medical worker making the entries		
9	The presence of an established clinical diagnosis in conjunction with the head of department no later than three working days from the day of the patient's admission to the health care organisation in form № 001/y "Medical card of inpatient".		
10	Availability of supporting documentation (Form № 001/y "Medical card of inpatient") on daily examination of patients in the hospital by the attending a physician, except for weekends and public holidays. In case of examination and appointment of additional diagnostic and therapeutic manipulations by the doctor on duty, appropriate entries shall be made in the medical record. If the patient's condition worsens, the doctor on duty notifies the head of the department and (or) the attending physician, approves changes in the process of diagnosis and treatment, and makes an entry in the medical record (paper and (or) electronic) version. An entry shall be made in the electronic version of the medical record no later than 24 hours after the change in the patient's condition. In case of emergency, the frequency of entries depends on the dynamics		

	of the severity of the condition. The records of the hospital doctor reflect specific changes in the patient's condition and the need for correction of prescriptions, justification of the prescribed examination and treatment, evaluation and interpretation of the results obtained and the effectiveness of the treatment. The frequency of examination for emergency conditions shall be at least every 3 hours, indicating the time of emergency care by hours and minutes.		
11	Compliance with the requirements for planned hospitalisation: 1) availability of a referral for hospitalisation in the hospital and a coupon for planned hospitalisation; 2) hospitalisation of the patient in accordance with the date of planned hospitalisation specified in the referral; 3) the presence of clinical and diagnostic (laboratory, instrumental and functional) examinations and consultations of specialised specialists according to the diagnosis of the extract from the medical card of an outpatient, form № 052/y.		
12	Availability of medical records of consultations or Concilium in case of difficulty in identifying the diagnosis, ineffectiveness of the current treatment, as well as other indications		
	Availability of medical documentation of compliance with discharge criteria, in particular:		

13	1) generally accepted treatment outcomes (recovery, improvement, no change, death, transferred to another medical organisation); 2) a written statement by the patient or his/her legal representative when there is no immediate danger to the patient's life or to others; 3) cases of violation of the internal order of the health care organisation, as well as obstruction of the treatment and diagnostic process, infringement of the rights of other patients to receive proper medical care (in the absence of an immediate threat to his/her life), about which an entry shall be made in the medical record.		
14	A discharge summary shall be issued to the patient upon discharge, indicating the full clinical diagnosis, the scope of diagnostic tests, therapeutic measures and recommendations for further follow-up and treatment. Discharge data shall be entered into the information systems on a day-to-day basis, indicating the actual time of discharge .		
	Availability of documentation on compliance with the requirements for transfusion of blood components and in case of complications (orders on establishment of the commission, algorithm of staff interaction, "Medical card of an inpatient" form № 001/y): Before transfusion of blood components, the recipient		

15	shall be examined for markers of haem transmissible infections HIV, hepatitis B and C, and after the end of treatment, the discharge epicrisis shall indicate the need for repeated examination for HIV and hepatitis B and C at the place of residence. HIV testing of recipients as part of the guaranteed scope of free medical care shall be carried out in state health-care organisations working in the area of HIV prevention Information on transfusion and obstetric anamnesis shall be entered in the patient's medical record before transfusion therapy shall begin: previous transfusions, when and in connection with what; whether there have been any post-transfusion complications, pregnancies that have resulted in the birth of babies with haemolytic disease of the new-born. In case of development of complications during the biological test, during transfusion or after it, a detailed record(s) is made describing the recipient's condition, vital function monitoring data, treatment methods and their effectiveness. Immediate laboratory control of the recipient's blood and urine shall be performed.		
	Availability of supporting medical documentation on indications for hospitalisation in day hospital at outpatient and		

		polyclinic health care organisations and in hospital at home: 1) exacerbation of chronic diseases that do not require round-the-clock medical supervision; 2) active planned recuperation of a group of patients with chronic diseases subject to dynamic monitoring; 3) follow-up treatment of a patient on the next day after inpatient treatment on medical grounds; 4) second and third stage medical rehabilitation courses; 5) palliative care; 6) orphan diseases in children associated with a high risk of infectious complications and requiring isolation during seasonal viral diseases to receive regular enzyme replacement and antibacterial therapy.		
16		The indications for hospitalisation in a day hospital at a 24-hour hospital shall be: 1) carrying out operations and interventions with special preoperative preparation and resuscitation support; 2) performance of complex diagnostic tests requiring special preliminary preparation and not available in outpatient and polyclinic health care organisations; 3) monitoring of patients whose treatment involves transfusion of blood products, intravenous infusions of blood substituting fluids, specific hyposensitising therapy, injections of potent drugs,		

	intra-articular injections of drugs; 4) treatment on the next day after inpatient treatment if there are indications for early discharge after surgical treatment; 5) palliative care; 6) chemotherapy, radiation therapy, correction of pathological conditions arising after specialised treatment of oncological patients		
	Availability of medical documentation on examination of individuals for HIV infection on clinical indications when the following diseases, syndromes and symptoms shall be detected: 1) enlargement of two or more lymph nodes of more than 1 month duration, persistent, generalised lymphadenopathy; 2) fever of unclear etiology (persistent or recurrent for more than 1 month); 3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained loss of 10% of weight or more; 4) chronic diarrhoea for 14 days or more (in children), unexplained chronic diarrhoea lasting more than a month; 5) seborrhoeic dermatitis, pruritic papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) shingles;		

17	9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis , isosporosis, extrapulmonary histoplasmosis, strongyloidosis, actinomycosis); 10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, except tuberculosis of peripheral lymph nodes; 11) hairy leukoplakia of the oral cavity, linear erythema of the gums; 12) severe prolonged recurrent pneumonia and chronic bronchitis not amenable to conventional therapy (two or more times per year), asymptomatic and clinically evident lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent-bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis, meningoencephalitis, bone and joint infections, purulent myositis, Salmonella septicaemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) pneumocystis pneumonia; 15) infections caused by herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of the disease)			

	lesions of skin and mucous membranes, including eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unclear etiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the oesophagus, bronchi, trachea, lungs, oral and nasal mucous membranes; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unclear etiology; 26) prolonged recurrent pyoderma not amenable to conventional therapy; 27) severe chronic inflammatory diseases of the female genital sphere of unclear etiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis after 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhoea, genital herpes, viral papillomatosis and others) with an established diagnosis; 31) viral hepatitis B and C, with confirmed diagnosis; 32) extensive plumose condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum;			

	34) primary dementia in previously healthy individuals; 35) patients with haemophilia and other diseases who systematically receive transfusion of blood and its components; 36) generalised cytomegalovirus infection.		
18	Availability of an agreement for provision of paid medical services in healthcare organisations. Availability of documents establishing the fact of co-payment		
	Availability of medical documentation on compliance with the following requirements during the examination of temporary incapacity for work, issuance of temporary incapacity for work and certificates of temporary incapacity for work (form № 001/y " Medical card of hospital patient", form № 052/y " Medical card of hospital patient", stubs of sheets of temporary incapacity for work of patients, form № 025/y "Journal for recording conclusions of medical advisory commission", form № 029/y "Book of registration of sheets of temporary incapacity for work", form № 037/y "Certificate of temporary incapacity for work", form № 037/y " Certificate of temporary incapacity for work", form № 037/y "Certificate of temporary incapacity for work", form № 037/y " Certificate of temporary incapacity for work".		

19	1) examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient) patient justifying the need for temporary exemption from work; 2) issuance of a sheet and certificate of temporary incapacity for work on the day of discharge of individuals under inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing of the sheet and certificate of temporary incapacity for work on the date of discharge from the hospital if the individual's ability to work has been fully restored; 4) extension of the temporary disability certificate and certificate of temporary incapacity for work for a period of time, taking into account the time necessary for the individual to visit a medical worker at the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Individuals who received treatment outside the region of residence shall be taken into account the time required to arrive at the place of his/her permanent residence (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug			

	intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and a certificate of temporary incapacity for work to individuals suffering from mental illness in the event of failure to apply to a medical organisation in a timely manner for the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical officer (psychiatrist) in conjunction with the head of the medical organisation ; (7) Issuance of a sheet and a certificate of temporary incapacity for work to individuals sent by court decision for forensic medical or forensic psychiatric examination and recognised as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work at the same time to an individual who shall combine training with work.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit conducted by the Patient support service and internal expertise and its evaluation according to the following criteria: Quality of history taking, which shall be assessed by the following criteria: absence of anamnesis collection;		

	Completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haem transfusions, tolerance of medicines, allergology status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor quality anamnesis collection; 2) completeness and validity of diagnostic tests, which shall be evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or absence of a conclusion based on the results of diagnostic investigations, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; carrying out diagnostic tests with high, unjustified risk for the patient's health, justification of diagnostic tests not included in clinical protocols; carrying out diagnostic tests that are not informative for making a correct diagnosis and that lead to an unjustified increase in treatment time and the cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalisation, investigations conducted at the pre-hospital stage shall		

	be also taken into account), which shall be assessed according to the following criteria: the diagnosis is absent, incomplete or incorrect, shall not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis is correct but incomplete, the leading pathological syndrome shall not be highlighted with the highlighted complications, comorbidities affecting the outcome shall not be recognised; the diagnosis of the main disease shall be correct, but comorbidities affecting the outcome of treatment shall not be diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) shall be reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) shall be assessed; 4) timeliness and quality of consultations of specialised specialists, which shall be assessed according to the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that		

20	negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion shall have been taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion has been wrong and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which shall be assessed according to the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the specifics of the course of the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical			

	protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which shall be assessed according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the specifics of the course of the disease, concomitant diseases, complications, prescription of medicines		
	7) the achieved result, which shall be assessed by the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis		

	collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which shall be assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care provided.		
	There is documentation of compliance with the following actions when performing pathological autopsies: 1) conducting a pathological anatomical autopsy of corpses after the doctors have ascertained biological death, after providing the medical record of a hospital patient or the medical record of an outpatient patient with a written order from the chief physician or his deputy for the medical (treatment) part of the health care organisation to send for a pathological anatomical autopsy; 2) registration of the results of the pathological anatomical autopsy in the form of a pathological		

	anatomical diagnosis (pathological anatomical diagnosis includes: main disease, complication of the main disease, concomitant disease, combined main disease); 3) transfer of the medical record of an inpatient or medical record of an outpatient with the pathological anatomical diagnosis entered into it to the medical archive of the health care organisation no later than ten working days after the pathological anatomical autopsy; 4) conducting clinical and pathological anatomical examination in cases of death of patients in health care organisations; 5) pathological anatomical autopsy in cases of suspected acute infectious diseases, oncological diseases, pathology of childhood, lethal outcome due to medical manipulations in order to establish the cause of death and clarify the diagnosis of a fatal disease; 6) organisation by the chief physician and head of the pathology department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathological anatomical bureau, centralised pathological anatomical bureau and pathological anatomical department of medical records of in-patients for all deceased for the previous day not later than 10 a.m. of the			

21		day following the establishment of the fact of death; 8) execution of: - medical certificate of death (preliminary, final) by a doctor in the speciality of "pathological anatomy (adult, paediatric)" on the day of the pathological anatomical autopsy; - medical certificate of perinatal death (preliminary, final) by a doctor specialising in " pathological anatomy (adult, child)" on the day of the pathological anatomical autopsy; 9) registration of autopsy results in the form of a protocol of pathological anatomical examination; 10) written notification to the forensic investigative authorities to address the issue of transferring the corpse for forensic medical examination in case of detection of signs of violent death and termination of pathological anatomical examination of the corpse; 11) written notification of the doctor in the speciality "pathological anatomy (adult, child)" in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service bodies immediately after their detection; 12) carrying out pathological and anatomical examination of the placenta: - in case of stillbirth;		

	- in all diseases of new-borns detected at the time of birth; - in cases suspected of haemolytic disease of new-borns; - in cases of early discharge and dirty waters; - in cases of maternal illness with fever in the last trimester of pregnancy; 9) registration of autopsy results in the form of a protocol of pathological anatomical examination; 10) written notification to the forensic investigative authorities to address the issue of transferring the corpse for forensic medical examination in case of detection of signs of violent death and termination of pathological anatomical examination of the corpse; 11) written notification of the doctor in the speciality "pathological anatomy (adult, child)" in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service bodies immediately after their detection; 12) carrying out pathological and anatomical examination of the placenta: - in case of stillbirth; - in all diseases of new-borns detected at the time of birth; - in cases suspected of haemolytic disease of new-borns;			

	- in cases of early discharge and dirty waters; - in cases of maternal illness with fever in the last trimester of pregnancy; - If there is an obvious abnormality in the development or attachment of the placenta; - suspected congenital anomalies of the foetus; - in cases of pre-eclampsia and eclampsia. 13) mandatory registration of a foetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) the establishment of pathological anatomical autopsy, depending on the complexity, into the following categories: - first category; - second category; - third category; - fourth category; 15) establishment of the category of pathological anatomy (adult, paediatric) by a doctor in the specialty "pathological anatomy (adult, paediatric)" and the reason for the divergence of diagnoses when the final clinical and pathological anatomical diagnoses diverge 16) availability of a detailed analysis defining the profile and categories of iatrogenesis in all cases of iatrogenic pathology identified as a result of pathological and anatomical autopsies		
	Availability of a written application from the spouse , close relatives or legal representatives of the deceased, or a written will		

22	be given by the person during his/her lifetime to release the corpse without a pathological anatomical autopsy, in the absence of suspicion of violent death		
23	Availability of a medical worker's entry in the medical documentation with the subsequent collection of biological materials to determine the content of a psychoactive substance and recording the results in the medical record when signs of psychoactive substance use are detected during the application for medical assistance to a health care organisation without issuing a medical examination conclusion to establish the fact of psychoactive substance use and the state of intoxication .		
24	Availability of medical documentation on treatment and diagnostic measures, medication, therapeutic nutrition and appropriate care of the patient from the moment of admission to the health care organisation (Medical card of an inpatient" form № 001/y)		
25	Availability of medical documentation on the use of opportunities for consultation with relevant national organisations, through the telemedicine network in case of difficulties in verifying the diagnosis of the child and determining the tactics of management. If necessary, the child is transferred to specialised national organisations.		

26	Medical documentation of supportive care (support for adequate feeding, water balance, pain control, fever management, oxygen therapy).		
27	Medical documentation of the use of less painful, equally effective alternative treatments when available, to avoid unnecessary painful procedures		
28	Availability of medical documentation on daily examination of the child by a doctor, examination by the head of the department (on admission on the first day, repeatedly at least once a week)		
	Availability of medical documentation on compliance with the requirements of anaesthesia and resuscitation care: 1) provision of specialised medical care to patients in emergency and planned procedures, including high-tech medical services; 2) determination of the method of anaesthesia, implementation of medical preoperative preparation and implementation of different methods of anaesthesia for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring the condition of patients in the post-lenarchemic period in the "waking up" wards until recovery of consciousness and stabilisation of the function of vital organs; 4) assessment of the degree of dysfunction of vital organs and systems and carrying out an extended		

29	complex of resuscitation and intensive care measures in various critical situations, including methods of extracorporeal detoxification, hyperbaric oxygenation, electro-cardio stimulation; 5) intensive monitoring (express control of the state of life support systems and metabolism using laboratory and functional diagnostics methods, respiratory and circulatory monitoring), full and targeted correction of disorders; 6) resuscitation of patients (if indicated) in other departments; 7) establishing indications for further treatment of patients in ARICD (Anaesthesiology, Reanimation and Intensive Care Department), as well as transfer of patients from ARICD (Anaesthesiology, Reanimation and Intensive Care Department) to specialised departments after stabilisation of vital organs function with recommendations on treatment and examination for the next 24 hours; 8) consulting doctors of other departments on practical anaesthesiology and resuscitation issues; 9) analysing the efficiency of the department and the quality of medical care, developing and implementing measures to improve the quality of medical care and reduce mortality rates		
30	Availability of medical documentation on compliance of treatment		

	and diagnostic measures with the recommendations of clinical protocols		
31	Availability of medical documentation on the provision of the first stage of medical rehabilitation for the main disease (form № 001/y "Medical card of an inpatient", "form № 047 /y" rehabilitation card).		
32	Availability of medical documentation on the examination by the head of the department upon admission of neurosurgical patients and subsequently, if necessary, on the disease (Medical card of an inpatient form № 001/y)		

Official(s) _____ _____
position signature

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surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

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surname, first name, patronymic (if any)

Annex 3
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ RK MH-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 3 - in the wording of the joint order of the Minister of Healthcare of the RK dated 29.05.2023 № 90 and the Minister of National Economy of the RK dated 29.05.2023 № 91 (shall enter into force upon expiry of ten calendar days after the date of its first official publication).

in the area of quality of health care delivery

_____

in accordance with Article 138

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Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) providing outpatient and polyclinic care
(primary medical and sanitary care and consultative-diagnostic
assistance)

_____

name of a homogeneous group of control entities (facilities) _____

_____

State body that ordered the inspection/preventive control
with a visit to the entities (facilities) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the entities (facilities) of control (facility) of control

_____

_____ №, date

Name of the entity (facility) of control _____

_____

(Individual identification number), business identification number
of the entity (facility) of control _____

_____

Address of residence_____

_____

№	List of requirements	Complies with the requirements	Does not comply with the requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed scope of free medical care and (or) the system of compulsory social health insurance on a free-of-charge basis		
2	Presence of written voluntary consent of the patient or his/her legal representative for invasive		

	interventions and therapeutic and diagnostic measures		
3	Availability of medical records of an outpatient patient on compliance of treatment and diagnostic measures with the recommendations of clinical protocols		
4	Availability of documentation on compliance with the following requirements when organising and conducting a medical advisory board: 1) availability of the order of the head of the medical organisation: - on the establishment of the medical advisory commission; - on the composition, number of members (at least three doctors), - the work and schedule of the medical advisory commission 2) availability of the conclusion of the medical advisory commission		
5	Availability of documentation on compliance by primary health care organisations in conducting preventive medical examinations of target population groups: 1) availability of lists of target groups of individuals subject to screening examinations; 2) ensuring continuity with specialised medical organisations for conducting these examinations; 3) informing the population about the need to undergo screening examinations; 4) entering data on the completion of screening		

	examinations in the medical information system; 5) conducting monthly analyses of screening examinations and providing information to local public health authorities by the 5th day of the month following the reporting month.		
6	Availability of documentation on compliance with the levels of medical rehabilitation provision to patients: 1) primary level - medical organisations of primary medical and sanitary care that have in their structure a rehabilitation room/unit, day hospital and provide medical rehabilitation to patients whose condition is assessed from 1 to 2 points on the Rehabilitation routing scale (hereinafter referred to as the RRS); 2) secondary level - medical organisations with specialised departments and (or) centres providing medical rehabilitation in outpatient, inpatient substitution and inpatient settings, providing medical rehabilitation to patients whose condition shall be assessed from 2 to 4 points on the Rehabilitation Routing Scale; 3) tertiary level - specialised medical organisations with departments and (or) centres providing medical rehabilitation, including with the use of high-tech services, in outpatient, inpatient substitution and inpatient settings, to patients whose condition is		

	assessed from 2 to 4 points on the RRS.		
7	Availability of documentation on compliance of tuberculosis care at the outpatient and polyclinic level with the following requirements: 1) carrying out information and awareness-raising work on prevention, early detection of tuberculosis; 2) planning (forming lists of individuals to be examined, drawing up a schedule), organising and carrying out fluorographic examinations and documenting the results of the examinations in medical records; 3) planning (compiling lists of individuals to be examined, drawing up a schedule), organising and carrying out tuberculin diagnostics of children and adolescents, documenting the results of the examination in medical records, and conducting follow-up examinations of tuberculin-positive children); 4) referral for examination of individuals suspected of tuberculosis according to the diagnostic algorithm of examination 5) referral of individuals with positive results of fluorographic examination, children and adolescents with a positive and hyperergic tuberculin test for the first time, with tuberculin sensitivity increasing by 6 mm or more, children with adverse reactions and complications to tuberculosis vaccination to a phthisiatrician;		

	6) planning, organisation and implementation of tuberculosis vaccination; 7) controlled treatment of latent tuberculosis infection (hereinafter referred to as the LTI) as prescribed by a phthisiatrist, including in video monitoring mode; 8) examination of contact individuals; 9) outpatient directly supervised or video-observed treatment of tuberculosis patients; 10) diagnosis and treatment of adverse reactions to tuberculosis drugs as prescribed by a phthisiatrist ; 11) diagnosis and treatment of concomitant diseases; 12) maintenance of medical records of tuberculosis patients on outpatient treatment, including multidrug-resistant and extensively drug-resistant tuberculosis; 13) regular entry of data into the National Register of tuberculosis patients within the scope of competence		
	Availability of documentation on compliance with the requirements for oncological care in the form of outpatient care: Formation of groups of individuals at risk of developing oncological diseases; Examination by a doctor to determine the patient's condition and establish a diagnosis; laboratory and instrumental examination of the patient in order to establish a diagnosis;		

8	dynamic monitoring of oncological patients; selection and referral for hospitalisation of oncological patients to receive specialised medical care, including high-tech medical services; follow-up examination of individuals with suspected MN in order to verify the diagnosis; determining the patient's management and treatment tactics; conducting outpatient anti-tumour therapy; conducting outpatient anti-tumour therapy		
9 77	Availability of mandatory confidential medical screening for HIV infection of individuals on clinical and epidemiological indications, including sexual partners of pregnant women, individuals who applied voluntarily and anonymously		
	Documentation of compliance with the following measures by an obstetrician-gynaecologist when a woman applies for pregnancy at the peri-pregnancy stage and wishes to continue the pregnancy: 1) presence of anamnesis collection, presence of diseases in the pregnant woman and relatives (diabetes mellitus, arterial hypertension, tuberculosis, mental disorders, oncological diseases and others), birth of children with congenital malformations and hereditary diseases; 2) a record of diseases (somatic and gynaecological), surgeries, transfusions of		

10		blood and its components in childhood and adulthood ; 3) presence of a "risk" group for congenital and hereditary pathology for referral to a doctor in the speciality of "Medical Genetics" (without ultrasound screening and analysis of maternal serum markers) on the following grounds: the age of the pregnant woman shall be 37 years and older, there shall be a history of pregnancy termination on genetic grounds and/or birth of a child with CHD or chromosomal pathology, there is a history of birth of a child (or relatives) with a monogenic hereditary disease, there is a family carrier of a monogenic hereditary disease, and there is a family history of birth of a child (or relatives) with a monogenic hereditary disease. 4) availability of the result of blood sampling of pregnant women for analysis of maternal serum markers in the first trimester of pregnancy and appointment of ultrasound screening in the first, second and third trimesters of pregnancy; 5) Availability of a record of reproductive features; 6) the presence of a record of the spouse's health status , blood group and rhesus affiliation; 7) availability of a record of the nature of production, where the spouses work, bad habits; 8) availability of examination for early registration of pregnant women up to 12 weeks and		

	registration on the day of detection of pregnancy for timely examination; 9) presence of contraindications to pregnancy; 10) availability of a management plan taking into account the identified factors		
	Availability of documentation on compliance with the requirements of an obstetrician-gynaecologist for the provision and organisation of obstetric and gynaecological care to women during pregnancy, after childbirth, provision of family planning and reproductive health services, as well as prevention, diagnosis and treatment of gynaecological diseases of the reproductive system 1) Availability of visits for dispensary monitoring of pregnant women for the prevention and early detection of complications of pregnancy, childbirth and the postnatal period, with the allocation of women "by risk factors"; 2) availability of the results of prenatal screening - a comprehensive examination of pregnant women to identify the risk group for chromosomal abnormalities and congenital malformations of the intrauterine foetus; (3) Timely hospitalisation of pregnant women in need of hospitalisation in day hospitals and pregnancy pathology departments of inpatient medical institutions providing obstetric and gynaecological care and		

11		specialised medical institutions with extragenital pathology, in accordance with the principles of regionalisation of perinatal care; 4) referral of pregnant women, women in labour and maternity for specialised care with medical supervision, including the use of high-tech medical services, to medical organisations at the national level; 5) records of prenatal education of pregnant women in preparation for childbirth, including partner childbirth, informing pregnant women about warning signs, effective perinatal technologies, principles of safe motherhood, breastfeeding and perinatal care; 6) Patronage of pregnant women and maternity women, as indicated; (7) Providing counselling and services on family planning and reproductive health care; (8) Identification of sexually transmitted infections for referral to specialised specialists; (9) Examination of women of childbearing age, with the prescription, if necessary, of in-depth examinations using additional methods and the involvement of specialised specialists for the timely detection of extragenital and gynaecological pathology and their inclusion in the dispensary register; (10) Based on the results of the examination, inclusion		

	of women of fertile age in the dynamic monitoring group, depending on the state of their reproductive and somatic health, for timely preparation for the planned pregnancy in order to improve the outcome of pregnancy for mother and child; (11) Availability of preventive examinations of the female population for early detection of extragenital diseases; (12) The availability of examination and treatment of gynaecological patients using modern medical technologies; 13) availability of identified and examined gynaecological patients for preparation for hospitalisation in specialised medical organisations; 14) results of gynaecological patients' medical examination, including rehabilitation and sanatorium treatment; 15) the number of small gynaecological operations performed using modern medical technologies; (16) Lists of pregnant women, women in labour and gynaecological patients to ensure continuity of interaction in examination and treatment (17) Availability of expert examination of temporary disability for pregnancy, childbirth and gynaecological diseases, determination of the need for and timing of temporary or permanent transfer of an employee for health reasons to another job, referral for medical and social expert		

	assessment of women with signs of permanent loss of working capacity		
12	Availability of results and additional data of follow-up examinations and investigations in the Individual card of pregnant and maternity women and the exchange card of pregnant and maternity women at each visit of a pregnant woman to an obstetrician-gynaecologist		
13	Home patronage by a midwife or a patronage nurse for pregnant women who do not attend an appointment within 3 days of the scheduled date.		
14	Availability of a medical advisory commission's opinion on the possibility of carrying a pregnancy in women with contraindications to pregnancy due to extragenital pathology.		
15	Availability of an agreement for provision of paid medical services in healthcare organisations. Availability of documents establishing the fact of co-payment		
16	Availability of documentation on compliance by the paramedical staff of the medical unit of the educational organisation with the following requirements: 1) availability of a unified list of students in educational organisations; 2) availability of the list of students (target groups) subject to screening examinations; 3) organisation and carrying out of		

	immunoprophylaxis with subsequent post-vaccinal observation of the vaccinated person; 4) control over compliance with the deadlines for compulsory medical examinations of all school staff and food service workers; 5) Maintaining accounting and reporting documentation		
	Availability of medical documentation on compliance with the following requirements during the examination of temporary incapacity for work, issuance of temporary incapacity for work and certificates of temporary incapacity for work (form № 001/y " Medical card of inpatient patient", form № 052/y " Medical card of outpatient patient", stubs of sheets of temporary incapacity for work of patients, form № 025/y "Journal for recording conclusions of medical advisory commission", form № 029/y "Book of registration of sheets of temporary incapacity for work", form № 037/y "Certificate of temporary incapacity for work", form № 037/y " Certificate of temporary incapacity for work", form № 037/y "Certificate of temporary incapacity for work", form № 037/y " Certificate of temporary incapacity for work". 1) examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient)		

17		patient justifying the need for temporary exemption from work; 2) issuance of a sheet and certificate of temporary incapacity for work on the day of discharge of individuals under inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing of the sheet and certificate of temporary incapacity for work on the date of discharge from the hospital if the individuals' ability to work has been fully restored; 4) extension of the temporary disability certificate and certificate of temporary incapacity for work for a period of time, taking into account the time necessary for the person to visit a medical worker at the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Individuals who received treatment outside the region of residence shall be taken into account the time required to arrive at the place of his/her permanent residence (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and a certificate of temporary incapacity for work to individuals suffering from mental illness in the event		

	of failure to apply to a medical organisation in a timely manner for the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical officer (psychiatrist) in conjunction with the head of the medical organisation ; (7) Issuance of a sheet and a certificate of temporary incapacity for work to individuals sent by court decision for forensic medical or forensic psychiatric examination and recognised as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work at the same time to a person who combines training with work.		
	Compliance with the following requirements when issuing a maternity leave and certificate of temporary incapacity for work: - A sheet or certificate of temporary disability for pregnancy and childbirth shall be issued by a medical worker (obstetrician-gynaecologist) , or in his absence, by a physician, in conjunction with the head of the department after the conclusion of the Medical consultative commission from thirty weeks of pregnancy for a period of one hundred and twenty-six calendar days (seventy calendar days before childbirth and fifty-six calendar days after		

	childbirth) in the case of normal childbirth. For women residing in territories affected by nuclear tests, a sheet or certificate of incapacity for pregnancy and childbirth shall be issued from twenty-seven weeks of pregnancy for a duration of one hundred and seventy calendar days (ninety-one calendar days before childbirth and seventy-nine calendar days after childbirth) for normal childbirth; (2) For women who have temporarily left their permanent place of residence within the Republic of Kazakhstan, a sheet or certificate of temporary disability for pregnancy and childbirth shall be issued (extended) in the medical organisation where the birth occurred or in the antenatal clinic (office) at the place of observation in accordance with the discharge (exchange card) of the obstetric organisation. (3) In the case of complicated labour or the birth of two or more children, the sheet or certificate of temporary incapacity for work is extended for an additional fourteen calendar days by a medical worker (obstetrician-gynaecologist) or, in his/her absence, by a physician, in conjunction with the head of the department, after the conclusion of the Medical consultative commission at the place of observation in accordance with the discharge of the obstetric health-care organisation. In		

18	such cases, the total duration of prenatal and postnatal leave is one hundred and forty calendar days (seventy calendar days before and seventy calendar days after childbirth). For women residing in areas affected by nuclear tests, in the case of complicated childbirth or the birth of two or more children, the sheet or certificate of temporary incapacity for work is extended for an additional fourteen calendar days, and the total duration of prenatal and postnatal leave is one hundred and eighty-four days (ninety-one calendar days before childbirth and ninety-three calendar days after childbirth); (4) In the case of childbirth between twenty-two and twenty-nine weeks of pregnancy and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, the woman is given a certificate of incapacity for work for seventy calendar days after childbirth. In the case of childbirth at twenty-two to twenty-nine weeks of pregnancy and the birth of a dead foetus or a child with a body weight of five hundred grams or more, who died before seven days of life, the woman is issued a sheet or certificate of temporary disability for fifty-six calendar days after childbirth; (5) Women living in territories affected by nuclear tests, in the event			

	of childbirth at twenty-two to twenty-nine weeks' gestation and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, a certificate of temporary incapacity for work shall be issued for ninety-three calendar days after childbirth. For women residing in territories affected by nuclear tests, in the case of childbirth at twenty-two to twenty-nine weeks of pregnancy and the birth of a dead foetus or a child with a body weight of five hundred grams or more who died before seven days of life, a certificate of temporary incapacity for work shall be issued for seventy-nine calendar days after childbirth; 6) when a woman applies for a temporary disability certificate during pregnancy, maternity leave is calculated cumulatively and is granted in full, regardless of the number of days actually used before the birth. When a woman applies for a temporary disability certificate after childbirth, only the leave after childbirth shall be granted for the duration provided for in this paragraph; 7) if a woman becomes pregnant while on paid annual leave or unpaid leave to care for a child up to the age of three, a temporary disability certificate shall be issued for all days of maternity leave, except in the cases			

provided for in the second part of subparagraph 6) of this paragraph;

8) in case of death of the mother during childbirth or in the postnatal period, a sheet or certificate of temporary incapacity for work shall be issued to the person caring for the new-born;

9) in the case of an operation for artificial termination of pregnancy, a sheet or certificate of temporary incapacity for work shall be issued by a doctor together with the head of the department for the period of stay in the hospital and outpatient department where the operation was performed, and in the case of complications - for the entire period of temporary incapacity for work.

In case of spontaneous abortion (miscarriage), a sheet or certificate of temporary incapacity for work is issued for the entire period of temporary incapacity for work;

10) in the case of embryo transfer surgery, a sheet or certificate of temporary incapacity for work is issued by the medical organisation that performed the surgery from the day of embryo transfer until the pregnancy is established.

Individuals who have adopted a new-born child (children), as well as the biological mother in the case of surrogate motherhood directly from the maternity hospital shall be issued a sheet or certificate of temporary incapacity for work from the day of adoption and

	until the expiry of fifty-six calendar days from the date of birth of the child.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient Support Service and internal expertise and its evaluation according to the following criteria: 1) quality of anamnesis collection, which is assessed according to the following criteria: absence of anamnesis collection; Completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor quality anamnesis collection; 2) completeness and validity of diagnostic tests, which shall be evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or absence of a conclusion based on the results of diagnostic investigations, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; carrying out diagnostic tests with high, unjustified		

	risk for the patient's health, justification of diagnostic tests not included in clinical protocols; carrying out diagnostic tests that are not informative for making a correct diagnosis and that lead to an unjustified increase in treatment time and the cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalisation, investigations conducted at the pre-hospital stage are also taken into account), which shall be assessed according to the following criteria: the diagnosis shall be absent, incomplete or incorrect, shall not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, comorbidities affecting the outcome are not recognised ; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease,		

19	asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) is assessed; 4) timeliness and quality of consultations of specialised specialists, which shall be assessed according to the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was wrong and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria:			

	absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the specifics of the course of the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is assessed by the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to			

	ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which shall be assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care provided.		
20	Availability of documentation on compliance with the requirements for the guaranteed volume of free medical care		
	Availability of documentation on compliance with the requirements of surgical (abdominal, thoracic, coloproctological) care to patients at the outpatient and polyclinic level 1) Presence of records by a doctor in the speciality " Therapy (adolescent therapy, dietetics)", " Emergency and urgent medical care", "General medical practice (family medicine)" when a patient applies to a health care organisation providing primary health care with complaints and symptoms		

21		of surgical nature, referrals for patient consultation to profile specialists. 2) Whether indications for surgery, assessment of the scope of surgical intervention, type of anaesthesia, risks of intra- and post-operative complications, obtaining the patient's written consent to surgery have been determined in the case of surgical treatment at the outpatient and polyclinic level (in personnel management organisations and inpatient substitute care). 3) Whether a specialised specialist of the outpatient clinic monitors the condition of patients discharged from the hospital in the postoperative period. 4) In case of prolonged treatment of patients after surgical intervention, the profile specialist shall consult with doctors of medical control commissions and, based on their conclusions, refer patients to medical and social expert assessment (hereinafter referred to as the SEA) for the purpose of primary examination and (or) re-examination (re-examination) to determine temporary (up to 1 year) and permanent disability). 5) Compliance with the requirement for a profile specialist of a polyclinic (number district, district, city), clinical diagnostic department/centre in case of suspicion and (or) establishment of a diagnosis of acute surgical pathology to ensure that the		

	patient is called and transported by an ambulance brigade to a hospital with round-the-clock medical supervision, providing urgent surgical care; in case of unstable hemodynamics and life-threatening condition of the patient - to the nearest hospital 6) Compliance with the requirements of temporary incapacity for work expertise		
22	Availability of documentation on compliance with the requirements of primary health care organisations for dynamic monitoring of individuals with chronic diseases, compliance with the frequency and timing of monitoring, mandatory minimum and frequency of diagnostic tests		
23	Availability of documentation on compliance with the requirements for active home visits by primary health care workers		
	Availability of documentation on compliance with the requirements for paediatric care: 1) counselling, diagnostic, therapeutic and preventive care, dynamic monitoring; 2) patronages and active visits to pregnant women, new-borns and young children according to the universal-progressive model of the patronage service; (3) Planning, organisation and implementation of		

24	vaccinations in accordance with preventive vaccination schedules; (4) Referral of children for consultations with specialised specialists when indicated; (5) Detection of acute and chronic diseases and timely implementation of emergency and planned treatment measures; (6) Referral of children to 24-hour inpatient care, day care and home care, if indicated; (7) Dynamic monitoring, treatment and rehabilitation of children with chronic diseases on the dispensary register; (8) Restorative treatment and medical rehabilitation of children; (9) Screening of new-borns and young children; (10) Organisation of children's health improvement before they enter preschool or school institutions; (11) Information work with parents and family members or legal representatives on issues of rational nutrition, prevention of childhood diseases and the development of a healthy lifestyle.		
	Availability of documentation on compliance with the requirements for traumatological and orthopaedic care at the outpatient and polyclinic level 1) assessment by a traumatologist of the patient's general condition, his/her traumatological and orthopaedic status,		

25		provision of medical care in an emergency, additional laboratory and instrumental tests to clarify the diagnosis and, if medically indicated in cases requiring medical care in inpatient settings, referral of the patient to the appropriate departments where specialised medical care in the traumatological and orthopaedic profile is provided. 2) In the absence of medical indications for hospitalisation of a patient with Cabinet of medical statistics injuries, consultation on further observation and treatment in outpatient conditions at the place of attachment. 3) Medical care on traumatological and orthopaedic profile in primary health care organisations is provided by surgeons, traumatologists and orthopaedic doctors. 4) availability of traumatology and orthopaedics rooms, trauma centres and carrying out: examination and assessment of the severity of the patient's condition, his/her traumatological and orthopaedic status, additional laboratory and instrumental tests to clarify the diagnosis and treatment (pain relief, primary surgical treatment of wounds, closed repositioning of bone fragments, immobilisation). 5) carrying out expertise of temporary incapacity for work		

	6) availability of the Medical consultative commission and referral of patients with persistent signs of musculoskeletal system dysfunction and Cabinet of medical statistics to the medical and social expert commission;		
26	Availability of documentation on compliance with the requirements of neurological care at outpatient and polyclinic level 1) Neurological care for patients with neurological diseases shall be provided upon referral from a primary care physician or other specialised specialist within the framework of the State health care system . In the absence of a referral from a primary care physician or other specialised specialist, as well as in the case of patients' own initiative, Personnel management is provided on a fee-for-service basis. 2) A primary care physician or other specialised specialist shall follow up the patient after receiving a diagnostic and consultative report in accordance with the recommendations of the neurologist who provided the Personnel management		
	Availability of documentation of compliance with nephrological care, which includes: 1) examination by a doctor, identification of signs of kidney damage and clinical and diagnostic tests according to positivity		

	coefficient to determine the stage, etiology and degree of disease activity; 2) referral of the patient for counselling and diagnostic assistance with an extract from the medical card of an outpatient in form № 097/y , with data entry into the medical information system (hereinafter referred to as the MIS); 3) formation of risk groups for the development, prevention of progression and development of complications of chronic kidney disease depending on the stage and nosological forms, as well as registration and dynamic monitoring of patients with kidney disease are carried out by primary health care specialists, taking into account the recommendations of nephrologists on positivity coefficient; 4) selection and referral for hospitalisation in the medical department for specialised medical care and high-tech medical care, taking into account the recommendations of nephrologists and Multidisciplinary team on positivity coefficient; 5) dynamic monitoring of patients with kidney damage of various genesis, including in the postoperative (posttransplantation) period, including monitoring of disease activity, control and correction of immunosuppressive therapy; 6) medical rehabilitation of patients with nephrological diseases, chronic kidney disease and Acute renal		

27	failure, including those receiving dialysis therapy and those who underwent surgery after kidney transplantation (including monitoring of immunosuppressive therapy drug concentrations, prevention and timely detection of infectious complications); 7) organisation and monitoring of provision of patients with kidney diseases (including patients on renal replacement therapy) with medicines for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions)". 8) examination of temporary incapacity for work (9) Referral for medical and social expert assessment to determine and establish disability 10) registration and regular data entry of patients with chronic kidney disease stage 1-5, Acute renal failure of all stages according to the international classification of Acute renal failure according to RIFLE: Risk, Injury, Failure, Lost, End Stage Renal Disease into the IS of the medical organisation with indication of the stage of chronic kidney disease for monitoring, timely start of renal replacement therapy and ensuring continuity of the patient's route. If the IS is not available or unavailable, patient registration is done in the Electronic chronic kidney disease registry.			

	Registration of patients with chronic kidney disease stages 1 to 3a shall be carried out annually by general practitioners (family physicians), district general practitioners, paediatricians at the renal replacement therapy level. Registration of patients with chronic kidney disease stages 3b-5 shall be carried out by nephrologists of the polyclinic, Cabinet, nephrology centre.		
	Availability of documentation on compliance with the requirements of neurosurgical care in outpatient settings 1) renal replacement therapy physician: -when patients present with complaints and symptoms of neurosurgical diseases and injuries of the central and peripheral nervous system, prescribes general clinical and radiological examinations (as indicated) and refers them to the neurosurgeon of the health care organisation providing medical care at the secondary level to clarify the diagnosis and receive consultative and diagnostic assistance. The referral shall be made electronically in medical information systems; - perform dynamic follow-up of patients with a diagnosis of neurosurgical diseases according to the positivity coefficient and recommendations of the neurosurgeon; - refer for hospitalisation when indicated. 2) Neurosurgical care in outpatient conditions at the		

28	secondary level shall be provided in the form of consultative and diagnostic care and shall include: 1) examination by a neurosurgeon; 2) laboratory and instrumental examination of the patient in order to make a diagnosis of neurosurgical diseases and injuries of the central and peripheral nervous system, differential diagnosis; 3) selection and prescription of treatment for the detected disease according to the positivity coefficient; 4) referral for hospitalisation on emergency indications to provide specialised medical care, including with the use of high-tech medical services in inpatient conditions; 5) referral for planned hospitalisation for the provision of specialised medical care, including with the use of high-tech medical services in inpatient substitution and inpatient settings; 6) expert assessment of temporary incapacity for work, issuing a temporary incapacity certificate or certificate of temporary incapacity for work		
	Availability of documentation on compliance with the requirements of neurological care at outpatient and polyclinic level 1) Neurological care for patients with neurological diseases shall be provided upon referral from a primary care physician or		

29	other specialised specialist within the framework of the State Health Care System. In the absence of a referral from a primary care physician or other specialised specialist, as well as in the case of patients' own initiative, personnel management shall be provided on a fee-for-service basis. 2) A primary care physician or other specialised specialist shall follow up the patient after receiving a diagnostic and consultative report in accordance with the recommendations of the neurologist who provided the personnel administration.		
30	Reasoned execution of the notification of the expert conclusion of medical and social expertise, form № 031/e (availability of data for a comprehensive assessment of the state of the organism and the degree of restriction of life activity)		

Official(s) _____ _____
position signature

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surname, first name, patronymic (if any)
Head of the entity of control _____ _____
position signature

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surname, first name, patronymic (if any)

Annex 4
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ RK MH-32

and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 4 - in the wording of the joint order of the Minister of Healthcare of the RK dated 29.05.2023 № 90 and the Minister of National Economy of the RK dated 29.05.2023 № 91 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

in the area of quality of health care delivery

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in accordance with Article 138

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Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities), obstetrical and (or) in-patient organisations,
having maternity wards and departments of pathology of new-borns
name of a homogeneous group of control entities (facilities)

_____

State body that ordered the inspection/preventive control
with a visit to the entity (facility) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the entity (facility) of control

(facility)) of control

_____

_____ №, date

Name of the entity (facility) of control _____

_____

(Individual identification number), business identification number
of the entity (facility) of control _____

_____

Address of residence _____

_____

№	List of requirements	Complies with the requirements	Does not comply with the requirements
1	2	3	4

1	Availability of an opinion on the compliance of a healthcare entity to provide high-tech medical care when the organisation provides high-tech services, including in vitro fertilisation		
2	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free-of-charge basis		
3	Presence of written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures		
	Availability of supporting documentation (emergency medical team call card form № 085/y, admission and refusal of hospitalisation log, inpatient medical card form № 001/y) that the stay of the emergency medical team or emergency medical care department in the hospital's emergency room shall not exceed 10 minutes (the time for transferring the patient to the emergency room doctor) from the moment of its arrival at the hospital, except in cases of emergency medical care in emergency situations. After the transfer of the patient to the inpatient admission department by the ambulance crews or the ambulance department in the organisation of primary health care, the nurse shall distribute the incoming		

4	patients (medical triage according to the triage system) into groups, based on the priority of emergency medical care. Medical triage according to the triage system (hereinafter referred to as medical triage) shall be carried out continuously and in succession. and successive. Upon completion of the assessment, patients shall be marked with a colour of one of the triage categories in the form of a special-coloured tag or coloured tape. According to the medical triage, there shall be 3 groups of patients: The first group (red zone) - patients whose condition shall be immediately life-threatening or at high risk of deterioration and who require emergency medical care; the second group (yellow zone) - patients whose condition shall pose a potential threat to health or may progress with the development of a situation requiring emergency medical care; third group (green zone) - patients whose condition shall not pose an immediate threat to life and health and shall not require hospitalisation. Presence of a record in the medical documentation on identification of the patient by medical triage groups according to the triage system.		
	Availability of a medical report issued by the doctor of the emergency room with a written justification		

5	of the refusal in the absence of indications for hospitalisation in a health care organisation. The presence of an asset sent by the emergency room nurse to the renal replacement therapy organisation at the patient's place of attachment		
6	Availability of supporting records in medical documentation on indications for hospitalisation: The need to provide pre-hospital, qualified, specialised medical care, including the use of high-tech medical services, with round-the-clock medical supervision of patients: 1) on a planned basis - by referral of renal replacement therapy specialists or other health care organisation: 2) on emergency indications (including weekends and public holidays) - regardless of the availability of a referral		
7	There shall be records in the medical records of the examination of heavy patients by the head of the department on the day of admission, and daily thereafter. Patients in a moderately severe condition shall be examined at least once a week. Presence of the results of the patient's examination recorded in the medical record with recommendations on further tactics of patient management with obligatory identification of the medical worker making the entries		

8	Presence of records in the medical records confirming the daily examination of inpatients by the attending physician, except for weekends and public holidays. Appropriate entries in the medical records for examination and prescription of additional diagnostic and therapeutic manipulations by the doctor on duty		
9	Justification in the medical record for dynamic assessment of the patient's condition according to clinical protocols of diagnosis and treatment when additional and repeated tests performed before hospitalisation in primary health care or other health care organisations shall be identified for medical reasons		
	Availability of supporting documentation that the following requirements shall have been met when issuing a maternity leave and certificate of temporary disability: - A sheet or certificate of temporary disability for pregnancy and childbirth shall be issued by a medical worker (obstetrician-gynaecologist) , or in his/her absence, by a physician, together with the head of the department after the conclusion of the Medical consultative commission from thirty weeks of pregnancy for a period of one hundred and twenty-six calendar days (seventy calendar days before childbirth and fifty-six calendar days after childbirth) in the case of normal childbirth.		

	For women residing in territories affected by nuclear tests, a sheet or certificate of incapacity for pregnancy and childbirth shall be issued from twenty-seven weeks of pregnancy for a duration of one hundred and seventy calendar days (ninety-one calendar days before childbirth and seventy-nine calendar days after childbirth) for normal childbirth; (2) For women who have temporarily left their permanent place of residence within the Republic of Kazakhstan, a sheet or certificate of temporary disability for pregnancy and childbirth shall be issued (extended) in the medical organisation where the birth occurred or in the antenatal clinic (office) at the place of observation in accordance with the discharge (exchange card) of the obstetric organisation. (3) In the case of complicated labour or the birth of two or more children, the sheet or certificate of temporary incapacity for work is extended for an additional fourteen calendar days by a medical worker (obstetrician-gynaecologist) or, in his/her absence, by a physician, in conjunction with the head of the department, after the conclusion of the Medical consultative commission at the place of observation in accordance with the discharge of the obstetric health-care organisation. In such cases, the total duration of prenatal and			

10		postnatal leave is one hundred and forty calendar days (seventy calendar days before and seventy calendar days after childbirth). For women residing in areas affected by nuclear tests, in the case of complicated childbirth or the birth of two or more children, the sheet or certificate of temporary incapacity for work is extended for an additional fourteen calendar days, and the total duration of prenatal and postnatal leave i one hundred and eighty-four days (ninety-one calendar days before childbirth and ninety-three calendar days after childbirth); (4) In the case of childbirth between twenty-two and twenty-nine weeks of pregnancy and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, the woman shall be given a certificate of incapacity for work for seventy calendar days after childbirth. In the case of childbirth at twenty-two to twenty-nine weeks of pregnancy and the birth of a dead foetus or a child with a body weight of five hundred grams or more, who died before seven days of life, the woman shall be issued a sheet or certificate of temporary disability for fifty-six calendar days after childbirth; (5) Women living in territories affected by nuclear tests, in the event of childbirth at twenty-two to twenty-nine weeks'		

	gestation and the birth of a child with a body weight of five hundred grams or more who has lived for more than seven days, a certificate of temporary incapacity for work shall be issued for ninety-three calendar days after childbirth. For women residing in territories affected by nuclear tests, in the case of childbirth at twenty-two to twenty-nine weeks of pregnancy and the birth of a dead foetus or a child with a body weight of five hundred grams or more who died before seven days of life, a certificate of temporary incapacity for work shall be issued for seventy-nine calendar days after childbirth; 6) when a woman applies for a temporary disability certificate during pregnancy, maternity leave shall be calculated cumulatively and shall be granted in full, regardless of the number of days actually used before the birth. When a woman applies for a temporary disability certificate after childbirth, only the leave after childbirth shall be granted for the duration provided for in this paragraph; 7) if a woman becomes pregnant while on paid annual leave or unpaid leave to care for a child up to the age of three, a temporary disability certificate shall be issued for all days of maternity leave, except in the cases provided for in the second part of subparagraph 6) of this paragraph;		

	8) in case of death of the mother during childbirth or in the postnatal period, a sheet or certificate of temporary incapacity for work shall be issued to the person caring for the new-born; 9) In the case of an operation for induced termination of pregnancy, a sheet or certificate of temporary incapacity for work shall be issued by a doctor in conjunction with the head of the department for the period of stay in the hospital and outpatient department where the operation has been performed, and in the case of a complication - for the entire period of temporary incapacity for work. In case of spontaneous abortion (miscarriage), a sheet or certificate of temporary incapacity for work is issued for the entire period of temporary incapacity for work; 10) in the case of embryo transfer surgery, a sheet or certificate of temporary incapacity for work is issued by the medical organisation that performed the surgery from the day of embryo transfer until the pregnancy is established. Individuals who have adopted a new-born child (children), as well as the biological mother in the case of surrogate motherhood directly from the maternity hospital shall be issued a sheet or certificate of temporary incapacity for work from the day of adoption and until the expiry of fifty-six calendar days from the date of birth of the child.		

	Availability of medical documentation on compliance with the following requirements during the examination of temporary incapacity for work, issuance of certificates and certificates of temporary incapacity for work (form № 001/y " Medical card of inpatient patient", form № 052/y " Medical card of outpatient patient", stubs of certificates of temporary incapacity for work of patients, form № 025/y " Journal for recording conclusions of medical advisory commission", form № 029/y "Book of registration of certificates of temporary inability to work", form № 037/y " Certificate №_____ on temporary disability of a student, college student, vocational school, sickness, quarantine and other reasons for absence of a child attending school, pre-school organisation (underline)", form № 038/y "Certificate №_____ on temporary disability" and others): 1) the presence of an examination of the person and the recording of data on his/her state of health in the medical card of an outpatient (inpatient) patient, justifying the need for temporary exemption from work;1) examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient) patient justifying the need for temporary exemption from work; 2) issuance of a sheet and certificate of temporary			

11		incapacity for work on the day of discharge of individuals under inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing of the sheet and certificate of temporary incapacity for work on the date of discharge from the hospital if the individuals' working capacity has been fully restored; 4) extension of the temporary disability certificate and certificate of temporary incapacity for work for a period of time, taking into account the time necessary for the person to visit a medical worker at the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Individuals who received treatment outside the region of residence shall be taken into account the time required to arrive at the place of his/her permanent residence (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and a certificate of temporary incapacity for work to individuals suffering from mental illness in the event of failure to apply to a medical organisation in a timely manner for the past days, upon the conclusion of the medical advisory		

	commission of a psychoneurological dispensary or a medical officer (psychiatrist) in conjunction with the head of the medical organisation ; (7) issuance of a sheet and a certificate of temporary incapacity for work to individuals sent by court decision for forensic medical or forensic psychiatric examination and recognised as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work at the same time to a person who combines training with work.		
12	Availability of informed written consent of the patient for transfusion of blood components		
13	There shall be records in the medical documentation on compliance with the requirements for transfusion of blood components. Before transfusion of blood components, the recipient shall be examined for markers of haemotransmissible infections HIV, hepatitis B and C, and after the end of treatment the discharge epicrisis shall indicate the need for repeated examination for HIV and hepatitis B and C at the place of residence. HIV testing of recipients as part of the guaranteed scope of free medical care shall be carried out in state health		

	care organisations engaged in HIV prevention activities		
	There shall be documentation of compliance with the following actions when performing pathological autopsies: 1) conducting a pathological anatomical autopsy of cadavers after the physicians have ascertained biological death, after providing the medical record of an inpatient patient or the medical record of an outpatient patient with a written order from the chief physician or his deputy for the medical (treatment) part of the health care organisation to send for a pathological anatomical autopsy; 2) transfer of the medical record of an inpatient or medical record of an outpatient with the pathological anatomical diagnosis entered into it to the medical archive of the health care organisation no later than ten working days after the pathological anatomical autopsy; 3) conducting clinical and pathological anatomical examination in cases of patient deaths in health care organisations; 4) organisation of virological (immunofluorescence) and bacteriological examination of autopsy materials in cases of suspected infectious diseases by the chief physician and head of the pathology department; 5) transfer to pathological anatomical bureaus,		

14		centralised pathological anatomical departments and pathological anatomical departments of medical records of inpatients for all deceased patients for the previous day not later than 10 a.m. of the day following the establishment of the fact of death 6) registration of the results of pathological anatomical autopsy in the form of pathological anatomical diagnosis (pathological anatomical diagnosis includes: main disease, complication of the main disease, concomitant disease, combined main disease); 7) execution of: - medical certificate of death (preliminary, final) by a doctor in the speciality " pathological anatomy (adult, paediatric)" on the day of the pathological anatomical autopsy; - medical certificate of perinatal death (preliminary, final) by a doctor specialising in " pathological anatomy (adult, child)" on the day of the pathological anatomical autopsy; 8) registration of the autopsy results in the form of a protocol of pathological anatomical examination; 9) written notification to the forensic investigative authorities to resolve the issue of transferring the corpse for forensic medical examination if signs of violent death are detected, and termination of the pathological and anatomical examination of the corpse;		

10) written notification of the doctor in the speciality "pathological anatomy (adult, child)" in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service bodies immediately after their detection;

11) conducting a pathological and anatomical examination of the placenta:

- in all diseases of new-borns detected at the time of birth;
- in cases suspected of haemolytic disease of new-borns;
- in cases of early discharge of waters and dirty waters;
- in cases of maternal illness with high fever in the last trimester of pregnancy;
- if there is an obvious abnormality in the development or attachment of the placenta;
- suspected congenital anomalies of the foetus;
- in cases of pre-eclampsia and eclampsia.

12) mandatory registration of a foetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference);

13) the establishment of pathological anatomical autopsy, depending on the complexity into the following categories:

- first category;

	- second category; - third category; - fourth category; 14) establishment of the category of pathological anatomy (adult, paediatric) by a doctor in the specialty "pathological anatomy (adult, paediatric)" of the category of pathological anatomical autopsy and the reason for the divergence of diagnoses when the final clinical and pathological anatomical diagnoses diverge; 15) detailed analysis with the definition of the profile and categories of iatrogenic pathology in all cases of iatrogenic pathology identified as a result of pathological anatomical autopsy		
	Availability of supporting documentation on compliance with the following requirements in the organisation of obstetric and gynaecological care at the outpatient and polyclinic level: 1) ensuring early registration of pregnant women, on the day of their application to the medical organisation, without taking into account the insured status; 2) home health care for pregnant women, maternity patients, gynaecological patients and the group of women of fertile age (hereinafter referred to as " WFA") at social risk, universal (compulsory) patronage observation of pregnant women up to 12 weeks and 32 weeks of pregnancy		

15	(3) Dispensary monitoring of pregnant women for the prevention and early detection of complications of pregnancy, childbirth and the postnatal period, with the selection of women "at risk"; (4) Prenatal screening - a comprehensive examination of pregnant women to identify the risk group for chromosomal abnormalities and congenital malformations of the intrauterine foetus; (5) Identification of pregnant women in need of timely hospitalisation in day hospitals and pregnancy pathology departments of inpatient medical institutions providing obstetric and gynaecological care and specialised medical institutions with extragenital pathology, in accordance with the principles of regionalisation of perinatal care; 6) referring pregnant women, women in labour and maternity for specialised care with medical supervision, including the use of high-tech medical services, to medical organisations at the national level; (7) Conducting prenatal education for pregnant women in preparation for childbirth, including partner births, informing pregnant women about warning signs, effective perinatal technologies, principles of safe motherhood, breastfeeding and perinatal care;			

	8) patronage of pregnant women and maternity women, as indicated; (9) Counselling and provision of services on family planning and reproductive health care; (10) Prevention and detection of sexually transmitted infections for referral to specialised specialists; (11) Examination of women of childbearing age , with the prescription, if necessary, of in-depth examinations using additional methods and the involvement of specialised specialists for the timely detection of extragenital and gynaecological pathology and their registration on the dispensary register; (12) Organising and conducting preventive examinations of the female population for the early detection of extragenital diseases; (13) Examination and treatment of gynaecological patients using modern medical technologies; 14) Dispensary examinations of gynaecological patients, including rehabilitation and sanatorium-resort treatment ; 15) performance of minor gynaecological operations using modern medical technologies; 16) Expert assessment of temporary disability for pregnancy, childbirth and gynaecological diseases, determination of the need for and timing of temporary or permanent transfer of an employee for		

	health reasons to another job, referral for medical and social expert assessment of women with signs of permanent loss of working capacity; 17) double HIV testing during pregnancy with the patient's informed consent and data recording.		
16	The use of sex cells, tissues of reproductive organs by a recipient who is (are) married (spouse) shall be carried out with the written consent of both spouses.		
17	Availability of supporting documentation on the birth of 10 (ten) children from one donor 6 which is the basis for termination of the use of this donor for recipients.		
18	Availability of supporting documentation on donation of germ cells, tissues of reproductive organs from the donor under the following conditions: 1) the donor freely and knowingly expresses informed consent in writing for the donation of germ cells, tissues of reproductive organs; 2) the oocyte donor is informed in writing about complications for her health in connection with the forthcoming surgical intervention; 3) the donor undergoes a medical and genetic examination and there is an opinion of a reproductologist or uroandrologist on the possibility of donation of germ cells, tissues of reproductive organs.		
	Oocyte donation shall be carried out with the donor's written informed consent		

19	for superovulation induction or in a natural cycle in compliance with the requirements for donors of germ cells, tissues of reproductive organs, and oocyte donors undergo medical and genetic examinations.		
20	Availability of supporting documentation on in vitro fertilisation (hereinafter referred to as IVF) using donor oocytes shall be carried out according to the indications: 1. absence of oocytes due to natural menopause. 2. Premature ovarian exhaustion syndrome, resistant ovaries syndrome, condition after ovarioectomy, radiotherapy or chemotherapy. 3. 3. anomalies of genital development, absence of ovaries. 4. Functional inferiority of oocytes in women with sex-linked hereditary diseases. 5. Unsuccessful repeated attempts of in vitro fertilisation with insufficient response of ovaries to induction of superovulation, repeated receipt of embryos of poor quality, transfer of which did not lead to pregnancy. 6. Rhesus - conflict between male and female. 7. Anomalies in the karyotype of the woman. 8. Twin (blood) marriages with birth of children with malformations. 9. Somatic diseases in which ovarian stimulation is contraindicated.		
	Availability of supporting documentation on work with donors by an		

21	obstetrician-gynaecologist (reproductologist), medical examination of the donor before each procedure of donor material collection, controls the timeliness and results of laboratory tests in accordance with the calendar plan of examination.		
22	Availability of supporting documentation on oocyte donation according to the following algorithm: 1) selection of an oocyte donor (according to individual selection criteria and recipient's preferences); 2) examination of the donor and recipient; 3) synchronisation of menstrual cycles of the donor and recipient with the help of medications in case of embryo transfer into the uterine cavity of the recipient in the donor's stimulated cycle; 4) in the procedure of transfer of cryopreserved embryos, no synchronisation of cycles is performed; 5) the procedure of oocyte retrieval for use by recipients or cryopreservation for the germ cell bank.		
23	Availability of supporting documentation of compliance with the requirements for refusal of IVF using donor oocytes for the following contraindications: 1. Somatic and mental illnesses that are contraindications for pregnancy and delivery. 2. Congenital malformations or acquired deformations of the uterine		

	cavity, in which it is impossible to implant embryos or carry a pregnancy. 3. 3. ovarian tumours. 4. Benign uterine tumours requiring surgical treatment . 5. Acute inflammatory diseases of any localisation . 6. Malignant neoplasms of any localisation		
24	Availability of supporting documentation on the use of donor sperm in assisted reproductive methods and technologies (hereinafter referred to as the ART). Sexual abstinence shall be required for 3-5 days before sperm donation. Sperm shall be obtained by masturbation. The ejaculate shall be collected in a special sterile, pre-labelled container. This procedure shall be carried out in a special room with a separate entrance, appropriate interior, sanitary unit with a washbasin. In the absence of donor sperm in the medical organisation, or at the patient's request, donor sperm from other organisations that have a donor sperm bank is used. Only cryopreserved donor sperm shall be used after repeated (6 months after cryopreservation) negative results of HIV, syphilis and hepatitis B and C tests. The use of cryopreserved (thawed) sperm shall ensure : 1) carrying out measures to prevent the transmission of HIV, syphilis, hepatitis and other sexually transmitted infections;		

	2) excluding the possibility of meeting between the donor and the recipient. Requirements for donor semen: 1) volume of ejaculate more than 1.5 millilitres (hereinafter - ml); 2) concentration of spermatozoa in 1 ml of ejaculate is 15 million or more; total number of spermatozoa in the whole ejaculate is 22.5 million or more; 3) the proportion of progressively motile forms (A+B) 32% or more; 4) the proportion of morphologically normal forms 4% or more (according to strict Krueger criteria 14% or more); 5) cryotolerance; 6) test determining immunocompetent bodies of the sperm surface (IDA-test) - as indicated.			
25	IVF with the use of donor sperm shall be performed when indicated 1. azoospermia, severe oligoasthenozoospermia, necrospermia, akinozoospermia, globulozoospermia. 2. Condition after radiotherapy or chemotherapy. 3. developmental anomalies of the reproductive system. 4. Absence or functional inferiority of spermatozoa in men with sex-linked hereditary diseases. 5. Unsuccessful repeated attempts of in vitro fertilisation with high DNA (deoxyribonucleic acid) fragmentation index of spermatozoa and repeated receipt of embryos of poor			

	quality, the transfer of which did not lead to pregnancy. 6. Rhesus - conflict between male and female. 7. Anomalies in the male karyotype.		
26	The individual donor card shall be filled out and coded by a doctor. The coding scheme shall be free . The donor's application and his/her individual card shall be kept in a safe as documents for official use.		
27	Availability of supporting documentation on work with donors by a doctor-uroandrologist and a doctor-embryologist. The doctor organises medical examinations of the donor, controls the timeliness and results of laboratory tests in accordance with the calendar plan of examination. The doctor-embryologist shall perform cryopreservation and thawing of sperm, shall assess the quality of sperm before and after cryopreservation, shall provide the necessary storage regime for sperm, shall keep records of the material. Donor sperm shall be registered in the donor sperm receipt log and in the donor sperm receipt and consumption card.		
	Availability of supporting documentation of compliance, that the embryo donors shall be IVF patients who have unused cryopreserved embryos left in the bank. Upon free decision and written informed consent of the patients, these		

28	embryos shall be disposed of or donated to a medical organisation. Embryos transferred to the medical organisation shall be used for donation free of charge to infertile married couples, women (recipients) who shall not be married (matrimonial). Embryos for donation shall also be obtained as a result of fertilisation of donor oocytes with donor sperm. Patients shall be informed that the outcome of the procedure using leftover cryopreserved embryos from IVF patients shall be lower than using embryos derived from donor germ cells. Recipients shall be provided with a phenotypic profile of the donors. IVF using donor embryos shall be performed according to the following indications: 1. Lack of oocytes. 2. Unfavourable medical and genetic prognosis. 3. Repeated receipt (more than three times) of embryos of poor quality, the transfer of which did not lead to pregnancy. 4. Failure to obtain or use sperm from a married couple.		
29	Availability of supporting documentation of compliance with assisted reproductive techniques and technologies		
	Availability of supporting documentation of the following functions in the provision of pre-hospital care to women during and outside pregnancy by paramedics (obstetricians, paramedics, nurses/nurses):		

30	1) self-admission and medical examination to determine the patient's health status, identify diseases and complications of pregnancy 2) entering data into the " Register of pregnant women and women of childbearing age" subsystem of the electronic portal "Register of the attached population" for the purpose of automated maintenance of groups of pregnant women and women of childbearing age (hereinafter referred to as " PAF") and monitoring of health indicators of pregnant women and PAFs ; 3) Provision of emergency and urgent pre-hospital medical care to pregnant women, maternity women and women of fertile age for conditions threatening the life and health of women according to clinical protocols for diagnosis and treatment; 4) dynamic monitoring of pregnant women with chronic diseases together with district doctors and specialised specialists; 5) fulfilment of prescriptions of obstetrician-gynaecologist; 6) management of physiological pregnancy and patronage of pregnant and maternity women with timely provision of referrals and recommendations on clinical protocols of diagnostics and treatment; 7) home medical care for pregnant women, maternity patients, gynaecological patients and social risk groups;			

	8) preventive medical examination of women for early detection of pre-tumour and cancerous diseases of the female genital organs and other localisations (skin, mammary glands); (9) Conducting medical nursing examinations of women of all age groups who seek medical assistance; (10) Participation in screening and preventive examinations for the detection of diseases		
	Availability of supporting documentation on compliance with the following requirements when organising obstetric and gynaecological care at the inpatient level: 1) provision of inpatient consultative, diagnostic, therapeutic, preventive and rehabilitative care to pregnant women, women in labour, women in labour and new-borns; 2) joint examination of the attending physician with the head of the department upon admission of pregnant women up to 36 weeks of pregnancy, suffering from chronic diseases, requiring treatment in specialised departments of multidisciplinary hospitals, to assess the severity of the disease, the course of pregnancy and treatment tactics. 3) drawing up a plan for the management of pregnancy, childbirth and the postnatal period, taking into account an individual approach;		

31		4) management of pregnancy, labour and postnatal period according to clinical protocols of diagnostics and treatment, as well as according to the management plan; 5) counselling pregnant women, women in labour and maternity, monitoring compliance with the level of medical care; 6) carrying out rehabilitation measures for mothers and new-borns, including care for premature new-borns; 7) consultations on the provision of medical assistance to pregnant women, women in labour, maternity and new-borns using telecommunication systems; 8) Expertise on temporary incapacity for work, issuance of certificates and certificates of temporary incapacity for work for maternity and gynaecological patients; (9) Providing resuscitation care and intensive care to mothers and new-borns, including those with low and extremely low body weight; 10) providing medical and psychological assistance to women; 11) notification of medical organisations of a higher level of regionalisation of perinatal care and local public health authorities in case of detection of a critical condition of a pregnant woman, a woman in labour or a woman in maternity during admission or stay in hospital; 12) adherence to the notification scheme in case		

	of critical situations in women; 13) transportation of pregnant women, women in critical condition to the third level of perinatal care, to regional and republican health care organisations is carried out by decision of the Concilium of doctors with the participation of specialists of the medical team of medical aviation after recovery of haemodynamics and stabilisation of vital functions with notification of the receiving medical organisation; 14) in case of non-transportable condition of pregnant women, women in labour, women in maternity, to call qualified specialists "on their own", to provide a complex of primary resuscitation care in case of emergencies, to diagnose threatening conditions in mother and foetus, to decide on delivery, to conduct intensive and supportive therapy until transfer to a higher level		
Provision of medical care to new-borns			
	Availability of supporting documentation on compliance with the following requirements when organising medical care for new-borns at the inpatient level: 1) provision of medical care to new-borns according to the levels of regionalisation of perinatal care depending on the indications; 2) the presence in the structure of the first level of regionalisation of perinatal care: individual		

32	maternity wards, wards for the joint stay of mother and child, vaccination rooms, intensive care wards for new-borns, as well as the position of a doctor in the specialty of paediatrics (neonatology) and a round-the-clock post of a neonatal nurse; 3) The availability in hospitals of the second level of regionalisation of neonatal resuscitation and intensive care wards with a full set of resuscitation equipment, artificial ventilation devices with different ventilation modes (constant positive pressure in the respiratory tract), cuvéses, a clinical and diagnostic laboratory, and a 24-hour post (a neonatologist and a paediatric nurse) as stipulated in the staff schedule; 4) Compliance with the following requirements in hospitals of the third level of regionalisation of perinatal care: Availability of a round-the-clock neonatal post, clinical, biochemical and bacteriological laboratory, intensive care unit for women and new-borns, as well as neonatal pathology and prematurity nursing unit of joint stay with the mother. Availability of a neonatal intensive care unit, a neonatal pathology unit and a premature infant care unit equipped with modern therapeutic and diagnostic equipment, medicines, a 24 -hour post (doctor and nurse) and an express laboratory.			

	5) Observance of the following requirements in the first level hospitals to the sick new-born: primary resuscitation care; intensive and supportive therapy; oxygen therapy; invasive or non-invasive respiratory therapy; phototherapy; therapeutic hypothermia; infusion therapy and/or parenteral nutrition; treatment according to clinical protocols for diagnosis and treatment. Compliance with the following requirements in second-level hospitals for the sick neonate: Provision of primary resuscitation care to the new-born and stabilisation of the condition, nursing premature babies with a gestational age of more than 34 weeks; catheterisation of central veins and peripheral vessels; detection and treatment of congenital malformations, intrauterine developmental delay, neonatal hypoglycaemia, hyperbilirubinaemia, neonatal sepsis, central nervous system damage, respiratory distress syndrome, pneumothorax, necrotizing enterocolitis and other pathological conditions of the neonatal period; intensive care, including correction of vital functions (respiratory, cardiovascular, metabolic disorders), invasive and non-invasive respiratory therapy, infusion therapy and parenteral nutrition;			

	If highly specialised care is required, the degree of readiness to be transported with the mother to a third-level obstetrics organisation or a national institution is determined.		
33	Availability of supporting documentation on compliance with the requirements for the provision of medical care to new-borns in third-level medical organisations: 1) provision of primary resuscitation to new-borns and care of new-borns 2) intensive and supportive therapy: respiratory therapy , catheterisation of central veins and peripheral vessels, therapeutic hypothermia, parenteral nutrition, nursing premature infants; 3) diagnosis and treatment of congenital malformations, delayed intrauterine development of the foetus (low birth weight by gestational age), neonatal hypoglycaemia, neonatal sepsis, respiratory distress syndrome, hyperbilirubinaemia, necrotising enterocolitis, pneumothorax, bronchopulmonary dysplasia, persistent pulmonary hypertension of new-borns, perinatal lesions of the central nervous system and other pathological conditions of the neonatal period; 4) carrying out intensive and supportive therapy, therapeutic hypothermia, parenteral nutrition; 5) invasive and non-invasive respiratory therapy;		

	6) nursing premature babies; (7) Providing round-the-clock consultative, therapeutic and diagnostic assistance to specialists at the first and second levels of regionalisation, and providing emergency and urgent medical assistance with travel to a medical organisation.		
34	Supporting documentation of compliance with requirements to provide a healthy new-born with basic care, including prevention of hypothermia with "heat chain", skin-to-skin or skin-to-skin contact with the mother, early initiation of breastfeeding within the first hour (if the infant shows signs of readiness), and prevention of hospital-acquired infections.		
35	Availability of supporting documentation of compliance with the requirements of healthy new-born anthropometry, full examination and other measures 2 hours after delivery		
36	Availability of supporting documentation on compliance with the requirements of emergency medical care in case of detection of disorders of the new-born's condition, transfer to the intensive care ward or neonatal intensive care unit, if indicated.		
	Availability of supporting documentation of compliance with requirements for observation of the mother		

37	and healthy new-born in the labour ward by an obstetrician within two hours of birth: 1) measurement of the new-born's body temperature 15 minutes after birth, then every 30 minutes thereafter; 2) observation of the new-born's heart rate and respiratory rate, breathing pattern (detection of expiratory groaning, assessment of the degree of lower chest extension), skin colouring, activity of the sucking reflex, if necessary, determines saturation with a pulse oximeter.		
38	Availability of supporting documentation of compliance with the transfer 2 hours after birth of a healthy new-born with the mother to a mother-baby unit		
39	Supporting documentation of round-the-clock observation by medical staff and continuous involvement of the mother in the care of the child, except in cases of moderate and severe maternal conditions in the postnatal ward in the mother-baby wards.		
40	Availability of supporting documentation on compliance with the requirements for dynamic monitoring of the new-born with timely detection of disorders of the new-born's condition, conducting the necessary examination, examination by the head of the department, organisation of a Concilium to clarify the tactics of management.		

	Provision of emergency medical care when indicated, timely transfer to an intensive care ward or neonatal intensive care unit		
41	Compliance with the requirements for medical workers in the wards of joint stay of mother and child: 1) a record in medical documents of counselling on the benefits of breastfeeding, the technique and frequency of manual breast milk decanting, visual assessment of breastfeeding to provide practical assistance in the correct positioning and putting the baby to the mother's breast to avoid conditions such as nipple cracks or lactostasis; 2) availability of records in medical documents on training the mother (parent or legal representative) in alternative methods of child feeding in the presence of contraindications to breastfeeding; counselling of mothers in labour on how to maintain lactation in cases of separate stay of new-borns.		
42	A record in medical records of daily check-ups of new-borns by a neonatologist, consultations with mothers on care, prevention of hypothermia and vaccinations		
	Availability of supporting documentation on compliance with the requirements to organise consultations by specialised specialists, with therapeutic and diagnostic		

43	measures and recommendations to the mother on examination, treatment and rehabilitation in the presence of three or more developmental micro-anomalies or the detection of congenital pathology of new-borns.		
44	Availability of supporting documentation on compliance with the requirements of medical care in case of emergency conditions in the new-born (asphyxia, respiratory distress syndrome, etc.) Stabilisation of its condition and determination of the degree of readiness for transportation with the mother to the second or third level obstetric care organisation.		
45	Availability of supporting documentation on vaccination of new-borns on the basis of voluntary informed consent of parents (mother, father or legal representatives) for prophylactic vaccinations within the terms of prophylactic vaccinations in the Republic of Kazakhstan.		
46	Availability of supporting documentation of compliance with the requirements for all new-borns to undergo neonatal screening for phenylketonuria, congenital hypothyroidism and audiological screening prior to discharge		
	Availability of supporting documentation on compliance with the requirements for a neonatologist to assess the severity of the condition,		

47	stabilise the condition, assess the degree of readiness for transport in the event of emergency conditions in the new-born, and arrange its transfer with the mother (in coordination with the obstetrician-gynaecologist) to a second- or third-level medical organisation.		
48	Availability of supporting documentation on compliance with the requirements in case of suspicion and (or) detection of acute surgical pathology in a new-born, in case of emergency consultation of a doctor in the speciality "Paediatric surgery (neonatal surgery)" . After stabilisation of vital signs, the new-born shall be transferred to the surgical department of another medical organisation (children's or multidisciplinary hospital) or to a neonatal (or paediatric) surgical department, if there is one within the structure of the obstetric medical organisation, to provide the appropriate specialised medical care.		
49	Availability of supporting documentation on compliance with the requirements for transfer to a paediatric inpatient facility for premature new-borns after 28 days of age or premature new-borns after post-conceptional age of 42 weeks who require further round-the-clock medical care.		
	Mandatory pathological and anatomical examination of the foetus		

50	and placenta in cases of medical termination of pregnancy for suspected congenital anomalies in the foetus.		
51	Documentation of clinical and pathological review of all maternal and infant deaths after all pathological investigations have been completed		
52	Availability of an agreement for provision of paid medical services in healthcare organisations. Availability of documents establishing the fact of co-payment		
53	Availability of medical documentation on the consultation of a paediatric cardiologist (cardiac surgeon) when a congenital malformation of the cardiovascular system shall be detected in obstetric institutions, and, if medically indicated, transfer of the new born to a specialised hospital.		
54	Availability of medical documentation on the use of opportunities for consultation with relevant national organisations, through telemedicine network in case of difficulty in verifying the diagnosis of the child, determining the tactics of management. If it is necessary to transfer the child to specialised republican organisations.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient support service and internal		

	expertise and its evaluation according to the following criteria: 1) quality of anamnesis collection, which shall be assessed according to the following criteria: absence of anamnesis collection; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergology status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor quality anamnesis collection; 2) completeness and validity of diagnostic tests, which shall be evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or absence of a conclusion based on the results of diagnostic investigations, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; carrying out diagnostic tests with high, unjustified risk for the patient's health, justification of diagnostic tests not included in clinical protocols; carrying out diagnostic tests that shall not be informative for making a correct diagnosis and that			

	lead to an unjustified increase in treatment time and the cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalisation, investigations conducted at the pre-hospital stage shall also be taken into account), which shall be assessed according to the following criteria: the diagnosis shall be absent, incomplete or incorrect, shall not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, comorbidities affecting the outcome are not recognised ; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the		

55	subsequent stages of medical services (care) shall be assessed; 4) timeliness and quality of consultations of specialised specialists, which shall be assessed according to the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion has been taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was wrong and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which shall be assessed according to the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the specifics of the course of			

	the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which shall be assessed according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the specifics of the course of the disease, concomitant			

	diseases, complications, prescription of medications . 7) the achieved result, which is assessed according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care provided.		

Official(s) _____ _____
position signature

_____

surname, first name, patronymic (if any)
Head of the entity of control _____ _____
position signature

_____

surname, first name, patronymic (if any)

Annex 5
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ RK MH-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Сноска. Приложение 5 - в редакции совместного приказа Министра здравоохранения РК от 29.05.2023 № 90 и Министра национальной экономики РК от 29.05.2023 № 91 (вводится в действие по истечении десяти календарных дней после дня его первого официального опубликования).

in the area of quality of health care delivery

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

subjects (objects) providing cardiological, cardiac surgical care
name of homogeneous group of control entities (facilities)

_____

State body that appointed the inspection/prophylactic control
with a visit to the entity (facility) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the entity (facility) of control

(facility) of control

_____

_____ №, date

Name of the entity (facility) of control _____

_____

(Individual identification number), business identification number
of the entity (facility) of control _____

_____

Address of residence _____

_____

№	List of requirements	Complies with the requirements	Does not comply with the requirements
1	2	3	4
1.	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free-of-charge basis		
2.	Availability of medical documentation on the compliance of treatment and diagnostic measures with the recommendations of clinical protocols		
3.	Presence of written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures.		
	Availability of supporting documentation (emergency medical team call card form № 085/y, admission and refusal of hospitalisation log, medical card of an inpatient form № 001/y) that the stay of the emergency medical team or emergency medical care department in the emergency department of the hospital shall not exceed 10 minutes (the time for transferring the patient to the doctor of the emergency department) from the moment of its arrival at the hospital, except in cases of emergency medical care in emergency situations. After the transfer of the patient to the inpatient admission department by the ambulance crews or the		

4.	ambulance department in the organisation of primary health care, the nurse shall distribute the incoming patients (medical triage according to the triage system) into groups, based on the priority of emergency medical care. Medical triage according to the triage system (hereinafter referred to as medical triage) shall be carried out continuously and in succession. Upon completion of the assessment, patients shall be marked with a colour of one of the triage categories in the form of a special-coloured tag or coloured tape. According to the medical triage, there shall be 3 groups of patients: The first group (red zone) - patients whose condition shall be immediately life-threatening or at high risk of deterioration and who require emergency medical care; the second group (yellow zone) - patients whose condition poses a potential threat to health or may progress with the development of a situation requiring emergency medical care; the third group (green zone) - patients whose condition shall not pose an immediate threat to life and health and shall not require hospitalisation. Availability of a record in the medical documentation on identification of the patient by medical triage groups according to the triage system.		

5.	Availability of documentation on ensuring the hospitalisation of a serious patient in need of constant monitoring of vital functions for medical indications, by decision of a Concilium and notification of the heads of health care organisations with subsequent transfer to another medical organisation according to the profile of the disease for further examination and treatment after stabilisation of the condition		
6.	A medical report with a written justification of refusal in the absence of indications for hospitalisation in a health care organisation shall be issued to the patient by the doctor of the reception department. The reception unit nurse shall send the active to the renal replacement therapy organisation at the patient's place of attachment		
7.	Availability of supporting documentation on the indications for hospitalisation: The need to provide pre-hospital, qualified, specialised medical care, including the use of high-tech medical services, with round-the-clock medical supervision of patients: 1) on a planned basis - by referral of renal replacement therapy specialists or other health care organisation: 2) on emergency indications (including weekends and public holidays) - regardless of the availability of a referral		

8.	Severe patients shall be examined by the head of the department on the day of admission and daily thereafter. Patients in a moderately severe condition shall be examined at least once a week. The results of the patient's examination shall be recorded in the medical record with recommendations on further tactics of the patient's management with obligatory identification of the medical worker making the entries		
9.	Availability of supporting documentation on the establishment of the main diagnosis in emergency conditions within 24 (twenty-four) hours from the moment of the patient's admission to the 24-hour hospital on the basis of clinical and anamnestic examination data, results of instrumental and laboratory methods of research with recording in the medical record of an inpatient in form № 001/y, in stable patients - availability of the established clinical diagnosis in conjunction with the head of department no later than three calendar days from the date of admission to the hospital.		
10.	Availability of supporting documentation of planned hospitalisation in the presence of indicators: - daily electrocardiogram monitoring; - ergometric study (stress tests, spiroergometry) based on treadmill and/or cycle ergometer;		

	daily monitoring of blood pressure;		
11.	Availability of documentation on urgent (round-the-clock, including weekends and public holidays) procedures, in particular: - laboratory tests necessary to assess the functional state of organs and systems in the pre- and postoperative period; - electrocardiogram and its analysis; - echocardiography; - gastroduodenoscopy; - bronchoscopy; - vascular ultrasound; - cardiac cavity catheterisation with angiocardiography; - micro-ultrafiltration and dialysis; - albumin dialysis (using a molecular adsorbent recirculating system); - extracorporeal membrane oxygenation; - intra-aortic counterpulsation; - pacemaker implantation; - X-ray endovascular treatment methods.		
12.	Availability of documentation on admission to the catheterisation laboratory, bypassing the admission department, intensive care unit (ward) if the patient is diagnosed with acute coronary syndrome with segment elevation, acute myocardial infarction.		
	Availability of documentation on ensuring daily examination by the attending physician of patients staying in the hospital except weekends and public holidays. When		

13.	examining and prescribing additional diagnostic and treatment manipulations by the doctor on duty, appropriate entries are made in the medical record . If the patient's condition worsens, the doctor on duty notifies the head of the department and (or) the attending physician, agrees to make changes in the process of diagnosis and treatment, and makes an entry in the medical record (paper and (or) electronic) version. An entry is made in the electronic version of the medical record no later than 24 hours after the change in the patient's condition. In case of emergency, the frequency of entries depends on the dynamics of the severity of the condition. The records of the hospital doctor reflect specific changes in the patient's condition and the need for correction of prescriptions, justification of the prescribed examination and treatment, evaluation and interpretation of the results obtained and the effectiveness of the treatment. The frequency of examination for emergency conditions is at least every 3 hours, indicating the time of emergency care by hours and minutes.		
14.	Availability of documentation on the assessment of the complexity of surgical interventions for congenital heart disease according to the Aristotle Basic Scale and the effectiveness of		

	operations in the cardiac surgical unit		
15.	Availability of documentation on the compliance of medical care for patients with acute coronary syndrome and (or) acute myocardial infarction by levels of regionalisation: 1) at the first level - provision of medical care by organisations providing emergency medical care, primary medical and sanitary care, as well as organisations providing inpatient care without the possibility of percutaneous coronary interventions to patients with acute coronary syndrome or acute myocardial infarction ; 2) at the second level - organisations providing inpatient care with the possibility of percutaneous coronary interventions without a cardiac surgery department; 3) at the third level - organisations providing inpatient care and national medical organisations with a cardiac surgical unit available		
16.	Availability of supporting documentation of compliance during planned hospitalisation: 1) availability of a referral for hospitalisation in the hospital and a scheduled hospitalisation coupon; 2) hospitalisation of the patient in accordance with the date of planned hospitalisation specified in the referral; 3) clinical and diagnostic (laboratory, instrumental and functional)		

	examinations and consultations of specialised specialists according to the diagnosis shall be available		
17.	Consultations or consultations in case of difficulty in identifying the diagnosis, ineffectiveness of the current treatment, as well as other indications		
18.	Availability of supporting documentation during hospitalisation at the inpatient level: 1) initial examination of the patient by a physician to determine the patient's condition and establish a preliminary diagnosis; 2) therapeutic and diagnostic non-invasive testing methods to reduce the risk of invasive investigations; 3) selecting and prescribing treatment; 4) consultations with other specialists, if necessary		
19.	Ensuring that a discharge summary shall be issued to the patient upon discharge, indicating the full clinical diagnosis, the scope of diagnostic tests, therapeutic measures and recommendations for further follow-up and treatment. Discharge data shall be entered into the information systems on a day-to-day basis, indicating the actual time of discharge		
	Documentation of adherence to discharge criteria, such as: 1) generally accepted treatment outcomes (recovery, improvement, no change, death, transferred to another medical organisation); 2) a written statement by the patient or his/her legal		

20.	representative when there shall be no immediate danger to the patient's life or to others; 3) cases of violation of the internal order of the health care organisation, as well as obstruction of the treatment and diagnostic process, infringement of the rights of other patients to receive proper medical care (in the absence of an immediate threat to his/her life), which shall be recorded in the medical record.		
21.	Availability of an agreement for provision of paid medical services in healthcare organisations. Availability of documents establishing the fact of co-payment		
22.	Documentation of compliance with blood component transfusion requirements and in case of complications: Before transfusion of blood components, the recipient shall be examined for markers of haemotransmissible infections HIV, hepatitis B and C, and after the end of treatment the discharge epicrisis shall indicate the need for repeated examination for HIV and hepatitis B and C at the place of residence. HIV testing of recipients as part of the guaranteed scope of free medical care shall be carried out in State health-care organisations working in the field of HIV prevention Information on transfusion and obstetric anamnesis shall be entered in the patient's medical record		

	before transfusion therapy begins: previous transfusions, when and in connection with what; whether there have been any post-transfusion complications, pregnancies resulting in haemolytic babies. In case of development of complications during the biological test, during transfusion or after it, a detailed record(s) is made describing the recipient's condition, vital function monitoring data, treatment methods and their effectiveness. Immediate laboratory control of the recipient's blood and urine shall be performed.		
	Availability of examination of individuals on clinical indications for HIV infection upon detection of the following diseases, syndromes and symptoms: 1) enlargement of two or more lymph nodes with duration of more than 1month, persistent, generalised lymphadenopathy; 2) fever of unclear etiology (persistent or recurrent for more than 1 month); 3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained loss of 10% of weight or more; 4) chronic diarrhoea for 14 days or more (in children), unexplained chronic diarrhoea lasting more than a month;		

23.	5) seborrhoeic dermatitis, pruritic papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) shingles; 9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis , isosporosis, extrapulmonary histoplasmosis, strongyloidosis, actinomycosis); 10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, except tuberculosis of peripheral lymph nodes; 11) hairy leukoplakia of the oral cavity, linear erythema of the gums; 12) severe prolonged recurrent pneumonia and chronic bronchitis not amenable to conventional therapy (two or more times per year), asymptomatic and clinically evident lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent-bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis, meningoencephalitis, bone and joint infections, purulent myositis, Salmonella septicaemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis);		

	14) pneumocystis pneumonia; 15) infections caused by herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of the disease) lesions of skin and mucous membranes, including eyes ; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unclear etiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the oesophagus, bronchi, trachea, lungs, oral and nasal mucous membranes; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unclear etiology; 26) prolonged recurrent pyoderma not amenable to conventional therapy; 27) severe chronic inflammatory diseases of the female genital sphere of unclear etiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis after 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhoea, genital herpes, viral papillomatosis and others) with an established diagnosis; 31) viral hepatitis B and C, with confirmed diagnosis;		

	32) extensive plumose condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum; 34) primary dementia in previously healthy individuals; 35) patients with haemophilia and other diseases who systematically receive transfusion of blood and its components; 36) generalised cytomegalovirus infection.		
	Availability of medical documentation on compliance with the following requirements during the examination of temporary incapacity for work, issuance of certificates and certificates of temporary incapacity for work (form № 001/y " Medical Card of Inpatient Patient", form № 052/y " Medical card of outpatient patient", stubs of certificates of temporary incapacity for work of patients, form № 025/y " Journal for recording conclusions of medical advisory commission", form № 029y "Book of registration of certificates of temporary inability to work", form № 037/y " Certificate of temporary inability to work", form № 037y "Certificate of temporary inability to work ", form № 037/y " Certificate of temporary inability to work". 1) examination of the person and recording of data on his/her state of health in the medical card of an outpatient (inpatient)		

24.	patient justifying the need for temporary exemption from work; 2) issuance of a sheet and certificate of temporary incapacity for work on the day of discharge of individuals under inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing of the sheet and certificate of temporary incapacity for work on the date of discharge from the hospital if the individuals' working capacity has been fully restored; 4) extension of the temporary disability certificate and certificate of temporary incapacity for work for a period of time, taking into account the time necessary for the person to visit a medical worker at the outpatient clinic or to call a medical worker at home (but not more than one calendar day). Individuals who received treatment outside the region of residence shall be taken into account the time required to arrive at the place of his/her permanent residence (but not more than four calendar days); 5) issuance of a certificate of temporary incapacity for work for injuries sustained under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary incapacity for work; 6) issuance of a sheet and a certificate of temporary incapacity for work to individuals suffering from mental illness in the event			

	of failure to apply to a medical organisation in a timely manner for the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical officer (psychiatrist) in conjunction with the head of the medical organisation ; (7) Issuance of a sheet and a certificate of temporary incapacity for work to individuals sent by court decision for forensic medical or forensic psychiatric examination and recognised as incapable of work from the day of admission to the examination; 8) issuance of a sheet and a certificate of temporary incapacity for work at the same time to a person who combines training with work.		
25.	Compliance with the following requirements in the organisation and conduct of the medical advisory board: 1) availability of the order of the head of the medical organisation: - on the establishment of the medical advisory commission; - on the composition, number of members (at least three doctors), - the work and schedule of the medical advisory commission 2) availability of the conclusion of the medical advisory commission		
	Availability of supporting documentation on indications for hospitalisation in day		

26.	hospital at outpatient and polyclinic health care organisations and inpatient care at home: 1) exacerbation of chronic diseases that shall not require round-the-clock medical supervision; 2) active planned recuperation of a group of patients with chronic diseases subject to dynamic monitoring; 3) follow-up treatment of a patient on the next day after inpatient treatment on medical grounds; 4) second and third stage medical rehabilitation courses; 5) palliative care; 6) orphan diseases in children associated with a high risk of infectious complications and requiring isolation during seasonal viral diseases to receive regular enzyme replacement and antibacterial therapy. The indications for hospitalisation in a day hospital at a 24-hour hospital shall be: 1) carrying out operations and interventions with special preoperative preparation and resuscitation support; 2) performance of complex diagnostic tests requiring special preliminary preparation and not available in outpatient and polyclinic health care organisations; 3) monitoring of patients whose treatment involves transfusion of blood products, intravenous infusions of blood substituting fluids, specific hyposensitising therapy,			

	injections of potent drugs, intra-articular injections of drugs; 4) treatment on the next day after inpatient treatment if there are indications for early discharge after surgical treatment; 5) palliative care; 6) chemotherapy, radiation therapy, correction of pathological conditions arising after specialised treatment of oncological patients		
27.	Availability of a recovery and rehabilitation department		
28.	Availability of a cardiology room in the structure of organisations providing outpatient and polyclinic care to the population (district, city, region, republic) and organisations providing inpatient care		
29.	If it is impossible to establish the diagnosis of cardiovascular diseases in a primary health care organisation, the patient should be referred for consultation to a clinical diagnostic centre for the provision of Consultative and diagnostic polyclinic with a consultative meeting , if necessary, involving specialised specialists, including consultants from medical organisations at the national level.		
30.	Availability of supporting documentation of care provided to a patient with Consultative and diagnostic polyclinic by a specialised specialist on the referral of a renal replacement therapy specialist or other specialised specialist		

31.	Availability of an opinion on drawing up documents for referral for medical and social expert assessment in the presence of high blood pressure (crisis course), arrhythmia of various genesis, increased frequency of angina attacks and increasing symptoms of heart failure, issuance and extension of a sheet or certificate of temporary loss of working capacity, and in the case of permanent loss of working capacity (condition after myocardial infarction, aorto-coronary bypass, congestive heart failure)		
32.	Availability of supporting documentation on treatment and diagnostic measures, drug provision, organisation of therapeutic nutrition and appropriate care of the patient from the moment of admission to the health care organisation .		
33.	Availability of supporting documentation on the use of opportunities for consultation with relevant national organisations, via telemedicine network in case of difficulties in verifying the child's diagnosis and determining the tactics of management. If necessary, the child is transferred to specialised national organisations.		
34.	Provide supportive care (support adequate feeding, water balance, pain control, fever management, oxygen therapy)		
	Availability of medical documentation on the provision of the following		

35.	treatment and diagnostic measures as part of primary health care: 1) diagnostic - examination by a renal replacement therapy specialist, laboratory and instrumental non-invasive research methods; 2) therapeutic, including emergency and urgent medical care, therapeutic manipulations; 3) providing patients with Diseases of the circulatory system with prescriptions for medicines and medical devices for free and (or) preferential outpatient care; 4) preventive - medical examinations, screening preventive medical examinations of target population groups with subsequent health improvement and dynamic monitoring		
36.	Availability of supporting documentation on the use of less painful alternative treatments, if available, that shall be equally effective, to avoid unnecessary painful procedures		
	Availability of documentation on compliance with the requirements of anaesthesia and resuscitation care: 1) provision of specialised medical care to patients in emergency and planned procedures, including high-tech medical services; 2) determination of the method of anaesthesia, implementation of medical preoperative preparation and implementation of different methods of anaesthesia for various surgical interventions,		

37.	childbirth, diagnostic and therapeutic procedures; 3) monitoring the condition of patients in the post-lenarchemic period in the "waking up" wards until recovery of consciousness and stabilisation of the function of vital organs; 4) assessment of the degree of dysfunction of vital organs and systems and carrying out an extended complex of resuscitation and intensive care measures in various critical situations, including methods of extracorporeal detoxification, hyperbaric oxygenation, electrocardiostimulation; 5) intensive monitoring (express control of the state of life support systems and metabolism using laboratory and functional diagnostics methods, respiratory and circulatory monitoring), full and targeted correction of disorders; 6) resuscitation of patients (if indicated) in other departments; 7) establishing indications for further treatment of patients in Anaesthesiology , reanimation and intensive care department, as well as transfer of patients from Anaesthesiology, reanimation and intensive care department to specialised departments after stabilisation of vital organs function with recommendations on treatment and examination for the next 24 hours; 8) consulting doctors of other departments on practical anaesthesiology and resuscitation issues;			

	9) analysing the efficiency of the department and the quality of medical care, developing and implementing measures to improve the quality of medical care and reduce mortality rates		
	Compliance with the following actions when performing pathological anatomical autopsy: 1) conducting a pathological anatomical autopsy of corpses after the doctors have ascertained biological death, after providing the medical record of an inpatient patient or the medical record of an outpatient patient with a written order from the chief physician or his deputy for the medical (treatment) part of the health care organisation to send for a pathological anatomical autopsy; 2) registration of the results of the pathological anatomical autopsy in the form of a pathological anatomical diagnosis (pathological anatomical diagnosis includes: main disease, complication of the main disease, concomitant disease, combined main disease); 3) transfer of the medical record of an inpatient or medical record of an outpatient with the pathological anatomical diagnosis entered into it to the medical archive of the health care organisation no later than ten working days after the pathological anatomical autopsy; 4) conducting clinical and pathological anatomical		

38.	examination in cases of death of patients in health care organisations; 5) pathological anatomical autopsy in cases of suspected acute infectious diseases, oncological diseases, pathology of childhood, lethal outcome due to medical manipulations in order to establish the cause of death and clarify the diagnosis of a fatal disease; 6) organisation by the chief physician and head of the pathology department of virological (immunofluorescent) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathological anatomical bureau, centralised pathological anatomical bureau and pathological anatomical department of medical records of in-patients for all deceased for the previous day not later than 10 a.m. of the day following the establishment of the fact of death; 8) execution of: - medical certificate of death (preliminary, final) by a doctor in the speciality of "pathological anatomy (adult, paediatric)" on the day of the pathological anatomical autopsy; - medical certificate of perinatal death (preliminary, final) by a doctor specialising in " pathological anatomy (adult, child)" on the day of the pathological anatomical autopsy;			

	9) registration of the results of the autopsy in the form of a protocol of pathological anatomical examination; 10) written notification to the judicial and investigative authorities to address the issue of transferring the corpse for forensic medical examination in case of detection of signs of violent death and termination of the pathological anatomical examination of the corpse; 11) written notification of the doctor in the speciality "pathological anatomy (adult, child)" in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination, as well as emergency notification to the state sanitary and epidemiological service bodies immediately after their detection; 12) carrying out pathological and anatomical examination of the placenta: - in case of stillbirth; - in all diseases of new-borns detected at the time of birth; - in cases suspected of haemolytic disease of new-borns; - in cases of early discharge and dirty waters; - in cases of maternal illness with fever in the last trimester of pregnancy; - if there is an apparent abnormality in the development or attachment of the placenta; - suspected congenital anomalies of the foetus;			

	- in cases of pre-eclampsia, eclampsia and eclampsia 13) mandatory registration of a foetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) the establishment of pathological anatomical autopsy, depending on the complexity, into the following categories: - the first category; - the second category; - the third category; - the fourth category; 15) establishment of the category of pathological anatomy (adult, paediatric) by a doctor in the specialty "pathological anatomy (adult, paediatric)" and the reason for the divergence of diagnoses when the final clinical and pathological anatomical diagnoses diverged 16) detailed analysis with the definition of the profile and categories of iatrogenic pathology in all cases of iatrogenic pathology identified as a result of pathological anatomical autopsy		
39.	Availability of a written application from the spouse , close relatives or legal representatives of the deceased, or a written will be given by the person during his/her lifetime to release the corpse without a pathological anatomical autopsy, in the absence of suspicion of violent death		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical		

	audit by the Patient support service and internal expertise and its evaluation according to the following criteria: 1) quality of anamnesis collection, which is assessed according to the following criteria: absence of anamnesis collection; Completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor quality anamnesis collection; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or absence of a conclusion based on the results of diagnostic investigations, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; carrying out diagnostic tests with high, unjustified risk for the patient's health, justification of diagnostic tests not included in clinical protocols; carrying out diagnostic tests that are not informative for making a correct diagnosis and that			

	lead to an unjustified increase in treatment time and the cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalisation, investigations conducted at the pre-hospital stage are also taken into account), which are assessed according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, comorbidities affecting the outcome are not recognised ; the diagnosis of the main disease is correct, but comorbidities affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of			

40.	medical services (care) is assessed; 4) timeliness and quality of consultations of specialised specialists, which are assessed according to the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was wrong and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which shall be assessed according to the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the			

	specifics of the course of the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is assessed by the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription		

	of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care provided.		
41.	The patient shall be examined by a doctor in the admission department of an inpatient hospital with the completion of an inpatient card, if the patient or his/her legal representative has given written consent to the provision of medical care to the patient		
42.	Provision by a cardiologist (cardiac surgeon) of a consultative-diagnostic report in form № 075/y, indicating the results of the conducted examination and treatment, as well as further treatment of the patient with Diseases of the circulatory system to the primary care physician who referred the patient for consultative services in the course of personnel management provision		
	In the presence of abnormalities in blood pressure (crisis course), arrhythmias of various genesis, increased frequency of angina attacks and increasing symptoms of heart failure, the cardiologist of the medical organisation issues and		

43.	extends a temporary disability certificate or certificate, and in case of persistent disability (after myocardial infarction, aorto-coronary bypass surgery, congestive heart failure), the cardiologist of the Ministry of Health issues an opinion on drawing up documents for referral for medical and social expert assessment (hereinafter referred to as the MSE)		
44.	Availability of documentation on emergency hospitalisation of a patient with Diseases of the circulatory system to the intensive care unit (ward), bypassing the emergency room in life-threatening cases		
45.	Availability of documentation on hospitalisation of a patient with an established diagnosis of acute coronary syndrome (hereinafter referred to as the ACS) with segment elevation, acute myocardial infarction (hereinafter referred to as the AMI) to the catheterisation laboratory, bypassing the admission department, intensive care unit (ward).		
46.	Availability of documentation on the provision of cardiological (cardiac surgery) care in inpatient settings, which shall include: 1) initial examination of the patient by a doctor in order to determine the patient's condition and establish a preliminary diagnosis; 2) therapeutic and diagnostic investigations to		

	determine the patient's treatment tactics, as well as to reduce the risk of invasive methods of investigation and treatment ; 3) selection and prescription of treatment; 4) consultations with specialised specialists.		
47.	Availability of documentation on the immediate transfer of a patient undergoing treatment in the medical organisation without the possibility of IV in case of identification of indications for urgent interventional or cardiac surgical interventions by ambulance , including medical aviation to the medical organisation with the possibility of IV in 24-hour mode.		
	Availability of supporting documentation on the performance of surgical interventions in cardiac surgery according to the principle of regionalisation with regard to the level of complexity: 1) distribution of cardiac surgical operations for adults by categories of complexity: The level of regionalisation of cardiac surgical care for adults shall be carried out according to the principle of regionalisation; if the target values of the key indicators for regionalisation of cardiac surgical care (by level of complexity of the patient category) are achieved, within three evaluation periods the medical organisation shall perform surgical interventions of		

48.	the level of complexity provided for in Annex 1 to this order; 2) the complexity of surgical interventions for congenital heart defects shall be assessed using the Aristotle Basic Scale. If several operations are performed on one child, only one operation with the highest score on the Aristotle Base Scale is taken into account. To objectify the quality of work of the paediatric cardiac surgery department , a parameter such as the efficiency of operations shall be used, which shall be calculated according to the equation: (average value of complexity according to the Aristotle Basic Scale) x (30-day postoperative survival rate) /100 = (Efficiency of operations): Determining the level of regionalisation of cardiac surgical care for the paediatric population; if the target values of the key indicators of regionalisation of cardiac surgical care for the paediatric population (according to the complexity levels of the patient category) are achieved, the medical organisation performs surgical interventions according to the complexity levels during the three evaluation periods .			

Official(s) _____ _____
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surname, first name, patronymic (if any)
Head of the entity of control _____ _____

position signature

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surname, first name, patronymic (if any)

Annex 6
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ RK MH-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 6 - in the wording of the joint order of the Minister of Healthcare of the RK dated 29.05.2023 № 90 and the Minister of National Economy of RK dated 29.05.2023 № 91 (shall enter into force upon expiry of ten calendar days after the day of its first official publication).

in the area of quality of health care delivery

_____

in accordance with Article 138

_____

Entrepreneurial Code of the Republic of Kazakhstan in respect of

_____

entities (facilities) providing haemodialysis care

_____

name of a homogeneous group of control entities (facilities)

_____

State body that ordered the inspection/prophylactic control
with a visit to the entity (facility) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the entity (facility) of control

(facility) of control

_____

_____ №, date

Name of the entity (facility) of control _____

_____

(Individual identification number), business identification number
of the entity (facility) of control _____

Address of residence _____

№	List of requirements	Complies with the requirements	Does not comply with the requirements
1	2	3	4
1	Availability of written voluntary consent of the patient or his/her legal representative for invasive interventions and therapeutic and diagnostic measures		
2	Availability of an opinion on the compliance of the health care entity to provide high-tech medical services		
3	Availability of supporting documentation on the compliance of treatment and diagnostic measures with the recommendations of clinical protocols		
4	Availability of supporting documentation of eligibility for selection and initiation of renal replacement therapy, specifically: Indices (glomerular filtration rate); - presence of hyperhydration, acidosis; - potassium level; - assessment of the patient's nutritional status)		
5	Availability of supporting documentation of compliance with the indication for emergency extrarenal blood purification in patients with acute renal failure: - Absence of urine; - hyperkalemia; - hyperhydration.		

6	Availability of supporting documentation that the haemodialysis machine shall comply with quality certificates, with sufficient life and capacity as stipulated by the country of manufacture		
7	Availability of supporting documentation on compliance with the algorithm of haemodialysis procedure: - preparation of "artificial kidney" apparatus for work : testing and checking of AIP Atherogenic Index of Plasma apparatuses with control of ionic composition of dialysing solution on ionometer; preparation of the dialysis room nurse's workplace: laying out sterile layouts, preparation of fistula needles, dialyzer, solutions for filling the lines and dialyzer; - assembly of the extracorporeal circuit (blood pipelines, dialyser) with installation on the " artificial kidney" machine; - filling and flushing of the extracorporeal circuit with physiological solution with anticoagulant; - preparation of the patient: weighing on electronic scales with registration of interdialysis weight gain in the dialysis card, treatment of the skin surface with disinfectants at the site of puncture of vascular access ; - connection of the patient to the "artificial kidney" device; - setting the blood flow rate on the "artificial kidney" device;		

	- control of blood pressure, heart rate and pulse rhythmicity at least once an hour, with hourly registration of the results in the dialysis card; - control of correctness of ultrafiltration volume (at the end of dialysis), with registration of results in the dialysis card; - control of the position of fistula needles in the arteriovenous fistula (constantly); - control of readings of venous and arterial pressure sensors (constantly); - control of anticoagulation (constantly visually); -control of blood ionic composition during the procedure (as indicated); - at the end of the procedure time: stopping the blood pump, removal of fistula needles from the vascular access, control of bleeding stoppage from puncture sites, final stoppage of bleeding, fixation (bandaging) of the fistula limb with sterile dressing material; - control weighing of the patient on electronic scales with registration of the results in the dialysis card; - cold rinsing of the device, hot disinfection; - transport of used consumables for disposal.		
8	Availability of supporting documentation on the provision of drugs and consumables according to the dialysis protocol		
9	Availability of a water treatment system and compliance with requirements for preparation of		

	haemodialysis fluids, quality of solutions for haemodialysis and blood purification system		
10	Availability of a contract for provision of paid medical services in health care organisations. Availability of documents establishing the fact of co-payment		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analyses) of the clinical audit by the Patient support service and internal expertise and its evaluation according to the following criteria: 1) quality of anamnesis collection, which is assessed according to the following criteria: absence of anamnesis collection; Completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, performed haemotransfusions, tolerance of medicines, allergological status; development of complications as a result of tactical errors made during treatment and diagnostic measures due to poor quality anamnesis collection; 2) completeness and validity of diagnostic tests, which are evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or absence of a conclusion based on the results of diagnostic investigations,		

	which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; carrying out diagnostic tests with high, unjustified risk for the patient's health, justification of diagnostic tests not included in clinical protocols; carrying out diagnostic tests that are not informative for making a correct diagnosis and that lead to an unjustified increase in treatment time and the cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted investigations (in case of planned hospitalisation, investigations conducted at the pre-hospital stage are also taken into account), which are assessed according to the following criteria: the diagnosis shall be absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, comorbidities and complications have not been recognised; the diagnosis shall be correct but incomplete, the leading pathological syndrome shall not be highlighted with the highlighted complications, comorbidities affecting the outcome are not recognised ;			

11		the diagnosis of the main disease shall be correct, but comorbidities affecting the outcome of treatment shall not be diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) shall be reflected in the results of the expertise. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) is assessed; 4) timeliness and quality of consultations of specialised specialists, which shall be assessed according to the following criteria: lack of consultation, resulting in erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take the consultant's opinion into account when making the diagnosis partially influenced the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was wrong and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for untimely consultation and the impact		

	of untimely diagnosis on the subsequent stages of medical services (care); 5) volume, quality and validity of treatment measures, which shall be assessed according to the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures without taking into account the specifics of the course of the disease, concomitant diseases and complications; performance of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, the presence of polypragmasy, which led to the development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that occurred , including those caused by surgical interventions (delayed surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which is evaluated according to the following criteria: achievement of the expected clinical effect in			

	compliance with the technology of medical services (assistance); absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the peculiarities of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the state of health of patients, reflecting the nature, scope and quality of medical care provided.		
12	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free-of-charge basis		
13	Availability of supporting documentation on record keeping and reporting documentation		

Official(s) _____ _____
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surname, first name, patronymic (if any)

Head of the entity of control _____ _____
position signature

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surname, first name, patronymic (if any)

Annex 7
to the joint order of
the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 7 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2003 № 91 (shall come into effect ten calendar days after the day of its first official publication).

in the field of quality of medical services

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in accordance with Article 138

_____

of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____

subjects (objects) providing dental care

_____

name of a homogeneous group of subjects (objects) of control

_____

State body that appointed the inspection/preventive control
with a visit to the subject (object) of control

_____

_____

Act on appointment of inspection/preventive control with a visit to the subject (object) of control

_____

_____ №, date

Name of the subject (object) of control _____

_____

(Individual identification number), business identification number

of the subject (object) of control _____

_____

Location address _____

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№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
	Availability of supporting documentation of compliance with the following requirements when organizing dental care: 1) involvement of doctors of related specialities to provide advisory assistance in the presence of concomitant pathology in patients with dental diseases (for medical reasons); 2) referral of patients with dental diseases to the maxillofacial departments of multidisciplinary hospitals in cases requiring the provision of specialized medical care and high-tech medical services with round-the-clock medical supervision; 3) provision of dental medical care to the patient after receiving his/her informed consent according to the approved form of written voluntary consent of the patient for invasive interventions;		

2	4) compliance with indications for emergency hospitalization: - acute or exacerbation of chronic odontogenic and non-odontogenic inflammatory diseases of the maxillofacial area; - injuries of the maxillofacial area; - bleeding of the maxillofacial area; 5) compliance with the indications for planned hospitalization of a patient with dental diseases: - clarifying the diagnosis in cases that are unclear and difficult to diagnose and treat and selecting the necessary treatment regimen; - treatment of chronic diseases of the oral cavity and maxillofacial area in the acute stage; - surgical treatment of benign tumors and tumor-like diseases; - treatment of injuries and purulent-inflammatory diseases of the maxillofacial area; - surgical treatment of defects and deformations of the maxillofacial area; - surgical treatment of congenital pathology of the maxillofacial area.		
3	Availability of an agreement for the provision of paid services in healthcare organizations.		
4	Availability of medical documentation confirming compliance with clinical diagnostic studies at levels of dental care		
5	Availability of form № 058 /y "Medical record of a dental patient (including sanitation)" for each patient		

6	Availability of supporting documentation on the compliance of the therapeutic and diagnostic measures carried out with the recommendations of clinical protocols. In the absence of clinical protocols, according to international standards and guidelines based on evidence-based medicine.		
7	Availability of supporting documentation on the maintenance of accounting and reporting documentation by specialized experts working in healthcare organizations providing dental care		
8	Availability of completed documentation with information about the provision of dental care (electronic medical records, related materials about the patient's health status and diagnosis), including in the MIS for each tooth in the examination card of primary teeth and the examination card of permanent teeth		
9	Availability of documentation on determining the allergy history of the patient before dental interventions requiring local anaesthesia, and, if indicated, referral of the patient to primary health care organizations or medical organizations for laboratory examination to identify drug allergies		
	Availability of supporting documentation on the provision of dental care to children on an outpatient basis in the form of consultative and diagnostic assistance upon referral		

10	and self-referral shall include: 1) examination by a dentist ; 2) referral according to indications for laboratory, functional, instrumental, visual research methods (x-ray, computed tomography, magnetic resonance imaging, ultrasound) for the purpose of diagnosis and differential diagnosis; 3) provision of dental care for the identified disease according to clinical protocols; 4) referral for hospitalization for emergency indications and planned hospitalization for the provision of specialized medical care, including the use of HTMS, in inpatient and stationary conditions settings.		
11	Availability of informed consent of parents or representatives when performing dental interventions on children associated with the risk of pain; manipulations shall be carried out according to indications using anaesthesia (local, sedation , general)		
	Availability of supporting documentation on the provision of dental care to adults on an outpatient basis in the form of consultative and diagnostic assistance on self-referral and referral, which shall include: 1) examination by a dentist ; 2) referral according to indications for laboratory, functional, instrumental, visual research methods (		

12	x-ray, computed tomography, magnetic resonance imaging, ultrasound) for the purpose of diagnosis and differential diagnosis; 3) provision of dental care for the identified disease according to clinical protocols. 4) referral for hospitalization for emergency indications and planned hospitalization for the provision of specialized medical care in inpatient and stationary conditions settings		
13	Availability of supporting documentation on the provision of dental care in a hospital setting by oral and maxillofacial surgeons and includes prevention, diagnosis, treatment of diseases and conditions requiring the use of special medical methods and technologies, as well as medical rehabilitation		
14	Availability of supporting documentation of the consultation or the use of remote medical services in the differential diagnosis of complex, unclear cases to verify the diagnosis		
15	Children aged 0 to 17 years inclusive and pregnant women are subject to dynamic observation and dental examinations		
16	Availability of supporting documentation on the provision of preventive measures for pregnant women and adults, which shall include control over the hygienic condition of the oral cavity, instruction in brushing teeth, selection of oral hygiene products and items		

	, professional oral hygiene, oral sanitation (using modern materials and technologies), informational outreach about risk factors for dental diseases, carried out along the route primary preventive examination of a pregnant woman		
17	Compliance with the following requirements when organizing and conducting a medical advisory commission: 1) the presence of an order from the head of the medical organization: - on the creation of a medical advisory commission; - on the composition, number of members (at least three doctors), - about the work and schedule of the medical advisory commission 2) availability of the conclusion of the medical advisory commission		
	Availability of medical documentation on compliance with the following requirements when examining temporary disability, issuing a sheet and certificate of temporary disability (form № 001/y "Medical record of an inpatient", form 052/y "Medical record of an outpatient", stubs of sheets on temporary disability of patients, form № 025/y " Journal for recording the conclusions of the medical consultation commission", form № 029/y "Book of registration of sheets on temporary incapacity for work", form № 037/y " Certificate №_____ on temporary incapacity		

18		for work of a student, college student, professional technical school, about illness, quarantine and other reasons for the absence of a child attending school, a preschool organization (underline as necessary)", form № 038/y "Certificate №_____ on temporary disability" and others): 1) availability of an examination of the person and a record of data on his/her state of health in the medical record of an outpatient (inpatient), justifying the need for his/her temporary release from work; 2) issuance of a sheet and certificate of temporary disability on the day of discharge of persons during inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing the sheet and certificate of temporary disability with the date of discharge from the hospital if the person's ability to work is fully restored; 4) extension to persons who continue to be temporarily disabled for a period of time and a certificate of temporary disability for a period, taking into account the time required for his/her appearance to a medical worker at a clinic or calling a medical worker at home (but not more than one calendar day). For persons who received treatment outside their region of residence, the time required to arrive at their place of permanent residence shall		

	be taken into account (but not more than four calendar days); 5) issuance of a certificate of temporary disability for injuries received while under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary disability; 6) issuing a sheet and certificate of temporary disability to persons suffering from mental illness, in case of untimely contact with a medical organization in the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical worker (psychiatrist) together with the head of the medical organization; 7) issuing a sheet and certificate of temporary disability to persons sent by court decision for a forensic medical or forensic psychiatric examination and recognized as disabled from the date of admission for the examination; 8) issuing simultaneously a sheet and a certificate of temporary incapacity for work to a person combining study with work .		
19	Availability of written voluntary consent of the patient or his/her legal representative for invasive interventions and for carrying out therapeutic and diagnostic measures		
	Availability of supporting documentation on compliance with the		

20		requirements for the provision of anesthesiological and resuscitation care: 1) provision of specialized medical care to patients on an emergency and planned basis, including high-tech medical services; 2) determining the method of anaesthesia, carrying out preoperative drug preparation and conducting various anaesthesia techniques for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring the condition of patients in the post-anaesthesia period in the "recovery" wards until consciousness is restored and the function of vital organs is stabilized; 4) assessing the degree of dysfunction of vital organs and systems and carrying out an expanded set of measures for resuscitation and intensive care in various critical situations, including methods of extracorporeal detoxification, hyperbaric oxygenation, and cardiac pacing; 5) intensive observation (express monitoring of the state of life support systems, as well as metabolism using laboratory and functional diagnostic methods, monitoring of respiration and blood circulation), complete and targeted correction of disorders; 6) carrying out resuscitation measures for patients (if indicated) in other departments; 7) establishing indications for further treatment of		

	patients in ICU conditions, as well as transfer of patients from ICU to specialized departments after stabilization of the function of vital organs with recommendations for treatment and examination for the next 24 hours; 8) consulting doctors of other departments on issues of practical anesthesiology and resuscitation; 9) analysis of the efficiency of the department and the quality of medical care provided, development and implementation of measures to improve the quality of medical care		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance , allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic		

	studies, which are assessed according to the following criteria: lack of diagnostic measures ; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, concomitant diseases and complications have not been recognized;			

21	the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) shall be reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on subsequent stages of the provision of medical services (assistance) shall be assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the			

	consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications; prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient's condition; 6) the absence or development of complications after medical interventions, all			

	complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		

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position signature

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surname, first name, patronymic (if any)
Head of the subject of control _____ ____
position signature

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surname, first name, patronymic (if any)

Annex 8
to the joint order of
the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 8 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2003 № 91 (shall come into effect ten calendar days after the day of its first official publication).

in the field of quality of medical services

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in accordance with Article 138

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of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____
subjects (objects) providing phthisiatric care

_____
name of a homogeneous group of subjects (objects) of control

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State body that appointed the inspection/preventive control
with a visit to the subject (object) of control

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Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____
_____ №, date
Name of the subject (object) of control _____

_____
(Individual identification number), business identification number

of the subject (object) of control _____

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Location address _____

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№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
Providing anti-tuberculosis care at the outpatient clinic level			
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
	Availability of supporting documentation on the implementation by PHC specialists of the following activities: 1) conducting awareness-raising work on the prevention and early detection of tuberculosis; 2) planning (formation of lists of subject persons, drawing up a schedule), organization and conduct of a fluorographic examination with registration of the examination results in medical documentation; 3) planning (formation of lists of eligible persons, drawing up a schedule), organization and conduct of tuberculin diagnostics of children and adolescents with registration of examination results in medical documentation, conducting additional examinations of tuberculin-positive children);		

2		4) referral for examination of persons suspected of tuberculosis according to the diagnostic examination algorithm; 5) referral to a phthisiatrician of persons with positive results of a fluorographic examination, children and adolescents with a newly diagnosed positive and hyperergic tuberculin test, with an increase in tuberculin sensitivity by 6 mm or more, children with adverse reactions and complications to vaccination against tuberculosis; 6) planning, organizing and conducting vaccination against tuberculosis; 7) Controlled treatment of tuberculosis infection (hereinafter referred to as TI) as prescribed by a phthisiatrician, including in video-supervised mode; 8) examination of contacts; 9) outpatient directly-supervised or video-observed treatment of tuberculosis patients; 10) diagnosis and treatment of adverse reactions to anti-tuberculosis drugs as prescribed by a phthisiatrician; 11) diagnosis and treatment of concomitant diseases; 12) maintaining medical records of tuberculosis patients undergoing outpatient treatment, including multidrug-resistant and extensively drug-resistant tuberculosis; 13) regular entry of data into the National Register			

	of Tuberculosis Patients within the scope of competence		
3	Availability of supporting documentation for the examination of a patient for suspected tuberculosis in organizations providing primary health care according to this scheme		
4	Availability of supporting documentation on the detection of tuberculosis using fluorography among the target population group : those at high risk of the disease and subject to mandatory annual fluorographic examination		
5	Availability of supporting documentation on the organization of directly observed treatment rooms (hereinafter referred to as DOT) in primary health care organizations for outpatient treatment. The patient shall receive and take medications in the DOT office under the supervision of a responsible medical professional. Once every 10 days, patients undergoing direct supervised treatment shall be examined by a primary care physician/clinic phthisiatrician, or more often if indicated. Patients living in rural areas shall be examined by a phthisiatrician once a month		
	An assessment of the clinical condition of a patient receiving anti-tuberculosis treatment for the presence of adverse reactions and events shall be carried out daily by the attending physician or phthisiatrician, or a		

6	medical worker in the directly observed treatment room. A medical professional who has identified adverse reactions and events to a drug shall fill out a report card and make an entry in the patient's medical records. Primary information about adverse reactions and events shall be provided by the responsible person of the medical organization to the state expert organization in the field of circulation of medicines and medical devices. Control over the registration of message cards shall be assigned to the person responsible for pharmacovigilance. Each case of adverse reactions and events shall be reviewed at a meeting of a centralized medical advisory commission to determine the cause-and-effect relationship with the medications taken.			
7	Availability of records of the movement of anti-tuberculosis drugs at the outpatient level in the anti-tuberculosis drug registration log			
8	Conducting a conversation with the patient (parents or guardians of children) before the start of treatment about the need for a full course of chemotherapy, followed by signing informed consent			
9	Availability of supporting documentation on registration and dispensary observation of tuberculosis patients shall be carried out in organizations providing primary health care at the			

	place of actual residence, work, study or military service, regardless of registration		
10	Availability of supporting documentation on compliance with the following requirements when organizing and conducting a medical advisory commission: 1) the presence of an order from the head of the medical organization: - on the creation of a central medical advisory commission; - on the composition, number of members (at least three doctors), - about the work and schedule of the central medical advisory commission 2) the presence of a conclusion from the central medical advisory commission the presence of MAC and referral of patients with persistent signs of dysfunction of the respiratory system to a medical and social expert commission;		
11	Availability of supporting documentation regarding compliance with the levels of medical rehabilitation provided to patients: 1) primary level - medical organizations of primary health care, which have in their structure a rehabilitation room/ department, a day hospital and provide medical rehabilitation to patients whose condition is assessed from 1 to 2 points on the Rehabilitation Routing Scale (hereinafter referred to as RRS);		

Providing anti-tuberculosis care at the hospital level			
12	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
13	Distribution of patients in departments across wards, taking into account laboratory test data and drug sensitivity at the time of admission and during treatment. Keeping patients with bacterial excretion of unknown drug sensitivity in single wards or boxes until the results of the drug sensitivity test are obtained		
14	Availability of daily examination by a phthisiatrician of patients in the hospital. When examining and prescribing additional diagnostic and therapeutic procedures by the doctor on duty, appropriate entries are made in the medical record. If the patient's condition worsens, the doctor on duty shall notify the head of the department and (or) the attending physician, agree on changes to the diagnostic and treatment process, and make an entry in the medical record (paper and (or) electronic version). An entry shall be made into the electronic version of the medical record no later than 24 hours from the moment the patient's condition changes. In emergencies, the frequency of recordings depends on the dynamics of the severity of the		

	condition. Hospital doctor's notes shall reflect specific changes in the patient's condition and the need to adjust prescriptions, the rationale for the prescribed examination and treatment, the assessment and interpretation of the results obtained and the effectiveness of the treatment. Frequency of examination in case of emergency conditions shall be at least every 3 hours, indicating the time of emergency care in hours and minutes		
15	Availability of supporting documentation on the organization of consultation in difficult situations to verify the diagnosis and determine treatment tactics with the participation of specialists at the regional and national levels in person or remotely via telemedicine		
16	Availability of records of the movement of anti-tuberculosis drugs at the hospital level in the anti-tuberculosis drug registration log		
17	Availability of supporting documentation on compliance with the criteria for discharge of a tuberculosis patient from the hospital: 1) absence of bacterial excretion and the need for round-the-clock medical supervision; 2) obtaining two negative microscopy results, successively taken with an interval of at least 10 calendar days in patients with initial bacterial excretion;		

	3) generally accepted outcomes of inpatient treatment (recovery, improvement, no change, deterioration, death and transfer to another medical organization); 4) at the written request of the patient (his/her legal representative) before completion of the course of treatment in the absence of immediate danger to the life of the patient or to others		
18	Availability of written voluntary consent of the patient or his/her legal representative for invasive interventions and for carrying out therapeutic and diagnostic measures		
19	Availability of examination of severely ill patients by the head of the department on the day of hospitalization, and subsequently - daily. Patients in moderate condition shall be examined at least once a week. The results of the patient's examination shall be recorded in the medical record, indicating recommendations for further tactics of patient management with mandatory identification of the medical worker making the notes		
20	Having an established clinical diagnosis together with the head of the department no later than three calendar days from the date of hospitalization of the patient in a healthcare organization		
21	Availability of consultations or council in case of difficulty in identifying the diagnosis,		

	ineffectiveness of the treatment, as well as for other indications		
22	Availability of issuing a discharge summary to the patient upon discharge, indicating the full clinical diagnosis, the scope of diagnostic tests performed, treatment measures and recommendations for further observation and treatment. Data on the discharge shall be entered into information systems on the same day, indicating the actual time of discharge .		
	Availability of supporting documentation on compliance with the requirements for the provision of anesthesiological and resuscitation care: 1) provision of specialized medical care to patients on an emergency and planned basis, including high-tech medical services; 2) determining the method of anaesthesia, carrying out preoperative drug preparation and conducting various anaesthesia techniques for various surgical interventions, childbirth, diagnostic and therapeutic procedures; 3) monitoring the condition of patients in the post-anaesthesia period in the "recovery" wards until consciousness is restored and the function of vital organs is stabilized; 4) assessing the degree of dysfunction of vital organs and systems and carrying out an expanded set of measures for resuscitation and intensive care in various critical situations,		

23	including methods of extracorporeal detoxification, hyperbaric oxygenation, and cardiac pacing; 5) intensive observation (express monitoring of the state of life support systems, as well as metabolism using laboratory and functional diagnostic methods, monitoring of respiration and blood circulation), complete and targeted correction of disorders; 6) carrying out resuscitation measures for patients (if indicated) in other departments; 7) establishing indications for further treatment of patients in ICU conditions, as well as transfer of patients from ICU to specialized departments after stabilization of the function of vital organs with recommendations for treatment and examination for the next 24 hours; 8) consulting doctors of other departments on issues of practical anesthesiology and resuscitation; 9) analysis of the efficiency of the department and the quality of medical care provided, development and implementation of measures to improve the quality of medical care and reduce mortality			
	Availability of supporting documentation on compliance with the requirements for transfusion of blood components and in the event of complications: Before transfusion of blood components, the recipient shall be examined for			

24	markers of blood-borne infections HIV, hepatitis B and C, and after completion of treatment, the discharge summary indicates the need for re-examination for HIV and hepatitis B and C at the place of residence. Examination of recipients for HIV infection within the framework of the guaranteed volume of free medical care shall be carried out in state health care organizations operating in the field of HIV prevention The following information regarding the transfusion history shall be entered into the patient's medical record before the start of transfusion therapy: the presence of previous transfusions, when and in connection with what; whether there were post-transfusion complications, pregnancies that resulted in the birth of children with hemolytic disease of the newborn. If complications develop during a biological sample, during or after a transfusion, a detailed record(s) shall be made describing the recipient's condition, vital signs monitoring data, treatment methods and their effectiveness. Immediate laboratory monitoring of the recipient's blood and urine shall be carried out.		
	Availability of examination of persons for clinical indications for HIV infection when identifying the following diseases, syndromes and symptoms:		

	1) enlargement of two or more lymph nodes lasting more than 1 month, persistent, generalized lymphadenopathy; 2) fever of unknown aetiology (persistent or recurrent for more than 1 month); 3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained weight loss of 10% or more ; 4) chronic diarrhoea for 14 days or more (in children), unexplained chronic diarrhoea lasting more than a month; 5) seborrheic dermatitis, itchy papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) herpes zoster; 9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis , isosporosis, extrapulmonary histoplasmosis, strongyloidiasis, actinomycosis); 10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, except tuberculosis of peripheral lymph nodes;		

25	11) hairy leukoplakia of the oral cavity, linear gingival erythema; 12) severe protracted recurrent pneumonia and chronic bronchitis that is not amenable to conventional therapy (two or more times during the year), asymptomatic and clinically pronounced lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent-bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis, meningoencephalitis, infections of bones and joints, purulent myositis, Salmonella septicemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) Pneumocystis pneumonia; 15) infections caused by the herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of illness) damage to the skin and mucous membranes, including the eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unknown aetiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the oesophagus, bronchi, trachea, lungs, mucous membranes of the oral cavity and nose;			

	24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unknown aetiology; 26) prolonged recurrent pyoderma that is not amenable to conventional therapy; 27) severe chronic inflammatory diseases of the female genital area of unknown aetiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhea, genital herpes, viral papillomatosis and others) with an established diagnosis; 31) viral hepatitis B and C, upon confirmation of the diagnosis; 32) extensive condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum; 34) primary dementia in previously healthy individuals; 35) patients with hemophilia and other diseases who systematically receive transfusions of blood and its components; 36) generalized cytomegalovirus infection		
	Availability of medical documentation on compliance with the following requirements when examining temporary disability, issuing a sheet and certificate of temporary disability (form		

26	№ 001/y "Medical record of an inpatient", form 052/y "Medical record of an outpatient", stubs of sheets on temporary disability of patients, form № 025/y " Journal for recording the conclusions of the medical consultation commission", form № 029/y "Book of registration of sheets on temporary incapacity for work", form № 037/y " Certificate №_____ on temporary incapacity for work of a student, college student, professional technical school, about illness, quarantine and other reasons for the absence of a child attending school, a preschool organization (underline as necessary)", form № 038/y "Certificate №_____ on temporary disability" and others): 1) availability of an examination of the person and a record of data on his/her state of health in the medical record of an outpatient (inpatient), justifying the need for his/her temporary release from work; 2) issuance of a sheet and certificate of temporary disability on the day of discharge of persons during inpatient treatment (including day hospitals, rehabilitation centres) for the entire period of inpatient treatment; 3) closing the sheet and certificate of temporary disability with the date of discharge from the hospital if the person’s ability to work is fully restored; 4) extension for persons who continue to be temporarily disabled for a			

	period of time and a certificate of temporary disability for a period, taking into account the time required for his/her appearance to a medical worker at a clinic or calling a medical worker at home (but not more than one calendar day). For persons who received treatment outside their region of residence, the time required to arrive at their place of permanent residence shall be taken into account (but not more than four calendar days); 5) issuance of a certificate of temporary disability for injuries received while under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary disability; 6) issuing a sheet and certificate of temporary disability to persons suffering from mental illness, in case of untimely contact with a medical organization in the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical worker (psychiatrist) together with the head of the medical organization; 7) issuing a sheet and certificate of temporary disability to persons sent by court decision for a forensic medical or forensic psychiatric examination and recognized as disabled from the date of admission for the examination; 8) issuing simultaneously a sheet and a certificate of			

	temporary incapacity for work to a person combining study with work .		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance , and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures ; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient’s health, the		

	validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course		

27	of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on subsequent stages of the provision of medical services (assistance) is assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, but failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance);			

	5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications; prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance);			

	lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		
	Availability of documentation on compliance with the following actions when conducting a pathological autopsy: 1) conducting a pathoanatomical autopsy of corpses after doctors have declared biological death, after providing a medical record of an inpatient or a medical record of an outpatient with a written order from the chief physician or his/her deputy for the medical (medical) part of the health care organization on referral for a pathoanatomical autopsy;		

	2) registration of the results of the pathological autopsy in the form of a pathological diagnosis (pathological diagnosis shall include: the main disease, a complication of the main disease, a concomitant disease, and a combined main disease); 3) transfer of a medical record of an inpatient or a medical record of an outpatient with a pathological diagnosis included in it to the medical archive of a health care organization no later than ten working days after the pathological autopsy; 4) conducting clinical and pathological analysis in cases of death of patients in healthcare organizations; 5) pathoanatomical autopsy in case of suspicion of acute infectious diseases, oncological diseases, pathology of childhood, death in connection with medical procedures to establish the cause of death and clarify the diagnosis of a fatal disease; 6) organization by the chief physician and head of the pathology department of virological (immunofluorescence) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathology bureau, the centralized pathology bureau and the pathology department of inpatient medical records for all those who died on the previous day no later than 10 a.m. on the day following the establishment of the fact of death;		

28		8) registration: - medical death certificate (preliminary, final) by a doctor specializing in " pathological anatomy (adult, pediatric)" on the day of the pathological autopsy; - medical certificate of perinatal death (preliminary, final) by a doctor specializing in " pathological anatomy (adult, pediatric)" on the day of the pathological autopsy; 9) registration of the autopsy results in the form of a postmortem examination report; 10) the presence of a written notification to the judicial investigative authorities to resolve the issue of transferring the corpse for a forensic medical examination if signs of violent death are detected and the termination of the pathological examination of the corpse; 11) the presence of a written notice from a doctor specializing in " pathological anatomy (adult, pediatric)" in the event of initial detection during autopsy of signs of an acute infectious disease, food or industrial poisoning, an unusual reaction to vaccination, as well as an emergency notification to the state sanitary and epidemiological service, immediately after their identification; 12) conducting a pathological examination of the placenta: - in case of stillbirth;		

	- for all diseases of newborns identified at the time of birth; - in cases suspected of hemolytic disease of the newborn; - with early release of water and with dirty water; - for maternal illnesses that occur with high fever in the last trimester of pregnancy; - with obvious anomalies in the development or attachment of the placenta; - if there is a suspicion of congenital anomalies of fetal development; - in cases of preeclampsia, eclampsia 13) mandatory registration of a fetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) establishing a pathological autopsy depending on the complexity into the following categories: - first category; - second category; - third category; - fourth category; 15) establishment by a doctor specializing in " pathological anatomy (adult, pediatric)" of the category of pathological autopsy and the reasons for the discrepancy in diagnoses when there is a discrepancy between the final clinical and pathological diagnoses 16) the presence of a detailed analysis defining the profile and categories of iatrogenicity in all cases of iatrogenic pathology identified as a result of a pathological autopsy		

29	Availability of a written statement from a spouse, close relatives or legal representatives of the deceased, or a written expression of will given by a person during his/her lifetime for the release of a corpse without performing a pathological autopsy, in the absence of suspicion of violent death		
30	Availability of an agreement for the provision of paid medical services in healthcare organizations. Availability of documents establishing the fact of co-payment		
31	Availability of supporting documentation on the compliance of the levels of medical rehabilitation provided to patients: 1) secondary level - medical organizations that have specialized departments and (or) centres in their structure that provide medical rehabilitation in outpatient, inpatient and stationary conditions settings, providing medical rehabilitation to patients whose condition is assessed from 2 to 4 points according to the SRR; 2) tertiary level - specialized medical organizations that have departments and (or) centres in their structure that provide medical rehabilitation, including the use of high-tech services, in outpatient, inpatient and stationary conditions settings, to patients whose condition is assessed from 2 to 4 points according to SRR		

32	Availability of a medical worker's entry in the medical record with subsequent collection of biological materials to determine the content of a psychoactive substance with the results being entered into the medical record if signs of psychoactive substance use are detected when seeking medical help from a health care organization without issuing a Medical Examination Conclusion to establish the fact of psychoactive substance use and state of intoxication		
33	Availability of supporting documentation on the compliance of the therapeutic and diagnostic measures carried out with the recommendations of clinical protocols.		

Official(s)_____ _____
position signature

_____
surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

_____
surname, first name, patronymic (if any)

Annex 9
to the joint order of
the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 9 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the

Republic of Kazakhstan dated 29.05.2003 № 91 (shall come into effect ten calendar days after the day of its first official publication).

in the field of quality of medical services

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in accordance with Article 138

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of the Entrepreneurial Code of the Republic of Kazakhstan concerning

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subjects (objects) providing oncological care
name of a homogeneous group of subjects (objects) of control

_____

State body that appointed inspection/preventive control
with a visit to the subject (object) of control

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Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____

_____ №, date

Name of the subject (object) of control _____

_____

(Individual identification number), business identification number
of the subject (object) of control _____

_____

Location address_____

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№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
Providing oncological care at the outpatient clinic level			
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
	The presence of a multidisciplinary team (MDT) to provide an		

2	individual approach to providing medical care to patients with malignant neoplasms. The MDT shall consist of a head (a healthcare manager or a doctor specializing in " Oncology"), doctors in the following specialities: " Oncology"; "Oncology and haematology for children"; "Radiation oncology", " Chemotherapy oncology", "Radiology", "Nuclear medicine", "Mammology", "Oncological surgery", " Ultrasound diagnostics according to the profile of the main speciality", " Endoscopy according to the profile of the main speciality", "Pathological anatomy", "Cytopathology" , "Hospice and Palliative Care", middle-level medical personnel to take minutes of the meeting. In complex clinical cases, specialized experts of relevant specialities and specializations, as well as psychological and social specialists, shall be involved.		
	Availability of supporting documentation on consideration at meetings of the MDT: 1) all primary patients with a verified diagnosis of malignant neoplasm (MN). If a diagnosis of MN shall be made after planned surgical treatment, a meeting of the MDT shall be held in the department, based on the results of the histological report obtained ; 2) patients with suspected MN, the diagnosis of which is difficult; 3) patients with recurrent MN;		

3	4) patients who need to change treatment tactics due to complications, contraindications, or progression of the process; upon receipt of additional data during treatment; 5) patients if it is impossible to implement the recommendations of the previous meeting of the MDT due to complications, progression, contraindications, or patient refusal; 6) patients in need of referral for diagnosis and treatment in a tertiary level organization and abroad; 7) patients in need of targeted and immunotherapy drugs.		
	Availability of supporting documentation about the organization of primary health care specialists: 1) a set of measures for the prevention and early detection of precancerous and oncological diseases, including awareness-raising work among the attached population on issues of cancer alertness; 2) screening studies of target groups of the adult population for early detection of MN and behavioural factors; 3) questioning and examining patients in examination rooms and pre-medical rooms for early detection of precancerous and oncological diseases; 4) examination by a general practitioner (hereinafter referred to as GP) to determine the patient's condition and referral to an oncologist,		

4	mammologist, specialized experts in case of suspected MN and progression of the process in case of suspected MN and (or) progression of the oncological process by a general practitioner organizing primary health care, a doctor specialist in the organization of consultative and diagnostic assistance; 5) formation of groups of people at risk of developing cancer for their subsequent recovery with the involvement of specialized experts, monitoring of behavioural risk factors and training in skills to reduce identified risk factors for cancer shall be carried out by monitoring groups at increased risk of cancer in medical organizations of primary health care and consultative and diagnostic help; 6) field visits of mobile groups to increase the level of diagnosis of malignancies consisting of a GP, oncologist, and specialized experts using mobile medical complexes; 7) dynamic monitoring of patients with cancer, chronic and precancerous diseases, depending on the clinical group; 8) palliative care and medical rehabilitation for patients with MN according to clinical protocols.		
	Availability of supporting documentation on the provision of consultative and diagnostic assistance, which shall include: 1) medical examination to determine the patient's		

5	condition and establish a diagnosis; 2) additional examination of persons with suspected MN to verify the diagnosis; 3) laboratory and instrumental examination of the patient; selection and referral for hospitalization of cancer patients to receive specialized medical care, including high-tech medical services; 4) management and treatment of the patient taking into account the recommendations of the MDT; 5) conducting outpatient antitumor therapy.		
6	Availability of supporting documentation on the referral of the patient's GP to an oncologist or oncology care coordinator if a tumor disease is suspected or detected. From the moment the referral is issued to the GP, the oncologist or oncology care coordinator shall conduct an examination and the necessary studies within seven working days, based on the results of which he/she refers the patient to an organization providing oncological care to confirm the diagnosis and determine subsequent management and treatment tactics. From the moment of establishing a preliminary diagnosis of MN or suspicion of relapse of the disease, the oncologist shall organise the collection of cytological, and histological material (biopsy, surgical material), preservation, labelling and referral for morphological		

	examination of the material, and shall also send for diagnostic studies necessary to establish a diagnosis, prevalence oncological process and determining the stage of the disease, relapse of the disease.		
7	Availability of supporting documentation of compliance with the requirements for the provision of oncological care in the form of outpatient care: formation of groups of people at risk of developing cancer; examination by a doctor to determine the patient's condition and establish a diagnosis; laboratory and instrumental examination of the patient for diagnosis; dynamic monitoring of cancer patients; selection and referral for hospitalization of cancer patients to receive specialized medical care, including high-tech medical services; additional examination of persons with suspected MN to verify the diagnosis; determination of patient management and treatment tactics; conducting outpatient antitumor therapy		
	Availability of supporting documentation on the conduct of IHC and molecular genetic studies to determine the molecular biological characteristics of tumours to individualize the treatment of patients, as well as to confirm (verify) the diagnosis of cancer. IHC studies shall be carried		

8		out at the level of pathological laboratories of organizations providing oncological care, secondary level and tertiary level reference centres and shall be carried out according to clinical protocols. The submission of material for IHC studies (paraffin blocks and microslides) shall be accompanied by an extract from the medical record of an outpatient or inpatient, an MDT report, and a histological report. Delivery of materials for IHC studies shall be carried out by mail, courier service , and personally by the patient and (or) his/her relatives. The time frame for conducting IHC studies shall not exceed fourteen working days from the date of receipt of the material. The conclusion of the IHC study, indicating the date, study number, and the name of the performer, shall be entered into the MIS and transferred to the organization that sent the material for the study, through information interaction or by mail. The reference centre shall provide consultations on complex diagnostic cases and examination of IHC studies using the capabilities of telemedicine consultation (remote medical services). The expertise of IHC studies conducted in pathomorphological laboratories shall be carried out by reference centres at least once a year. The storage of paraffin blocks, coverglass		

	preparations and reports in the archives of pathomorphological laboratories shall be carried out for fifteen years, in the archives of reference centres - for twenty-five years.		
9	Availability of supporting documentation on international teleconsultations of tumor biosamples through the telepathology system to clarify the diagnosis in complex clinical cases. The duration of teleconsultations shall not exceed thirty working days		
	Availability of supporting documentation about displaying in the MIS the entire period of examination of patients with suspected cancer in an outpatient setting, indicating markers of cancer alertness within the following examination periods: 1) a specialist in the examination room, if a tumour disease is suspected or detected, shall set the marker " Oncological alert 1" and refer the patient to a GP within three working days; 2) The GP, together with a specialized expert, shall conduct a further examination and refer the patient to an oncologist or oncology care coordinator within five working days with the installation of the " Oncology alert 2" marker ; 3) the oncologist or oncology care coordinator from the moment of issuing the referral to the GP, within ten working days,		

10	shall conduct an examination and the necessary studies, based on the results of which he refers the patient to an organization providing oncological care to confirm and establish a diagnosis, determine subsequent management and treatment tactics with the installation of a marker "Oncology alert 3"; 4) consultations with specialists and examination of patients with suspected MN in an outpatient setting shall be carried out along the "green" corridor - outside the general queue and restrictions, within eighteen working days; 5) an oncologist at a secondary level organization shall conduct diagnostic studies necessary to confirm and establish the final diagnosis and the extent of the process. 6) an in-depth examination of patients of clinical group Ia to verify the diagnosis shall be carried out within fifteen working days from the moment of contacting the organization providing oncological care, to clarify treatment tactics and personalize therapy - within thirty working days; 7) the entire route of the primary oncology patient, and the timing of the examination in accordance with markers of cancer alertness shall be monitored in the situational centre of the organization coordinating cancer care in the region.			
	Availability of supporting documentation that specialized treatment of a			

11	patient with MN shall begin no later than thirty calendar days from the date of diagnosis and placement under dynamic observation .		
	Availability of supporting documentation on dynamic observation for clinical groups of patients with suspected MN and a confirmed diagnosis of MN : 1) group Ia – patients with a disease suspicious for MN; 2) group Ib – patients with precancerous diseases; 3) group II – patients with MN who are subject to special treatment (surgical treatment, chemotherapy, radiation therapy, immune cell therapy); 4) group IIa – patients with early forms of MN subject to radical treatment; 5) group III – patients after radical treatment of a malignant tumour (practically healthy individuals); 6) group IV – patients with common forms of MN, subject to palliative or symptomatic treatment. Based on the results of an in-depth examination of a patient in clinical group Ia, primary-level doctors remove suspicion of MN or transfer to the appropriate clinical groups: 1) if a pretumor disease is detected, the patient shall be transferred to clinical group Ib; 2) upon confirmation (verification) of the diagnosis of MN, the patient is taken for dynamic observation in clinical group II;		

12		3) patients with advanced forms of MN that are not amenable to special treatment shall be transferred to clinical group IV. Patients of clinical group Ib shall be subject to dynamic observation and rehabilitation by primary health care and clinical care specialists in organizations providing medical care on an outpatient basis at the place of their attachment, carried out under the supervision of high-oncology risk groups in medical organizations; observation of high-oncology risk groups in primary health care organizations and consultative and diagnostic assistance. In clinical group II, all primary patients with MN who are indicated for special treatment shall be observed, regardless of the stage of the disease, including patients with stage 4 MN, if there are indications for special treatment. Transfer from clinical group II to group III shall be carried out after completion of the full course of special treatment upon receipt of diagnostically confirmed results of radical cure, as well as the absence of progression and recurrence of MN. Medical dynamic observation of patients of clinical group III shall be carried out: 1) during the first year of the disease – once every three months;		

	2) during the second year of the disease – once every six months; 3) from the third year - once a year. Dynamic observation of clinical group II by secondary-level specialists shall be carried out in accordance with periodic clinical protocols, at least once every three months. Patients from clinical group III shall be transferred to II with progression and relapse of MN. Clinical group IV shall include patients with advanced forms of MN, with aggravating concomitant pathology that does not allow special treatment, and who are subject to palliative or symptomatic treatment. Transfer from clinical group II to IV shall be carried out when the disease progresses during treatment. Transfer from clinical group III to IV shall be carried out when the disease progresses during dynamic observation and the condition worsens, which does not allow for special treatment. Patients of clinical group IV who need to receive palliative and symptomatic treatment shall be observed in the primary health care organization at the place of attachment. Patients of clinical group IV shall not be removed from the oncology register.		
	Patients with cancer shall be subject to lifelong medical dynamic observation in an		

13	organization providing medical care on an outpatient basis at the place of attachment - the primary level (III clinical group) and organizations providing oncological care at a secondary level (II clinical group) at the place of residence and attachment. When changing the place of residence and changing the organization of attachment within the country, or region, the patient shall not be removed from dynamic observation but shall be dislocated at the place of new attachment or residence, with documents sent to organizations of the primary and secondary levels. A patient with MN shall be removed from the register in the following cases: 1) moving to another country with the issuance of a detailed extract from the outpatient medical record; 2) observation in an organization providing oncological care with a diagnosis of "Skin basal cell carcinoma", or " Trophoblastic disease" for more than five years after treatment, in the absence of relapses; 3) death based on a medical death certificate.			
	When a diagnosis of cancer is established for the first time, form № 034/y " Notification" shall be filled out for each patient, which shall be sent within three working days to the organization providing oncological care at the secondary level at the			

14	patient's place of permanent residence for registration in the Electronic Register of Cancer Patients and registration, indicating the circumstances of the diagnosis (the patient's self-referral to a medical organization PHC, CDA - primary level, the patient's self-referral to an organization providing oncological care at the secondary and tertiary levels, the diagnosis was established during a screening examination, the diagnosis was established during a preventive examination).		
15	For each patient with a diagnosis of stage IV cancer for the first time in his/her life and with visually accessible stage III localizations, a protocol shall be filled out in case an advanced form of MN is detected in the patient (clinical group V). In the PHC organization to which a patient with identified advanced MN is assigned, a mandatory analysis of all identified advanced cases shall be carried out. Materials from the analysis of an advanced case shall be sent to the organization coordinating oncological care in the region within ten working days from the receipt of the protocol on an advanced case of cancer. Information on the analysis of advanced cases shall be provided monthly by the organization coordinating oncological care in the region to the authorized		

	body in the field of health care to the chief specialist (freelance oncologist).		
16	Availability of mandatory confidential medical examination for the presence of HIV infection of persons for clinical and epidemiological indications , including sexual partners of pregnant women, persons who applied voluntarily and anonymously		
17	Availability of supporting documentation on compliance with indications for hospitalization in a day hospital at outpatient healthcare organizations and hospitalization at home : 1) exacerbation of chronic diseases that do not require round-the-clock medical supervision; 2) active planned improvement of a group of patients with chronic diseases subject to dynamic monitoring; 3) follow-up treatment of the patient the next day after a course of inpatient treatment for medical reasons; 4) conducting medical rehabilitation courses in the second and third stages; 5) palliative care; 6) orphan diseases in children associated with a high risk of infectious complications and requiring isolation during seasonal viral diseases to receive regular enzyme replacement and antibacterial therapy. Compliance with the requirements for hospitalization in a day		

	hospital in a 24-hour hospital: 1) carrying out operations and interventions with special preoperative preparation and resuscitation support; 2) conducting complex diagnostic studies that require special preliminary preparation, and are also not available in outpatient healthcare organizations; 3) observation of patients whose treatment involves transfusion of blood products, intravenous infusions of blood-substituting fluids, specific hyposensitizing therapy, injections of potent drugs, intra-articular injections of drugs; 4) follow-up treatment the next day after hospital treatment if there are indications for early discharge after surgical treatment; 5) palliative care; 6) chemotherapy, radiation therapy, correction of pathological conditions that arose after specialized treatment for cancer patients		
	Availability of medical documentation on compliance with the following requirements when examining temporary disability, issuing a sheet and certificate of temporary disability (form № 001/y "Medical record of an inpatient", form 052/y "Medical record of an outpatient", stubs of sheets on temporary disability of patients, form № 025/y " Journal for recording the conclusions of the medical consultation commission",		

18	form № 029/y "Book of registration of sheets on temporary incapacity for work", form № 037/y " Certificate №_____ on temporary incapacity for work of a student, college student, professional technical school, about illness, quarantine and other reasons for the absence of a child attending school, a preschool organization (underline as necessary)", form № 038/y "Certificate №_____ on temporary disability" and others): 1) availability of an examination of the person and a record of data on his/her state of health in the medical record of an outpatient (inpatient), justifying the need for his/her temporary release from work; 2) issuance of a sheet and certificate of temporary disability on the day of discharge of persons during inpatient treatment (including day hospitals, and rehabilitation centres) for the entire period of inpatient treatment; 3) closing the sheet and certificate of temporary disability with the date of discharge from the hospital if the person's ability to work is fully restored; 4) extension to persons who continue to be temporarily disabled for a period of time and a certificate of temporary disability for a period, taking into account the time required for his/her appearance to a medical worker at a clinic or calling a medical worker at home (but not more than one			

	calendar day). For persons who received treatment outside their region of residence, the time required to arrive at their place of permanent residence shall be taken into account (but not more than four calendar days); 5) issuance of a certificate of temporary disability for injuries received while under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary disability; 6) issuing a sheet and certificate of temporary disability to persons suffering from mental illness, in case of untimely contact with a medical organization in the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical worker (psychiatrist) together with the head of the medical organization; 7) issuing a sheet and certificate of temporary disability to persons sent by court decision for a forensic medical or forensic psychiatric examination and recognized as disabled from the date of admission for the examination; 8) issuing simultaneously a sheet and a certificate of temporary incapacity for work to a person combining study with work .		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the		

	conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase			

	in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on		

19	subsequent stages of the provision of medical services (assistance) is assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications;			

	prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account		

	the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		
Providing oncological care at the inpatient level			
20	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
21	Availability of supporting documentation on the dilution of antitumor drugs in the rooms for centralized dilution of cytostatic drugs (hereinafter referred to as the RCDC) to ensure the safety of medical personnel from the toxic effects of anticancer drugs and the rational use of drugs. Applications for the dilution of antitumor drugs for each patient are submitted by a doctor of the clinical unit together with the responsible specialist of the RCDC. Antitumor drugs shall be distributed based on submitted applications. Diluted medications shall		

	be packaged in disposable sterile containers and labelled. A second copy of the application shall be attached to the container. The diluted antitumor drugs shall be received and transported by the clinical unit nurse. Transportation of medicines shall be carried out in containers. Before administering an antitumor drug, the procedural nurse of the clinical unit shall compare the patient's data, applications and labelling on bottles and (or) syringes .		
22	Availability of supporting documentation that radiation therapy shall be carried out according to the principle of "single doctor – radiation therapist (radiation oncologist)", which provides for clinical management of the patient, pre-radiation preparation and radiation treatment by one doctor – radiation therapist (radiation oncologist). Pre-radiation preparation procedures are performed using special X-ray machines (simulators, computed tomographs), which provide data on the irradiation sites and surrounding organs and tissues. These devices also transmit to computer planning systems the following topographical characteristics of the irradiation site: dimensions , weight, orientation and additional information necessary for subsequent dosimetric calculations. To ensure uninterrupted operation and quality control of radiation therapy		

	equipment, verification of radiation plans using phantom measurements in the presence of complex radiation therapy equipment, a physical and technical support service for radiation therapy or a group of medical physicists and engineers to maintain radiation therapy equipment shall be created.		
23	Availability of supporting documentation that in inpatient conditions, patients with cancer shall be provided with antitumor therapy, radiation and radionuclide therapy, palliative care in cases that do not require constant medical supervision, in organizations providing oncological care at the secondary and tertiary levels in chemotherapy, radiation departments therapy, palliative care, medical rehabilitation. Medical care in inpatient conditions shall be provided in oncological organizations of the secondary and tertiary levels in the direction of an oncologist with the results of laboratory, instrumental studies and consultations with specialized experts necessary for the treatment of a given patient, taking into account the recommendations of the MDT.		
24	Availability of hospitalization of a seriously ill patient requiring constant monitoring of vital functions for medical reasons, by decision of the council and notification of the heads of healthcare organizations, with		

	subsequent transfer to another medical organization according to the profile of the disease for further examination and treatment after stabilization of the condition		
25	Availability of examination of severely ill patients by the head of the department on the day of hospitalization, and subsequently - daily. Patients in moderate condition shall be examined at least once a week. The results of the patient's examination shall be recorded in the medical record, indicating recommendations for further tactics of patient management with mandatory identification of the medical worker making the notes		
26	Availability of an established clinical diagnosis together with the head of the department no later than three calendar days from the date of hospitalization of the patient in a healthcare organization		
	Availability of daily examination by the attending physician of patients in the hospital except weekends and holidays. When examining and prescribing additional diagnostic and therapeutic procedures by the doctor on duty, appropriate entries shall be made in the medical record. If the patient's condition worsens, the doctor on duty shall notify the head of the department and (or) the attending physician, agree on changes to the		

27	diagnostic and treatment process, and make an entry in the medical record (paper and (or) electronic version). An entry shall be made into the electronic version of the medical record no later than 24 hours from the moment the patient's condition changes. In emergencies, the frequency of recordings shall depend on the dynamics of the severity of the condition. The hospital doctor's notes shall reflect specific changes in the patient's condition and the need to adjust prescriptions , the rationale for the prescribed examination and treatment, the assessment and interpretation of the results obtained and the effectiveness of the treatment. The frequency of examination in emergency conditions shall be at least every 3 hours, indicating the time of emergency care in hours and minutes.		
28	Availability of consultations or council in case of difficulty in identifying the diagnosis, ineffectiveness of the treatment, as well as for other indications		
	Availability of examination of persons for clinical indications for HIV infection in identifying the following diseases, syndromes and symptoms: 1) enlargement of two or more lymph nodes lasting more than 1 month, persistent, generalized lymphadenopathy; 2) fever of unknown aetiology (persistent or		

	recurrent for more than 1 month); 3) unexplained severe cachexia or severe nutritional disorders that do not respond well to standard treatment (in children), unexplained weight loss of 10% or more ; 4) chronic diarrhoea for 14 days or more (in children), unexplained chronic diarrhoea lasting more than a month; 5) seborrheic dermatitis, itchy papular rash (in children); 6) angular cheilitis; 7) recurrent upper respiratory tract infections (sinusitis, otitis media, pharyngitis, tracheitis, bronchitis); 8) herpes zoster; 9) any disseminated endemic mycosis, deep mycoses (coccidioidosis, extrapulmonary cryptococcosis (cryptococcal meningitis), sporotrichosis, aspergillosis , isosporosis, extrapulmonary histoplasmosis, strongyloidiasis, actinomycosis); 10) pulmonary and extrapulmonary tuberculosis, including disseminated infection caused by atypical mycobacteria, except tuberculosis of peripheral lymph nodes; 11) hairy leukoplakia of the oral cavity, linear gingival erythema; 12) severe protracted recurrent pneumonia and chronic bronchitis that is not amenable to conventional therapy (two			

29		or more times during the year), asymptomatic and clinically pronounced lymphoid interstitial pneumonia; 13) sepsis, prolonged and recurrent purulent-bacterial diseases of internal organs (pneumonia, pleural empyema, meningitis, meningoencephalitis, infections of bones and joints, purulent myositis, Salmonella septicemia (except Salmonella typhi), stomatitis, gingivitis, periodontitis); 14) Pneumocystis pneumonia; 15) infections caused by the herpes simplex virus, with damage to internal organs and chronic (lasting more than one month from the moment of illness) damage to the skin and mucous membranes, including the eyes; 16) cardiomyopathy; 17) nephropathy; 18) encephalopathy of unknown aetiology; 19) progressive multifocal leukoencephalopathy; 20) Kaposi's sarcoma; 21) neoplasms, including lymphoma (brain) or B-cell lymphoma; 22) toxoplasmosis of the central nervous system; 23) candidiasis of the oesophagus, bronchi, trachea, lungs, mucous membranes of the oral cavity and nose; 24) disseminated infection caused by atypical mycobacteria; 25) cachexia of unknown aetiology; 26) prolonged recurrent pyoderma that is not		

	amenable to conventional therapy; 27) severe chronic inflammatory diseases of the female genital area of unknown aetiology; 28) invasive neoplasms of the female genital organs; 29) mononucleosis 3 months from the onset of the disease; 30) sexually transmitted infections (syphilis, chlamydia, trichomoniasis, gonorrhoea, genital herpes, viral papillomatosis and others) with an established diagnosis; 31) viral hepatitis B and C, upon confirmation of the diagnosis; 32) extensive condylomas; 33) molluscum contagiosum with extensive rashes, giant disfiguring molluscum contagiosum; 34) primary dementia in previously healthy individuals; 35) patients with haemophilia and other diseases who systematically receive transfusions of blood and its components; 36) generalized cytomegalovirus infection		
30	Availability of an agreement for the provision of paid medical services in healthcare organizations. Availability of documents establishing the fact of co-payment		
	Availability of supporting documentation of compliance with discharge criteria, in particular: 1) generally accepted treatment outcomes (recovery, improvement, no change, death, transferred		

31	to another medical organization); 2) a written statement from the patient or his/her legal representative in the absence of an immediate danger to the life of the patient or others; 3) cases of violation of the internal regulations of a healthcare organization, as well as the creation of obstacles to the diagnostic and treatment process, infringement of the rights of other patients to receive proper medical care (in the absence of an immediate threat to his/her life), which is recorded in the medical record.		
32	Availability of issuing a discharge summary to the patient upon discharge, indicating the full clinical diagnosis, the scope of diagnostic tests performed, treatment measures and recommendations for further observation and treatment. Data on the discharge shall be entered into information systems on the same day, indicating the actual time of discharge .		
	Availability of supporting documentation on compliance with the requirements for transfusion of blood components and in case of complications: Before transfusion of blood components, the recipient shall be examined for markers of blood-borne infections HIV, hepatitis B and C, and after completion of treatment, the discharge summary indicates the need for re-examination for HIV		

33	and hepatitis B and C at the place of residence. Examination of recipients for HIV infection within the framework of the guaranteed volume of free medical care shall be carried out in state health care organizations operating in the field of HIV prevention transfusion therapy, information regarding transfusion and obstetric history shall be entered into the patient's medical record: the presence of previous transfusions, when and in connection with what; whether there were post-transfusion complications, pregnancies that resulted in the birth of children with hemolytic disease of the newborn. If complications develop during a biological sample, during or after a transfusion, a detailed record(s) shall be made describing the recipient's condition, vital signs monitoring data, treatment methods and their effectiveness. Immediate laboratory monitoring of the recipient's blood and urine shall be carried out.		
	Availability of supporting documentation regarding the determination of the method and tactics of treatment for MDT. Meetings of the MDT shall be held at the cancer centre every day (except weekends and holidays). Availability of rooms for centralized dilution of cytostatic drugs (hereinafter referred to as		

34	RCDC) to ensure the safety of medical personnel from the toxic effects of anticancer drugs and the rational use of drugs. Work at the RCDC for the cultivation of antitumor drugs shall be organized in shifts. Availability and control of applications for dilution of anticancer drugs for each patient. Requirements for packaging, labelling, and transportation (medicines shall be packaged in disposable sterile containers (bottles, syringes), labelled. Medicines shall be transported in containers.)		
35	Availability of supporting documentation confirming compliance of the medical care provided with clinical protocols		
	Availability of medical documentation on compliance with the following requirements when examining temporary disability, issuing a sheet and certificate of temporary disability (form № 001/y "Medical record of an inpatient", form 052/y "Medical record of an outpatient", stubs of sheets on temporary disability of patients, form № 025/y " Journal for recording the conclusions of the medical consultation commission", form № 029/y "Book of registration of sheets on temporary incapacity for work", form № 037/y " Certificate №_____ on temporary incapacity for work of a student, college student, professional technical		

36	school, about illness, quarantine and other reasons for the absence of a child attending school, a preschool organization (underline as necessary)", form № 038/y "Certificate №_____ on temporary disability" and others): 1) availability of an examination of the person and a record of data on his/her state of health in the medical record of an outpatient (inpatient), justifying the need for his/her temporary release from work; 2) issuance of a sheet and certificate of temporary disability on the day of discharge of persons during inpatient treatment (including day hospitals, and rehabilitation centres) for the entire period of inpatient treatment; 3) closing the sheet and certificate of temporary disability with the date of discharge from the hospital if the person's ability to work is fully restored; 4) extension to persons who continue to be temporarily disabled for a period of time and a certificate of temporary disability for a period, taking into account the time required for his/her appearance to a medical worker at a clinic or calling a medical worker at home (but not more than one calendar day). For persons who received treatment outside their region of residence, the time required to arrive at their place of permanent residence shall be taken into account (but not more than four calendar days);			

	5) issuance of a certificate of temporary disability for injuries received while under the influence of alcohol or drugs, as well as acute alcohol or drug intoxication, for the entire period of temporary disability; 6) issuing a sheet and certificate of temporary disability to persons suffering from mental illness, in case of untimely contact with a medical organization in the past days, upon the conclusion of the medical advisory commission of a psychoneurological dispensary or a medical worker (psychiatrist) together with the head of the medical organization; 7) issuing a sheet and certificate of temporary disability to persons sent by court decision for a forensic medical or forensic psychiatric examination and recognized as disabled from the date of admission for the examination; 8) issuing simultaneously a sheet and a certificate of temporary incapacity for work to a person combining study with work .		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is		

	assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies			

	performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on subsequent stages of the provision of medical services (assistance) is assessed; 4) timeliness and quality of consultations of specialized			

37	experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications; prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications;		

	implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, availability of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient's condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the characteristics of the course of the disease, concomitant diseases, complications, and		

	prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		
	Availability of supporting documentation on compliance with the following actions when conducting a pathological autopsy: 1) conducting a pathoanatomical autopsy of corpses after doctors have declared biological death, after providing a medical record of an inpatient or a medical record of an outpatient with a written order from the chief physician or his/her deputy for the medical (medical) part of the health care organization on referral for a pathoanatomical autopsy; 2) registration of the results of the pathological autopsy in the form of a pathological diagnosis (pathological diagnosis shall include: the main disease, a complication of the main disease, a concomitant disease, and a combined main disease); 3) transfer of a medical record of an inpatient or a medical record of an outpatient with a pathological diagnosis included in it to the		

	medical archive of a health care organization no later than ten working days after the pathological autopsy; 4) conducting clinical and pathological analysis in cases of death of patients in healthcare organizations; 5) pathoanatomical autopsy in case of suspicion of acute infectious diseases, oncological diseases, pathology of childhood, or death in connection with medical procedures to establish the cause of death and clarify the diagnosis of a fatal disease; 6) organization by the chief physician and head of the pathology department of virological (immunofluorescence) and bacteriological examination of autopsy materials in cases of suspected infectious diseases; 7) transfer to the pathology bureau, the centralized pathology bureau and the pathology department of inpatient medical records for all those who died on the previous day no later than 10 a.m. on the day following the establishment of the fact of death; 8) registration: - medical death certificate (preliminary, final) by a doctor specializing in " pathological anatomy (adult, pediatric)" on the day of the pathological autopsy; - medical certificate of perinatal death (preliminary, final) by a doctor specializing in " pathological anatomy (adult, pediatric)" on the day of the pathological autopsy;			

38	9) registration of the autopsy results in the form of a postmortem examination report; 10) availability of a written notification to the judicial investigative authorities to resolve the issue of transferring the corpse for a forensic medical examination if signs of violent death are detected and the termination of the pathological examination of the corpse; 11) availability of a written notice from a doctor specializing in " pathological anatomy (adult, pediatric)" in the event of initial detection during autopsy of signs of an acute infectious disease, food or industrial poisoning, an unusual reaction to vaccination, as well as an emergency notification to the state sanitary and epidemiological service, immediately after their identification; 12) conducting a pathological examination of the placenta: - in case of stillbirth; - for all diseases of newborns identified at the time of birth; - in cases suspected of hemolytic disease of the newborn; - with early release of water and with dirty water; - for maternal illnesses that occur with high fever in the last trimester of pregnancy; - with obvious anomalies in the development or attachment of the placenta; - if there is a suspicion of congenital anomalies of fetal development;			

	- in cases of preeclampsia, eclampsia 13) mandatory registration of a fetus weighing less than 500 grams with anthropometric data (weight, height, head circumference, chest circumference); 14) establishing a pathological autopsy depending on the complexity into the following categories: - first category; - second category; - third category; - fourth category; 15) establishment by a doctor specializing in " pathological anatomy (adult, pediatric)" of the category of pathological autopsy and the reasons for the discrepancy in diagnoses when there is a discrepancy between the final clinical and pathological diagnoses 16) availability of a detailed analysis defining the profile and categories of iatrogenicity in all cases of iatrogenic pathology identified as a result of a pathological autopsy		
39	Availability of a written statement from a spouse, close relatives or legal representatives of the deceased, or a written expression of will given by a person during his/her lifetime for the release of a corpse without performing a pathological autopsy, in the absence of suspicion of violent death		
	Availability of supporting documentation on the provision of oncological care at home:		

40	1) when calling a primary care medical worker or clinical hospital (primary level), a patient under dynamic observation (Ib, III clinical groups) if it is impossible to provide face-to-face consultation in the organization; 2) when calling a mobile team to visit patients with MN outside of an exacerbation of the disease when movement is limited and in need of palliative medical care, including using remote medical services; 3) in the form of active patronage of patients with MN in serious condition with limited movement, discharged from the hospital or transfer of assets from an emergency medical care station; 4) when organizing treatment at home (hospital at home), for patients with clinical group IV.		

Official(s)_____ _____
position signature

_____
surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

_____
surname, first name, patronymic (if any)

Annex 10
to the joint order of
the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 10 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2003 № 91 (shall come into effect ten calendar days after the day of its first official publication).

in the field of quality of medical services

_____

in accordance with Article 138

_____

of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____

subjects (objects) providing medical and social assistance in the field of mental health

name of a homogeneous group of subjects (objects) of control

_____

State body that appointed the inspection/preventive control with a visit to the subject (object) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____

_____№, date

Name of the subject (object) of control _____

_____

(Individual identification number), business identification number of the subject (object) of control _____

_____

Location address _____

_____

_____

№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
Requirements for subjects (objects) providing medical and social assistance in the field of mental health at the outpatient clinic level			
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical		

	care and (or) the system of compulsory social health insurance on a free basis		
	Availability of supporting documentation on compliance with the criteria for taking persons with mental and behavioural disorders (MBD) for dynamic observation: Group 1 of dynamic psychiatric observation - persons who, due to their mental state, are prone to socially dangerous actions, including those who have a risk of committing violent acts of a sexual nature against minors, as well as those who have committed especially dangerous acts in a state of insanity, and for whom the court has determined compulsory medical measures nature in the form of outpatient compulsory treatment; Group 2 of dynamic psychiatric observation - persons with MBD with disabilities due to mental illness, except for mental health disorders indicated in diagnostic headings F8 and F9; persons diagnosed with F20 "Schizophrenia" within one year after diagnosis (in this case, if recognized as a person with a disability, he continues to be observed in group 2 of dynamic psychiatric observation); 2A – persons with frequent and severe exacerbations of psychotic symptoms, decompensations, requiring psychopharmacotherapy as part of free outpatient treatment, including persons with MBD indicated in diagnostic headings F8 and F9		

2		2B – persons with stable conditions, with a moderately progressive course of the process and spontaneous remissions; dynamic narcological observation group - persons prone to socially dangerous actions due to clinical manifestations of MBD caused by substance abuse. 1) MBD due to the use of psychoactive substances in persons sent by court decision to departments for compulsory treatment; 2) MBD due to the use of psychoactive substances in a person who, based on the conclusion of a forensic drug examination, was prescribed treatment by a court decision; 3) MBD due to the use of psychoactive substances, in persons sent from places of deprivation of liberty where compulsory medical measures were used; 4) MBD due to the use of psychoactive substances, after suffering a psychotic disorder due to the use of psychoactive substances in hospital treatment; 5) MBD due to the use of psychoactive substances in persons prone to socially dangerous actions; 6) MBD due to the use of psychoactive substances in persons who voluntarily consented to dynamic observation. The persons specified in subparagraph 1) – 5) are taken for dynamic observation by the decision of the medical advisory commission. Compliance with the periodicity and frequency of observation of persons		

	with mental and behavioural disorders (diseases): 1 group of dynamic psychiatric observation - at least once a month Group 2 of dynamic psychiatric observation: 2A - at least once every three months, 2B - at least once every six months; dynamic drug treatment group - at least six times a year, depending on the individual characteristics of the individual and the course of the disease		
3	Availability of supporting documentation on compliance with the requirements for drug provision for persons with MBD who are under dynamic observation Persons with MBD who are under dynamic observation shall be provided with medications		
	Availability of supporting documentation on compliance with the requirements for deregistration and transfer to another dynamic observation group: Termination of dynamic observation of persons with MBD and deregistration shall be carried out in the following cases: 1) lack of criteria for taking persons with MBD for dynamic observation for at least 12 months, indicating in the EIS – "recovery, persistent improvement"; 2) change of place of residence with travel outside the service territory ; 3) lack of reliable information about		

4	whereabouts for 12 months, confirmed by the report of the local police inspector and the patronage of the local nurse at least once every two months, with the indication in the EIS - " lack of information"; 4) death, based on a medical death certificate in form № 045/y and (or) confirmed by data in the registered population register, indicating "death" in the EIS; 5) persons sentenced to imprisonment for a term of more than 1 year are removed from dynamic observation after receiving a response to a request from the Committee on Legal Statistics and Special Records of the General Prosecutor's Office of the Republic of Kazakhstan; 6) persons with a diagnosis of F20 "Schizophrenia", registered in group 2 of dynamic psychiatric observation: if the disability group is not established within 12 months from the date of admission for dynamic observation. Criteria for transferring a person with MBD to another group: lack of criteria for taking persons with MBD for follow-up for at least 12 months		
	Availability of supporting documentation on the implementation of the following measures during the dynamic observation of a person with MBD by a psychiatric doctor: 1) informing the patient about the need for dynamic monitoring of him/her, the		

5		list, volumes, frequency of examinations, laboratory and instrumental studies, and observation periods; 2) establishment of dynamic observation in the case of written consent of the person with the MBD to take him for dynamic observation; 3) referral to a meeting of the medical advisory commission (hereinafter referred to as the MAC) to resolve the issue of establishing dynamic observation without his/her consent or his/her legal representative if a person with MBD or his/her legal representative refuses to voluntarily undergo dynamic observation; 1) when taking a person with MBD for dynamic observation, conducting an initial examination of the patient, determining the dynamic observation group , the frequency of examinations, the need to organize the provision of special social services in the field of healthcare, drawing up an individual treatment plan, an individual rehabilitation program and other measures taking into account an individual approach, entering data in electronic information systems (hereinafter referred to as EIS) according to the form of accounting documentation in the field of healthcare 2) 5) conducting periodic examinations and evaluating the results of diagnostic studies, conclusions and recommendations of specialized experts;		

	6) monitoring and control of the effectiveness of treatment, rehabilitation (habilitation) measures, making adjustments if necessary; 7) registration of documents and referrals for medical and social examination, medical and social rehabilitation, inpatient replacement, inpatient treatment, including compulsory treatment if there are appropriate indications; 8) referral to consultation with specialized healthcare specialists, necessary laboratory and instrumental examinations, examination by a psychologist, consultation with a social worker and other specialists; 9) visiting a person with MBD at their place of residence; 10) implementation of continuity of levels, conditions and types of medical and social care.		
	Availability of an individual treatment plan and rehabilitation program for persons after discharge from an organization providing medical assistance in the field of mental health, except for those discharged by court order as having been cured ahead of schedule. During maintenance treatment for people with MBD, a psychiatrist (narcologist) draws up an individual treatment plan and an individual rehabilitation program. An individual treatment plan and an individual		

6	rehabilitation program shall include: 1) diagnostic methods: analysis of surfactant content in biological fluids and tissues of the body, testing for HIV, experimental psychological diagnostics, determination of quality of life and social functioning, clinical and biochemical diagnostics, neurophysiological diagnostics; 2) drug therapy: psychopharmacotherapy, symptomatic therapy, therapy for comorbid pathology, antagonistic therapy using opioid receptor blockers; 3) advisory methods: medical, psychological and social counselling for persons dependent on psychoactive substances and codependent persons; 4) training methods: motivational training for the continuation of supportive anti-relapse therapy, for the formation of adaptive skills and stress resistance, for the formation of the properties of psychological resistance to re-involvement in addiction to psychoactive substances; 5) psychotherapeutic techniques: individual and group psychotherapy for persons dependent on psychoactive substances, individual express psychotherapy for persons dependent on psychoactive substances who are in a state of breakdown.		
	Availability of supporting documentation about the provision of primary health care by a doctor, if a person with MBD is		

7		suspected or identified, except for MBD requiring the provision of emergency and emergency medical and social care: 1) patient identification; 2) diagnostic measures according to clinical protocols; 3) establishes a diagnosis and carries out treatment measures for medical treatment according to the International Classification of Diseases, 10th revision (hereinafter referred to as ICD-10), which are within the competence of the primary care physician. If a person is suspected of having a diagnosis of MBD according to ICD-10, which is not within their competence, the primary health care doctor shall refer him/her to the MHC (Mental Health Center) or PMHC (Primary Mental Health Center) at his/her territorial location; 4) in the case of establishing diagnoses of borderline MBD that are within the competence of a primary health care physician for the first time in the current year - sending information to the MHC or PMHC at the territorial attachment about this patient, indicating passport data (last name, first name, patronymic (if any), individual identification number (hereinafter referred to as IIN), residential address), diagnosis and date of diagnosis, for entering data into the electronic information system (hereinafter referred to as		

	EIS) no later than 5 working days from the date of diagnosis; 5) carrying out activities when identifying a person at risk of committing suicide who applied independently, or when examining a minor referred by psychologists; 6) filling out primary medical documentation; 7) carrying out a reconciliation with the physician of the MHC or PMHC on newly entered patients into the EIS for registering persons with MBD, monthly, no later than the 5th day of the month following the reporting period.		
	Carrying out the following activities by a psychiatric specialist of the MHC or PMHC if a person with mental health problems is suspected or identified, except for mental health problems requiring the provision of emergency and urgent medical and social care: 1) patient identification; 2) diagnostic measures according to clinical protocols; 3) prescription of treatment according to clinical protocols (if necessary); 4) check in the EIS for registering persons with disabilities about the availability of information about the person who applied. When the diagnosis of MBD is initially established, enters information into the EIS, including it in the statistical accounting group; in case of a previously established diagnosis of MBD and		

8	there is no information in the specified EIS, enters information, and if the information is available, supplements it; 5) resolving the issue of dynamic observation, as well as termination of dynamic observation; 6) registration of a referral to a medical advisory commission (hereinafter referred to as the MAC); 7) preparation of medical documentation concerning a person with MBD who needs a medical and social examination (hereinafter referred to as MSE) 8) registration of documents for persons with MBD caused by the use of psychoactive substances for referral to compulsory treatment; 9) entering information about a person with MBD into the EIS no later than 3 working days after receiving a notification from a primary care doctor; 10) carrying out dynamic monitoring of persons in dynamic monitoring groups according to the territorial assignment; 11) referral of persons with a suspected or established diagnosis of MBD for examination and (or) treatment to the territorial Central Clinical Hospital or Republican Scientific and Practical Clinical Centre (as indicated); 12) referral of persons with mental health problems to organizations providing medical and social rehabilitation in the field of mental health; 13) maintaining primary medical documentation;			

	14) entering data into the EIS for registering persons with mental health problems; 15) conduct a reconciliation with the primary health care doctor regarding newly introduced and included persons in the EIS and provide the specified information to the head of the territorial primary care centre.		
9	Availability of supporting documentation on the implementation of the following measures by a psychiatric doctor of the MHC or PMHC when applying to a person who was previously on dynamic observation with MBD and was deregistered in the EIS , indicating the reason for the removal, except for " recovery, persistent improvement": 1) patient identification; 2) diagnostic measures according to clinical protocols; 3) resolving the issue of dynamic observation, as well as termination of dynamic observation; 4) in the absence of criteria for admission to dynamic observation, registration of a referral to the MAC to resolve the issue of removal from dynamic observation, indicating the reason for removal in the EIS.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment		

	according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment;			

	3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on subsequent stages of the			

10	provision of medical services (assistance) is assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, but failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications;			

	prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account		

	the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		
Requirements for subjects (objects) providing medical and social assistance in the field of mental health in inpatient conditions, providing for round-the-clock medical supervision			
11	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
12	Availability of grounds for hospitalization in inpatient clinical departments. The following shall be the grounds for hospitalization in inpatient clinical departments: 1) referral from a psychiatric doctor; 2) resolution, decision, and determination of judicial investigative bodies; 3) referral to a military medical commission; 4) a written statement from the person himself, if there is evidence; 5) a court decision on compulsory treatment of persons with mental disorders caused by the use		

	of psychoactive substances, which has entered into legal force; 6) a court decision on the application of compulsory medical measures provided for in Article 93 of the Criminal Code of the Republic of Kazakhstan, which has entered into legal force		
13	Completeness of measures taken during planned hospitalization in the inpatient clinical departments of the Republican Scientific and Practical Clinical Hospital, Central Clinical Hospital. During planned hospitalization in the inpatient clinical departments of the Republican Scientific and Practical Clinical Hospital, the Central Clinical Hospital, the head or psychiatrist (narcologist) of the clinical department, admission and diagnostic department shall carry out the following activities: 1) patient identification; 2) checks the availability of available medical and other documentation, if necessary, sends for regulated and (or) additional examinations; 3) checks the availability of a court decision on hospitalization that has entered into legal force, if any; 4) assesses the mental and somatic state, the results of laboratory diagnostic tests, determines the need for emergency care at the level of the admission and diagnostic department and (or) availability of indications and		

	contraindications for hospitalization; 5) establishes a preliminary diagnosis, determines the scope of differential diagnosis, observation regimen, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols for diagnosis and treatment; 6) fills out primary medical documentation.		
14	Completeness of measures taken during hospitalization in the inpatient clinical department of the Republican Scientific and Practical Clinical Hospital, Central Clinical Hospital for emergency indications. When hospitalized in the inpatient clinical department of the Republican Scientific and Practical Clinical Hospital, Central Clinical Hospital for emergency indications, the head or psychiatrist (narcologist) of the clinical department or admission and diagnostic department, or the doctor on duty shall carry out the following activities: 1) patient identification; 2) evaluates mental and somatic conditions, and results of laboratory diagnostic tests and determines the need for emergency care at the level of the admission and diagnostic department and (or) availability of indications and contraindications for hospitalization; 3) establishes a preliminary diagnosis, determines the scope of differential		

	diagnosis, observation regimen, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols for diagnosis and treatment; 4) fills out primary medical documentation		
15	Completeness of measures taken during planned hospitalization in SPOIS (a specialized psychiatric organization with intensive supervision). During a planned hospitalization at SPOIS, the doctor on duty shall carry out the following activities: 1) checks the availability and compliance of existing documentation: a court decision that has entered into legal force; identification document. 2) identifies the patient; 3) assesses the mental and somatic state, the results of laboratory diagnostic tests, determines the need for emergency care at the level of the admission and diagnostic department and (or) availability of indications and contraindications for hospitalization; 4) determines the department, establishes an observation regime, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols for diagnosis and treatment; 5) fills out primary medical documentation		
	The completeness of the measures taken after the		

16	admission of a person with MBD to the inpatient clinical department. After a person with MBD is admitted to the inpatient clinical department, the following activities shall be carried out: 1) patient identification; 2) checking the availability and compliance of existing medical and other documentation; 3) assessment of the mental and somatic state, results of laboratory diagnostic tests, establishment of a preliminary diagnosis, determination of the scope of differential diagnosis, observation regimen, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical diagnostic and treatment protocols; 4) filling out primary medical documentation and treatment;			
17	Completeness of measures taken after a person's admission to the inpatient clinical department SPOIS After a person is admitted to the inpatient clinical department of SPOIS, the following activities shall be carried out: 1) patient identification; 2) checking the availability and compliance of existing medical and other documentation; 3) assessment of the mental and somatic state, results of laboratory diagnostic tests, establishment of a preliminary diagnosis, determination of the scope of differential diagnosis, observation regimen, therapeutic nutrition and			

	other therapeutic and diagnostic measures according to clinical diagnostic and treatment protocols; 4) filling out primary medical documentation		
	Compliance with surveillance regimes. In the clinical inpatient departments of the Republican Scientific and Practical Clinical Hospital, the Central Clinical Hospital and multidisciplinary city (regional) hospitals, the following types of observation shall be expected: 1) general surveillance regime - round-the-clock surveillance without restriction of movement in the department. The general regimen for patients shall be established when: absence of danger to yourself and others; ability to maintain personal hygiene without assistance; 2) partial hospitalization mode - the possibility of staying in the department during the day or at night, taking into account the need for its adaptation to out-of-hospital conditions, as well as the possibility of carrying out work activities against the background of treatment and control of symptoms of MBD for resocialization. The partial hospitalization regime shall be established by the decision of the medical commission (hereinafter referred to as the MC) consisting of two doctors when:		

18	absence of danger to oneself and others; ability to maintain personal hygiene without assistance; stabilization of mental state , requiring daily, but not round-the-clock monitoring and control; 3) medical leave regime - the possibility of being outside the department for several hours to several days to gradually adapt to out-of-hospital conditions, resolve everyday and social issues, as well as evaluate the achieved therapeutic effect. The regime of medical leave shall be established by the decision of the Internal Committee consisting of two doctors and shall be provided when : absence of danger to yourself and others; ability to maintain personal hygiene without assistance; stabilization of mental state that does not require daily monitoring. 4) enhanced surveillance regime - round-the-clock surveillance and restriction of movement outside the department. An enhanced monitoring regime shall be established for patients with: acute MBD that does not pose a danger to oneself or others; ability to maintain personal hygiene without assistance; the absence of a mental or somatic disorder requiring a different regime of observation and maintenance; 5) strict observation regime - round-the-clock continuous observation in the observation ward,			

	constant accompaniment by medical personnel in the department and outside it. A strict regime for patients shall be established for patients with: immediate danger to yourself and others; helplessness, that is, the inability to independently satisfy one's life needs in the absence of proper care; possible significant harm to health if the person is left unsupervised. In the clinical inpatient departments of SPOIS, the following types of observation shall be assumed: 1) general observation regime - round-the-clock observation with movement in the department according to the daily routine, the opportunity to participate in occupational therapy outside the department; 2) enhanced surveillance regime - round-the-clock surveillance and restriction of movement within the department; 3) strict observation regime - round-the-clock continuous observation in the observation ward, constant accompaniment by medical personnel in the department and outside it		
	Availability of supporting documentation of compliance with the criteria for involuntary hospitalization: Compulsory hospitalization in a hospital is permitted based on a court decision. Forced hospitalization of a person in a hospital before		

19	a court decision is permitted only in cases in accordance with the law. For each case of forced hospitalization without a court decision, the administration of an organization providing medical assistance in the field of mental health to persons with a mental, or behavioural disorder (disease), within forty-eight hours from the moment the person is admitted to the hospital, sends a written notification to the prosecutor, and also informs the spouse), close relatives and (or) legal representatives if information about them is available. A person's stay in a hospital forcibly continues only as long as the grounds for which the hospitalization was carried out persist. A person hospitalized in a hospital forcibly during the first six months is subject to examination at least once a month by a commission of psychiatrists to decide on the extension of hospitalization. Extension of hospitalization for more than six months shall be carried out by a court decision based on an application from an organization providing medical care in the field of mental health to persons with mental and behavioural disorders (diseases), on the need to extend the period of compulsory hospitalization and treatment, to which is			

	attached the conclusion of a commission of psychiatrists.		
20	Availability of supporting documentation of compliance with the conditions of discharge. Discharge from inpatient clinical departments shall be carried out upon the patient's recovery or improvement in his/her mental state when no further inpatient treatment is required, as well as upon completion of the test, examination, safety measures, compulsory medical measures that were the basis for placement in the hospital. Discharge of a patient who is in inpatient clinical departments voluntarily shall be made upon his/her application, the application of his/her legal representative, or by the decision of his/her attending physician. The discharge of a patient to whom, by a court ruling, compulsory medical measures and security measures have been applied, shall be carried out only in accordance with a court ruling that has entered into force. A patient hospitalized in an inpatient clinical department voluntarily shall be refused discharge if the MAC has established grounds for involuntary hospitalization		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and		

	Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase			

	in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) shall be reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on		

21		subsequent stages of the provision of medical services (assistance) shall be assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications;		

	prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account		

	the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		
Requirements for subjects (objects) providing medical and social assistance in the field of mental health in inpatient conditions that do not require round-the-clock medical supervision and treatment and provide for medical supervision and treatment during the day with the provision of a bed			
22	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
23	Availability of indications for treatment in inpatient conditions for persons with MBD Indications for treatment in inpatient conditions for persons with MBD are: 1) the need for active treatment of people with MBD, including those caused by the use of psychoactive substances, which does not require round-the-clock monitoring; 2)2) the need for gradual adaptation to normal living conditions after receiving a course of treatment in a 24-hour hospital;		

	3)3) conducting examinations and examinations that do not require round-the-clock inpatient monitoring Hospitalization to an organization providing care in inpatient conditions shall be carried out as planned.		
24	Carrying out the following activities during hospitalization in a day hospital: 1) patient identification; 2) checking the availability and compliance of existing medical and other documentation; 3) assessment of the mental and somatic state, as well as the results of laboratory diagnostic tests, determination of indications and contraindications for hospitalization; 4) establishing a preliminary diagnosis, determining the scope of differential diagnosis, therapeutic nutrition and other therapeutic and diagnostic measures according to clinical protocols for diagnosis and treatment; 5) filling out primary medical documentation.		
25	Requirements for the duration of treatment and time of stay in a day hospital. The duration of treatment in a day hospital shall be no more than 30 calendar days. In cases of deterioration of the patient's condition requiring round-the-clock medical observation and treatment, he/she shall be		

	hospitalized in the appropriate inpatient department. The daily stay in the day hospital shall be at least 6 hours. In the day hospital, two meals a day shall be provided, taking into account the time of taking psychotropic medications		
26	Compliance with requirements for discharge from day hospital. The discharge shall be made upon the patient's recovery or improvement in his/her mental state, when transfer to outpatient treatment is possible, as well as upon completion of the examination and examination that served as the basis for placement in a day hospital. On the day the patient is discharged from the organization providing inpatient care, an epicrisis shall be drawn up, a copy of which is sent to the PMHC, MHC, at the patient's place of residence, for inclusion in the outpatient's medical record.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection;		

	availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be			

27	taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) shall be reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on subsequent stages of the provision of medical services (assistance) shall be assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms			

	and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications; prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications		

	without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences;			

	8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		
Requirements for entities (objects) providing medical and social assistance to persons with mental and behavioural disorders (diseases) in the form of emergency medical and social assistance			
28	The provision of emergency specialized psychiatric care shall be carried out by specialized teams organized as part of an organization providing emergency medical and social care or EMS.		
Requirements for subjects (objects) providing medical and social rehabilitation in the field of mental health			
29	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
30	Availability of supporting documentation of compliance with the requirements for medical and social rehabilitation in outpatient or inpatient settings. When providing medical and social rehabilitation in an outpatient or inpatient setting, the daily stay is at least 6 (six) hours, excluding weekends and holidays, and two meals a day are provided, taking into account the time of taking psychotropic medications. In the medical and social rehabilitation unit, the patient is provided with the necessary drug therapy and the necessary examination.		

	Medical and social rehabilitation of patients with MBD shall be provided according to an individual rehabilitation program for patients with MBD		
31	Availability of supporting documentation of compliance with the requirements for medical and social rehabilitation in inpatient settings. When hospitalized for medical and social rehabilitation, the following activities shall be carried out: 1) patient identification; 2) checking the availability and compliance of existing medical documentation, referral for regulated and (or) additional examinations ; 3) an individual rehabilitation program for a patient with MBD is developed; 4) primary medical documentation is completed. Identification of general contraindications for hospitalization for medical and social rehabilitation: 1) acute conditions requiring strict or enhanced monitoring; 2) availability of concomitant diseases requiring treatment in hospitals of a different profile; 3) infectious diseases during the period of epidemiological danger		
	Availability of supporting documentation for the activities of the multidisciplinary group. Medical and social rehabilitation of adults with		

32	MBD shall be carried out by a multidisciplinary group: 1) manager (health care manager or psychiatrist); 2) psychiatrist; 3) psychologist; 4) a social worker or social work specialist; 5) an occupational instructor or specialist in the field of occupational therapy, sports; 6) paramedical worker. The composition of the multidisciplinary team expands as the list and (or) volume of services increases		
33	Requirements for the duration of medical and social rehabilitation. The duration of medical and social rehabilitation of adult patients with MBD shall be no more than 3 (three) months. The duration of medical and social rehabilitation of children with mental retardation shall be no more than 3 (three) months . The duration of medical and social rehabilitation for adults with MBD due to the use of psychoactive substances shall be no more than 9 (nine) months. The duration of medical and social rehabilitation of children with mental retardation due to the use of psychoactive substances shall be no more than 9 (nine) months.		
Requirements for subjects (objects) conducting a medical examination to establish the fact of use of a psychoactive substance and state of intoxication			
	Availability of supporting documentation on the provision of medical care included in the guaranteed		

34	volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
35	Availability of supporting documentation confirming compliance with the requirements for identifying a person sent or coming for a medical examination. Before conducting a medical examination, a medical worker shall identify the person who was sent or came for a medical examination by reading his/her identity documents or electronic documents from the digital document service. In the absence of documents of the person being examined, in the conclusion of the medical examination to establish the fact of the use of a psychoactive substance and the state of intoxication (hereinafter referred to as the Conclusion), his/her special characteristics shall be indicated with the obligatory indication of obtaining passport data from the words of the referring person or the person being examined. The absence of identification documents or electronic documents from the digital document service shall not be grounds for refusal of examination. Establishing the identity of a person sent for a medical examination shall not be within the competence of a medical worker.		
	Availability of supporting documentation on compliance with the		

36	requirements for examination of foreign citizens and minor citizens of the Republic of Kazakhstan. Foreign citizens permanently residing and temporarily staying on the territory of the Republic of Kazakhstan, as well as stateless persons who are intoxicated in a public place, at work, or driving a vehicle, are subject to a medical examination on a general basis. Medical examination of minor citizens of the Republic of Kazakhstan shall be carried out in the availability of their legal representatives.			
37	Availability of supporting documentation of compliance with the requirements for medical examination of persons delivered in a severe unconscious state. In a specialized healthcare organization, when a person is delivered in a serious, unconscious state, to determine the condition associated with the use of surfactants, a double (with an interval of 30-60 minutes) quantitative study shall be carried out for the presence of surfactants in biological fluids of the body (blood, urine, saliva). In a specialized healthcare organization, at the time of rendering medical care, a record shall be made in the patient's medical record about the presence (absence) of a person's state of intoxication or the fact of using psychoactive substances based on the results of a clinical examination and laboratory			

	testing of biological samples, but conclusion shall not be drawn up		
38	Availability of supporting documentation on compliance with the requirements for the conditions of laboratory research or rapid testing of biological media. Conducting laboratory research or express testing of biological media (blood or urine if alcohol intoxication is suspected, urine if drug or substance abuse is suspected) shall be carried out in the following cases: 1) the impossibility of a full examination due to the severity of the condition of the person being examined; 2) if a medical worker has doubts about a comprehensive assessment of the state of intoxication (mental, behavioural, vegetative and somatoneurological disorders); 3) disagreement of the examinee with the results of the Conclusion; 4) re-examination; 5) upon establishing the fact of the use of surfactants and the absence of signs of intoxication (mental, behavioural, vegetative and somatoneurological disorders); 6) in case of a traffic accident or commission of an offence with injured persons; 7) if more than 3 (three) hours have passed since the commission of a traffic accident and offence without victims		

39	Availability of supporting documentation of compliance with the requirements for laboratory research or rapid testing of biological media. The nature and sequence of biological samples shall be determined by the medical worker conducting the examination, depending on the characteristics of the clinical condition of the person being examined. Sealing and labelling of selected biological samples for laboratory research shall be carried out in the presence of the examinee and the person who sent and (or) delivered the examinee. In cases where the person being examined is not able to objectively assess the events taking place, this procedure shall be carried out in the presence of witnesses (disinterested persons)			
40	Availability of supporting documentation of compliance with the requirements for conducting a quantitative test of exhaled air for alcohol. When conducting a medical examination to establish the fact of alcohol consumption and the state of alcohol intoxication, a quantitative test of exhaled air for alcohol shall be carried out. The examination of exhaled air for the presence of alcohol shall be carried out using technical measuring instruments officially registered in the Republic of Kazakhstan.			

	If a full examination is not possible due to mental and (or) somatoneurological disorders, or the person's refusal to undergo an examination, the Conclusion shall indicate the reasons for the impossibility of conducting a full examination		
41	Availability of supporting documentation of compliance with the requirements for registration of refusal of medical examination If a person refuses a medical examination, the medical worker shall fill out paragraph 1 of the Conclusion and put the signatures of witnesses (disinterested persons). The presence of witnesses (disinterested persons) in the case where the person being examined is unable to assess the events taking place or refuses to undergo a medical examination shall be ensured by the persons on whose initiative the examination is carried out.		
	Availability of supporting documentation on compliance with the requirements for establishing the condition of the person being examined. When drawing up the Conclusion and when conducting a full examination and the person 's consent to the examination, the medical worker shall establish one of the following conditions based on the available clinical and (if necessary) laboratory data or the results of rapid testing		

42	confirming the type of psychoactive substance that caused intoxication: 1) sober; 2) fact of the use of surfactants, signs of intoxication were not identified; 3) alcohol intoxication (mild, moderate, severe); 4) state of intoxication (narcotic, toxicomaniacal) caused by the use of surfactants (drugs - opioids , cannabinoids, cocaine; sedatives, hypnotics; psychostimulants; hallucinogens; volatile solvents)		
43	Availability of supporting documentation of compliance with the requirements for drawing up the Medical Examination Report. The conclusion shall be drawn up in 3 (three) copies, certified by the signature of a medical worker and the seal of the medical organization in which the examination was carried out. One copy shall be issued to the person who brought the person being examined, or to the person who came for the examination on their own, the second copy shall remain in the medical organization and be stored in the archive for 5 (five) years, the third copy shall be is given to the person brought for the medical examination. In the absence of an accompanying person, a copy of the Conclusion, upon an official written request of the person who sent for the medical examination, shall be sent		

	by mail or to the specified email address. The results of the examination shall be communicated to the person being examined immediately in the presence of the person who sent and (or) delivered it. In cases where the Conclusion is issued after receiving the results of laboratory tests, a copy of the Conclusion shall be issued no later than 5 working days from the date of receipt of the results of laboratory tests. If the person being examined or the official who delivered him disagrees with the results of the medical examination, a second medical examination shall be carried out		
44	Availability of supporting documentation of compliance with the requirements for repeated medical examination. A repeated medical examination shall be carried out no later than 2 (two) hours after the initial examination.		
Requirements for subjects (objects) providing temporary adaptation and detoxification			
45	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
	Availability of supporting documentation on compliance with the requirements for organizing the activities of the temporary adaptation and detoxification centre:		

46	A person suspected of being intoxicated shall be transported to the Central Administrative Administrative District by employees of the internal affairs bodies. Upon delivery, internal affairs officers shall: 1) assist medical personnel during examination and placement in the Central Medical Administrative Centre; 2) carry out the seizure of firearms, bladed weapons, explosives, toxic and poisonous substances, and other items prohibited for circulation in the Republic of Kazakhstan.		
47	Identification by employees of the internal affairs bodies of the person delivered and notification to the medical personnel of the Central Military District. The absence of documents proving the identity of the person delivered shall not serve as a basis for refusing to place him/her in the TADT (Temporary Adaptation and Detoxification Centre).		
48	Registration of a person admitted with suspicion of alcohol intoxication in the register of admissions and refusals to hospitalization according to the approved form After registration of the delivered person, a psychiatrist (narcologist) shall conduct a medical examination to determine the presence of indications and contraindications for placement in the TADT.		
	The results of the medical examination shall be		

49	documented in the conclusion of the medical examination conducted at the Central Medical Examination Centre (hereinafter referred to as the Conclusion) in the approved form The conclusion shall describe the clinical condition with the following conclusions: subject to placement in the TADT; denied placement in the TADT. The conclusion shall be drawn up in two copies, which shall be certified by the signature of a psychiatrist (narcologist). One copy of the conclusion shall be issued to the internal affairs officer who carried out the delivery, the second copy shall be stored in the Central Military Administrative District. The conclusion shall be attached to the patient's chart at the temporary adaptation and detoxification centre.		
50	Registration by medical personnel of personal belongings, documents, money and other valuables in the journal for registering documents and personal belongings of patients according to the form before placing the patient in the TADT. The clothes of patients placed in the TADT shall be stored in individual closets. Documents, money , and other valuables shall be stored in metal cabinets (safes) in appropriate containers. The wardrobe		

	and individual containers shall have the same serial number.		
51	Availability of a card placed in the TADT, located in the centre of temporary adaptation and detoxification (hereinafter referred to as the Patient's card). If there are medical indications, treatment shall be prescribed. The doctor's prescriptions shall be entered into the patient's chart. The frequency of medical examinations shall depend on the patient's condition.		
52	The patient shall be discharged by a psychiatrist (narcologist) as planned when an improvement in condition is achieved that does not require further observation and treatment in a TADT within 24 (twenty-four) hours from the date of admission. Upon discharge, a corresponding entry shall be made in the patient's chart and the log of admissions and refusals of hospitalization.		
53	Written confirmation from the patient that upon receipt of his/her documents and personal belongings, all documents and personal belongings were received in accordance with the entry in the register of documents and personal belongings of patients, except for things the storage of which is illegal.		
Requirements for subjects (objects) providing medical examination and gender reassignment for persons with gender identity disorders			
	Availability of supporting documentation on the provision of medical care included in the guaranteed		

54	volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
55	Availability of supporting documentation of compliance with the requirement to conduct a medical examination of persons with gender identity disorders for gender reassignment: A person with gender identity disorders, who has reached the age of twenty-one, is legally competent, except for a person with mental and behavioural disorders (diseases) (hereinafter referred to as MBD), who wishes to undergo a gender change (hereinafter referred to as the Person being examined), shall submit a written application to an organization providing medical assistance in the field of mental health (hereinafter referred to as a Medical organization). A psychiatrist shall conduct an examination and study of the available documents of the person being examined to establish MBDs that are contraindications for gender reassignment.		
56	Referral by a psychiatrist of the person being examined, if there are doubts about the mental state, for an inpatient examination at a medical organization		
	Referral of the person being examined by a psychiatrist, in the absence of MBD, which are contraindications for gender reassignment, to the		

57	clinic at the place of residence for a medical examination After passing a medical examination, the psychiatrist shall send the person being examined for a medical examination by a commission approved by the head of the medical organization.		

Official(s)_____ _____
position signature

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surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

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surname, first name, patronymic (if any)

Annex 11
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 11 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2003 № 91 (shall be enforced upon the expiration of ten calendar days after the day of its first official publication).

in the field of quality of medical services

_____
in accordance with Article 138

_____
of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____
subjects (objects) providing laboratory services
name of a homogeneous group of subjects (objects) of control

_____
State body that appointed inspection/preventive control

with a visit to the subject (object) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____

_____ №, date

Name of the subject (object) of control _____

_____

(Individual identification number), business identification number of the subject (object) of control

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Location address

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№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
2	Availability of written voluntary consent of the patient or his/her legal representative for invasive interventions and for carrying out therapeutic and diagnostic measures		
3	The presence of a biosafety specialist among the personnel of the laboratory (if the laboratory personnel has more than twenty full-time positions)		
4	Availability of portable test strip analyzers in primary health care organizations		

5	The presence at the hospital level in healthcare organizations as part of a consultative and diagnostic laboratory (hereinafter referred to as the CDL) of an additional unit created or a separate express laboratory at intensive care units to perform emergency and emergency laboratory tests in the shortest possible time from taking a sample to reporting the result (within 15- 60 minutes). To urgently assess the pathological condition of patients, general clinical and biochemical studies shall be carried out, including rapid tests. Laboratory diagnostics by the express laboratory shall be carried out in various emergency conditions (during surgical interventions, provision of anaesthesia, and management of patients in intensive care units) around the clock. In the absence of an express laboratory in healthcare organizations providing inpatient care in the evening and at night, as well as on Sundays and holidays, work in the clinical laboratory shall be provided by an on-duty team consisting of doctors and laboratory assistants		
6	Implementation of processes for managing the quality of clinical laboratory research according to the principle of stages, which shall include pre-analytical, analytical and post-analytical stages of laboratory research		

7	Use of certified and registered in the Republic of Kazakhstan equipment, diagnostic reagent kits, test systems and consumables to perform research		
8	Availability of a laboratory information system		
9	Conducting internal laboratory quality control of research		
10	Compliance with triple packaging and temperature conditions when transporting biomaterial, including by road, air and rail		
11	Availability of supporting documentation on compliance with the algorithm for analytical quality control in laboratory diagnostics		
12	Availability of an agreement for the provision of paid medical services in healthcare organizations. Availability of documents establishing the fact of co-payment		
13	Availability of supporting documentation on the competence and quality of laboratory diagnostics		
14	Documentation of laboratory diagnostics		

Official(s)_____ _____
position signature

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surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

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surname, first name, patronymic (if any)

Annex 12
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018

№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 12 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2003 № 91 (shall come into effect ten calendar days after the day of its first official publication).

in the field of quality of medical services

_____

in accordance with Article 138

_____

of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____

subjects (objects) providing emergency medical care and medical care in the form of medical aviation name of a homogeneous group of subjects (objects) of control

_____

State body that appointed the inspection/preventive control with a visit to the subject (object) of control

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Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____

_____ №, date

Name of the subject (object) of control _____

_____

(Individual identification number), business identification number of the subject (object) of control _____

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Location address _____

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№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4

General requirements			
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
2	Availability of supporting documentation on the compliance of the treatment and diagnostic measures carried out with the recommendations of clinical protocols		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the total number of identified violations, their structure, possible causes and solutions; 1) the number of identified violations that resulted in a deterioration in health; The service shall carry out an examination: in emergency medical services organizations, an examination of the quality of medical services (assistance) of at least 10% of serviced calls per quarter , including all cases: of visiting a patient after refusal of hospitalization by a medical organization providing inpatient care; the refusal of medical care indicating the possible consequences, recorded in medical documents, including in electronic form, signed by the patient		

3	or his/her legal representative, as well as a medical professional; refusal by the patient or his /her legal representative to sign a refusal of medical care, with a corresponding entry about this in the medical documentation, including in electronic form, signed by a medical professional; repeated calls to the same patient for the same disease within 24 hours from the moment of the first call, except for the following cases: mortality during calls: death before the arrival of the emergency team, death in the presence of the emergency team; The results of the internal examination, including their comparison with the results of the external examination, shall be presented and discussed at meetings of the Service, intra-hospital commissions, at medical conferences with the subsequent adoption of organizational decisions, to increase the level of knowledge of medical workers and develop optimal approaches to the diagnostic and treatment process, which shall be documented in a protocol. Based on the results of the internal examination, the Service shall make monthly proposals to the head of the medical organization to eliminate the identified causes and conditions for reducing the quality of the medical services (assistance) provided.		
For emergency medical services			

4	Equipping ambulance vehicles with radio communications and navigation systems		
5	The presence in the emergency medical service of regions, cities of republican significance and the capital of an automated control system for receiving and processing calls and systems that allow monitoring of ambulance vehicles through navigation systems , as well as a system for computer recording of dialogues with subscribers and an automatic identification of the telephone number from which a call comes in. Dialogue recordings shall be stored for at least 2 years.		
6	Availability of regional Call centres (call centres) as part of regional emergency medical care stations and emergency medical care stations in cities of republican significance and the capital		
7	Compliance with a five-minute processing time for an emergency medical call from the moment it is received by the dispatcher, during which sorting shall be carried out according to the category of urgency of the call.		
8	Compliance with the time of arrival of the emergency team to the patient's location from the moment of receiving a call from the dispatcher according to the list of categories of urgency of emergency medical calls (from 10 minutes to 60 minutes)		

9	Correct determination by the emergency medical service dispatcher of calls by urgency category according to: 1) call of 1 (first) category of urgency - the patient's condition poses an immediate threat to life, requiring immediate medical care; 2) call of 2 (second) category of urgency - the patient's condition poses a potential threat to life without medical assistance; 3) call of 3 (third) category of urgency - the patient's condition posing a potential threat to health without medical assistance; 4) call of the 4th (fourth) category of urgency - the patient's condition caused by an acute disease or exacerbation of chronic disease, without sudden and pronounced disorders of organs and systems, in the absence of an immediate and potential threat to the life and health of the patient.		
10	The paramedic or doctor of the emergency medical service team or emergency medical service department when organizing primary health care shall make one of the following decisions based on the results of examination, instrumental diagnostics, the dynamics of the patient's condition against the background or after the treatment measures taken, in accordance with the preliminary diagnosis reflecting the causes of this condition: - transportation of the patient to a medical organization providing		

	inpatient care (hereinafter referred to as the Hospital); - the patient is left at the place of call; - the patient is left at home (at his/her place of residence)		
11	Availability of medical recommendations for further contact with the primary health care organization (at the place of residence or attachment in the case of leaving a patient who does not need hospitalization at the place of call or home, the emergency medical service team or the emergency medical service department at the primary health care organization shall be provided		
12	Availability of a signal sheet for the patient in case the patient becomes ill and needs to be visited at home by a local doctor		
13	Availability of recording the following data when a call is received by the dispatch service of the emergency medical service station: 1) last name, first name, patronymic (if any), age and gender of the patient; 2) data on the patient's condition and the circumstances of the accident, injury or illness; 3) address and telephone number, as well as approximate travel information to the patient's location.		
	Compliance with the time of arrival of paramedics and specialized (medical) teams to the patient's location from the moment of receiving a call from the emergency medical station		

14	dispatcher, taking into account the category of urgency: 1) 1st category of urgency – up to ten minutes; 2) 2nd category of urgency – up to fifteen minutes; 3) 3rd category urgency - up to thirty minutes; 4) 4th category urgency - up to sixty minutes		
15	Availability of informing the emergency medical service dispatcher of the hospital admission department about the delivery of the patient in the event of a decision by the emergency medical service team or the emergency medical service department when organizing primary health care to transport the patient to the hospital		
16	Availability of a minimum list of medical devices for ambulance transport of an ambulance station in classes A, B and C		
For medical assistance in the form of air ambulance			
17	Availability of an assignment for a medical flight in form № 090/y		
18	Availability of supporting documentation about the mobile medical aviation team conducting an ongoing assessment of the condition and treatment of the patient(s) when transporting the patient (s) according to the relevant clinical protocols for diagnosis and treatment		
	Availability of grounds for the provision of medical care in the form of medical aviation (extract from the medical record of a patient in need of medical care in the form of medical		

19	aviation; application from the coordinating doctor of the medical aviation department to the dispatcher of the Coordinating organization; in emergency cases, an oral order from the authorized body, with written confirmation; call from the ambulance service and other emergency services)		
20	Availability of approval by the dispatcher of the Coordinating organization of the composition of the mobile medical aviation team and the involved qualified specialized expert (s) from medical organizations in the region with obtaining their informed consent		
21	Availability of a schedule of qualified specialists in the provision of medical care in the form of medical aviation approved by healthcare entities and medical education organizations in the Coordinating Organization		
22	Availability of informed consent of the patient(s) for the provision of medical care in the form of medical aviation during its transportation. Concerning minors and citizens recognized by the court as incompetent, consent shall be provided by their legal representatives. The provision of medical care to unconscious patients shall be made by a decision of the council or a doctor of a regional medical organization, or a mobile medical aviation team, or a qualified specialist with notification in any form to		

	officials of the medical organization.		

Official(s)_____ _____
position signature

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surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

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surname, first name, patronymic (if any)

Annex 13
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Annex 13 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2003 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2003 № 91 (shall come into effect ten calendar days after the day of its first official publication).

in the field of quality of medical services

_____
in accordance with Article 138

_____
of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____
subjects (objects) carrying out activities in the field of
HIV prevention name of a homogeneous group of subjects (objects) of control

_____
State body that appointed the inspection/preventive control
with a visit to the subject (object) of control

_____
Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____
_____№, date

Name of the subject (object) of control _____

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(Individual identification number), business identification number
of the subject (object) of control _____

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Location address _____

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№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
2	Conducting an examination using the rapid testing method with registration in the HIV research journal using the express testing method. In case of a positive result of the rapid test, with the informed consent of the person being tested and the availability of an identity document, an examination for HIV infection shall be carried out in accordance with the procedure for diagnosing HIV infection in adults and children over 18 months.		
3	Availability of a written notification from a health care organization that, during a medical examination, revealed the fact of HIV infection in the subject about the result obtained, about the need to take precautions aimed at protecting one's health and the health of others, as well		

	as a warning about administrative and criminal liability for evading treatment and infecting others persons with the patient signing a confidential interview sheet with a person infected with HIV in accordance with form № 095/y		
4	Availability of supporting documentation on compliance with the deadlines for issuing negative results. The subject receives a negative result at the place of blood sampling upon presentation of an identity document or an electronic document from the digital document service within 3 (three) working days from the date of receipt of the blood sample for testing in the laboratory.		
5	Availability of supporting documentation on compliance with the deadlines for sending serum samples to the republican state health care organization. Upon receipt of two positive test results, a serum sample with a volume of at least 1 (one) ml shall be sent to the republican state Healthcare Care organization laboratory for confirmatory studies no later than three working days from the date of the last diagnosis.		
	Availability of supporting documentation on compliance with the deadlines for re-examination in case of doubtful results. If conflicting research results are obtained, the result shall be considered		

6	doubtful. After 14 (fourteen) calendar days, blood shall be taken again and tested for HIV infection, according to the first stage of diagnosing HIV infection in adults (the republican state health care organization shall transmit information about a questionable result for HIV infection to the territorial state health care organization carrying out activities in the field of prevention HIV infection, for re-examination for HIV infection). If a second doubtful result for HIV infection is received after 14 (fourteen) calendar days, additional studies shall be carried out using other serological tests. A negative result shall be issued based on two negative results out of three studies performed. A positive result shall be given based on two positive results out of three studies performed. When examining pregnant women, molecular biological tests shall additionally be used (quantitative determination of HIV ribonucleic acid with a test sensitivity of no more than 50 copies/ml or determination of proviral HIV deoxyribonucleic acid).		
	Availability of pre-test and post-test counselling. Pre-test counselling shall be provided through visual aids displayed in waiting areas. Pre-test counselling shall include: 1) information about the benefits of testing for HIV infection, modes of		

7	transmission and the meaning of HIV-positive and HIV-negative test results; 2) an explanation of available services in the event of an HIV-positive diagnosis, including an explanation of free receipt of antiretroviral therapy; 3) a brief description of methods of prevention and examination of a partner in case of a positive test result for HIV infection; 4) guarantee of confidentiality of test results. Availability of post-test counselling for those examined. Post-test counselling shall include: 1) informing the patient of the test result and the meaning of the result; 2) information about the possibility of being in the seronegative window (if the result is uncertain or negative) and the need for re-examination for HIV infection; 3) explaining the possibilities of reducing the risk of infection through behaviour change; 4) informing about the possibilities of additional medical care for key populations, psychosocial assistance; 5) psychological assistance and support.		
8	Sending by a health care organization operating in the field of HIV prevention to the territorial state body in the field of sanitary and epidemiological welfare an emergency notification in form № 034/y for each case of HIV infection		

	allegedly associated with the provision of medical care (in-hospital)		
9	Availability of a Sheet for a confidential interview with a person infected with HIV, Form № 095/y, which shall include: consent to enter personal data into electronic informational resources. In case of refusal to enter personal data into the ES system, data shall be entered that includes the immunoblotting number (hereinafter referred to as IB), the IB date, initials, date of birth, and epidemiological history data.		
10	Monitoring and assessment of the coverage of key population groups and people living with HIV infection shall be carried out by maintaining a database of individual records of clients and appropriate forms of accounting and reporting documentation by specialists of health care organizations carrying out activities in the field of HIV prevention		
11	Transfer by the employer of medical workers with an established diagnosis of HIV infection to another job that does not involve violating the integrity of the skin or mucous membranes		
12	Availability of supporting documentation on the diagnosis and treatment of STIs. In friendly offices, STIs shall be diagnosed and treated according to		

	clinical protocols for the diagnosis and treatment of STIs		
13	Availability of equipped transport for mobile trust points		
14	Availability of supporting documentation on the implementation of pre-exposure and post-exposure prophylaxis among the population and key populations		
15	Availability of monitoring contacts on time. Contacts shall be monitored in a healthcare organization that carries out activities in the field of HIV prevention. The duration of observation of contacts shall be established for: 1) children born from HIV-infected mothers – eighteen months; 2) medical workers in case of an emergency – three months; 4) recipients of donor biomaterial – three months; 5) sexual partners of HIV-infected persons and contacts for joint injection of drugs - until they receive a negative test result for HIV infection 3 months after the end of the contract ; if contact continues, contacts shall be examined for HIV infection 2 times a year; 6) persons from an intra-hospital outbreak - three months after discharge from a medical organization; If more than three months have passed since discharge, contacts undergo a one-time examination; if the result is negative, the observation shall be terminated.		

16	Availability of dynamic monitoring and provision of antiretroviral therapy for HIV-infected persons. The results of laboratory examinations of contacts are recorded in the outpatient card of an HIV-infected person registered at a dispensary (discordant couples). The HIV-infected person dynamically shall submit data on changes in marital status, last name, first name , patronymic (if any), and data on new contact persons for examination and observation, which shall be entered into the electronic tracking database. The provision of antiretroviral therapy to reduce the risk of HIV transmission from the moment of diagnosis shall be carried out according to the recommendations of clinical protocols for the diagnosis and treatment of HIV infection in adults and children, with the involvement of outreach services workers and social workers.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which shall be assessed according to the following criteria: lack of medical history; completeness of anamnesis collection;		

	availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which shall be assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be			

	taken into account), which are assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) shall be reflected in the results of the examination. The impact of incorrect and (or) untimely diagnosis on subsequent stages of the provision of medical services (assistance) shall be assessed; 4) timeliness and quality of consultations of specialized experts, which are assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms			
17				

	and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated; prescribing treatment in the absence of indications; prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications		

	without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and preventive measures without taking into account the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences;			

	8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		

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surname, first name, patronymic (if any)
Head of the subject of control _____ _____
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surname, first name, patronymic (if any)

Annex 14
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR DSM-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist

Footnote. Appendix 14 - as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29/05/2023 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 05/29/2023 № 91 (shall come into effect upon the expiration of ten calendar days after the day of its first official publication).

in the field of quality of medical services

_____
in accordance with Article 138

_____
of the Entrepreneurial Code of the Republic of Kazakhstan concerning

_____
subjects (objects) operating in the field of blood service
name of a homogeneous group of subjects (objects) of control

_____
State body that appointed the inspection/preventive control

with a visit subject (object) of control

_____

_____

Act on the appointment of an inspection/preventive control with a visit to the subject (object) of control

_____

_____ №, date

Name of the subject (object) of control _____

_____

(Individual identification number), business identification number
of the subject (object) of control _____

_____

Location address _____

_____

_____

№	List of requirements	Meets requirements	Does not meet requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
2	Availability of supporting documentation on compliance in the organization of the blood service with the requirements for step-by-step labelling of blood and its components. Providing conditions for traceability of the movement of each blood product from the donor to the receipt of the finished product and its use		
	Availability of supporting documentation confirming compliance with the requirements for laboratory testing of the recipient's		

3	blood samples for the availability of markers of blood-borne infections before and after transfusions carried out using high-quality immunoserological and molecular biological methods on closed-type automatic analyzers.		
4	Availability of registration in the electronic information database after the donation of blood and its components of all information about the donation of blood and its components, including the type of reaction and volume of medical care provided, in case of side effects of donation, compliance of documents for transfer to the primary fractionation unit with accompanying documentation collected blood and its components		
5	Availability of blood and its components donor questionnaire provided to the donor, which he/she fills out independently or with the participation of a medical registrar, as well as an information sheet		
6	Availability of supporting documentation on compliance with the requirements for performing immunohematological studies for the availability of irregular anti-erythrocyte antibodies in liquid-phase systems on a plane and in test tubes, reading the result of an agglutination reaction with mandatory microscopy.		
	Availability of supporting documentation on compliance with the		

7	requirements for incoming and daily in-laboratory quality control of reagents to confirm their activity and specificity. The following shall be subject to incoming control: 1) purchased materials (containers for blood collection, reagents, test systems, disinfectants, instruments and other materials), the nomenclature of which is approved by the first head of the blood service organization; 2) units of donor blood and its components (upon acceptance for production)		
8	Placement of blood collected on-site in thermal containers marked " Unexamined blood products, not subject to issue" and at a temperature of 22±2°C shall be delivered within 18-24 hours to the blood service organization		
9	Use of reagents with monoclonal antibodies and equipment registered by the state body in the field of circulation of medicines and medical devices for immunohematological studies of blood samples of potential recipients		
10	Availability of supporting documentation on compliance with the requirements of blood transfusion and its components		
11	Availability of supporting documentation on compliance with the requirements for the donor to undergo a mandatory medical examination before donating blood and its components within the		

	framework of the guaranteed volume of free medical care		
12	Compliance with requirements for medical examination of donors, safety and quality in the production of blood products for medical use		
13	Availability of supporting documentation on compliance with the requirements of external assessment of the quality of laboratory research measurements in reference laboratories		
14	Compliance with the requirements for incoming and daily in-laboratory quality control of reagents to confirm their activity and specificity.		
15	Availability of a blood donor and its components questionnaire provided to the donor, which he/she fills out independently or with the participation of a medical registrar.		
16	The following shall be subject to incoming control : 1) purchased materials (containers for blood collection, reagents, test systems, disinfectants, instruments and other materials), the nomenclature of which shall be approved by the first head of the blood service organization;		
17	Compliance with requirements for medical examination of donors, safety and quality in the production of blood products for medical use		
	Availability of documentation (internal orders, regulations,		

	protocols, questionnaires, analytical reports) on the conduct of a clinical audit by the Patient Support and Internal Expertise Service and its assessment according to the following criteria: 1) the quality of medical history collection, which is assessed according to the following criteria: lack of medical history; completeness of anamnesis collection; availability of data on past, chronic and hereditary diseases, blood transfusions, drug tolerance, and allergy status; the development of complications as a result of tactical errors made during therapeutic and diagnostic measures due to poor quality history taking; 2) completeness and validity of diagnostic studies, which are assessed according to the following criteria: lack of diagnostic measures; incorrect conclusion or lack of conclusion based on the results of diagnostic studies, which led to incorrect diagnosis and errors in treatment tactics; carrying out diagnostic studies provided for by clinical protocols; conducting diagnostic studies with a high, unjustified risk for the patient's health, the validity of conducting diagnostic studies that are not included in the clinical protocols; carrying out diagnostic studies that are not informative for making a			

	correct diagnosis and lead to an unreasonable increase in treatment time and an increase in the cost of treatment; 3) the correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the studies performed (for planned hospitalization, studies carried out at the pre-hospital stage shall be taken into account), which shall be assessed according to the following criteria: the diagnosis is missing, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome that determines the severity of the disease has not been identified, and concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome for the identified complications has not been identified, and concomitant diseases affecting the outcome have not been recognized; the diagnosis of the underlying disease is correct, but concomitant diseases that affect the outcome of treatment have not been diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the underlying disease, asymptomatic course of the concomitant disease, rare complications and concomitant diseases) are reflected in the results of the examination. The		

18		impact of incorrect and (or) untimely diagnosis on subsequent stages of the provision of medical services (assistance) is assessed; 4) timeliness and quality of consultations of specialized experts, which shall be assessed according to the following criteria: lack of consultation, which led to an erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; the consultation was timely, failure to take into account the consultant's opinion when making a diagnosis partially influenced the outcome of the disease; the consultation was timely, the consultant's opinion was taken into account when making the diagnosis, failure to follow the consultant's treatment recommendations partially influenced the outcome of the disease; The consultant's opinion was erroneous and influenced the outcome of the disease. Availability of supporting documentation on the assessment of the objectivity of the reasons for untimely consultation and the impact of the untimely diagnosis on subsequent stages of the provision of medical services (assistance); 5) volume, quality and validity of treatment measures, which are assessed according to the following criteria: lack of treatment when indicated;		

	prescribing treatment in the absence of indications; prescribing ineffective treatment measures without taking into account the specific course of the disease, concomitant diseases and complications; implementation of therapeutic measures not in full, without taking into account the functional state of organs and systems, prescribing medications without proven clinical effectiveness; unreasonable deviation from the requirements of clinical protocols, the presence of polypharmacy, which led to the development of a new pathological syndrome and deterioration of the patient' s condition; 6) the absence or development of complications after medical interventions, all complications that have arisen are assessed, including those caused by surgical interventions (late surgical intervention, inadequate volume and method, technical defects) and diagnostic procedures; 7) the achieved result, which is assessed according to the following criteria: achieving the expected clinical effect while observing the technology for providing medical services (assistance); lack of clinical effect of therapeutic and preventive measures due to poor quality history taking and diagnostic studies; lack of the expected clinical effect due to ineffective therapeutic and		

	preventive measures without taking into account the characteristics of the course of the disease, concomitant diseases, complications, and prescription of medications without proven clinical effectiveness; the presence of polypharmacy, which led to the development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the presence, completeness and quality of records in the primary medical documentation intended to record data on the health status of patients, reflecting the nature, volume and quality of medical care provided		

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surname, first name, patronymic (if any)
Head of the subject of control _____ _____
position signature

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surname, first name, patronymic (if any)

Appendix 15
to the joint order of the Minister
of Healthcare of the Republic of
Kazakhstan
dated November 15, 2018
№ KR HCM-32 and
the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 № 70

Criteria for assessing the degree of risk in the sphere of circulation of medicines and medical devices Chapter 1. General provisions

1. These Criteria for assessing the degree of risks in the sphere of circulation of medicines and medical devices (hereinafter - the Criteria) have been developed in accordance with subparagraph 16) of Article 10 of the Code of the Republic of Kazakhstan “On Public Health

and Healthcare System", paragraphs 5 and 6 of Article 141 and paragraph 1 Article 143 of the Entrepreneurial Code of the Republic of Kazakhstan, the Rules for the formation of risks assessment and management system by regulatory state bodies, approved by order of the acting Minister of National Economy of the Republic of Kazakhstan dated June 22, 2022 № 48 (registered in the Register of state registration of regulatory legal acts under № 28577) and by order of the acting Minister of National Economy of the Republic of Kazakhstan dated July 31, 2018 № 3 "On approval of the checklist's form" (registered in the Register of state registration of regulatory legal acts under № 17371).

2. The following concepts are used in these Criteria:

1) a point – a quantitative measure of risk calculation;

2) data normalization – a statistical procedure that involves bringing values measured on various scales to a conventionally common scale;

3) risk - the probability of causing harm as a result of the activities of the subject of control of human life or health, the environment, the legitimate interests of individuals and legal entities, the property interests of the state, taking into account the severity of its consequences;

4) risks assessment and management system - the process of making management decisions aimed at reducing the probability of adverse factors occurring by distributing subjects (objects) of control according to risk levels for subsequent implementation of preventive control with a visit to the subject (object) of control and (or) inspections conducted for compliance with qualification or permitting requirements for issued permits, requirements for sent notifications in accordance with the Law of the Republic of Kazakhstan "On Permits and Notifications" (hereinafter - verification of compliance with the requirements) in order to limit the freedom of entrepreneurship to the minimum possible extent, while ensuring an acceptable level of risk in the relevant areas of activity, as well as those aimed at changing the level of risk for a specific subject (object) of control and (or) exemption of such subject (object) of control from preventive control with a visit to the subject (object) of control and (or) inspections for compliance with requirements;

5) objective criteria for assessing the degree of risk (hereinafter - objective criteria) - criteria for assessing the degree of risk used to select subjects (objects) of control depending on the degree of risk in a certain field of activity and not directly dependent on the individual subject (object) of control;

6) criteria for assessing the degree of risk - a set of quantitative and qualitative indicators related to the direct activities of the subject of control, features of industry development and factors influencing this development, allowing the subjects (objects) of control to be assigned to various degrees of risk;

7) subjective criteria for assessing the degree of risk (hereinafter - subjective criteria) - criteria for assessing the degree of risk used for selecting subjects (objects) of control and depending on the results of the activities of a particular subject (object) of control;

8) a checklist - a list of requirements for the activities of subjects (objects) of control, non-compliance with which entails a threat to human life and health, the environment, the legitimate interests of individuals and legal entities, the state;

9) sample set (sample) – a list of assessed subjects (objects) classified as a homogeneous group of subjects (objects) of control in a specific area of state control, in accordance with paragraph 2 of Article 143 of the Entrepreneurial Code of the Republic of Kazakhstan.

Chapter 2.
The procedure for forming risks assessment and management system when conducting preventive control of subjects (objects) of control

3. Risks management when carrying out preventive control with a visit to the subject (object) of control shall be formed by determining objective and subjective criteria, which are carried out in stages (multi-criteria analysis of decisions).

At the first stage, according to objective criteria, subjects (objects) of control are distributed to one of the following degrees of risk:

1) high risk;

2) medium risk;

3) low risk.

According to the indicators of the degree of risk according to subjective criteria, the subject (object) of control refers:

1) to a high degree of risk - with a risk degree indicator from 71 to 100 inclusive;

2) to an average degree of risk - with a risk degree indicator from 31 to 70 inclusive;

3) to a low degree of risk - with a risk degree indicator from 0 to 30 inclusive.

4. Criteria for assessing the degree of risk for conducting preventive control of subjects (objects) of control shall be formed by defining objective and subjective criteria.

Paragraph 1. Objective criteria

5. Determination of risk according to objective criteria shall be carried out depending on the specifics of the area in which state control is carried out, taking into account one of the following criteria:

1) level of danger (complexity) of the object;

2) the scale of severity of possible negative consequences, harm to the regulated area (region);

3) the possibility of an unfavorable incident for human life or health, the legitimate interests of individuals and legal entities, and the state.

6. After analyzing possible risks, subjects (objects) of control shall be distributed into three degrees of risk according to objective criteria (high, medium and low).

7. A high degree of risk includes subjects (objects) of control carrying out activities related to:

1) production of medicines;

2) manufacturing of medicines;

3) wholesale sales of medicines;

4) production of medical devices;

5) manufacturing of medical devices;

8. A medium degree of risk includes subjects (objects) of control:

1) subjects in the field of circulation of medicines and medical devices that carry out retail sales of medicines;

2) healthcare organizations providing outpatient care;

3) healthcare organizations providing inpatient care and (or) inpatient replacing care;

4) healthcare organizations providing emergency medical care and (or) air ambulance services;

5) healthcare organizations engaged in the procurement, preservation, processing, storage, and sale of blood and its components.

9. A low degree of risk includes subjects (objects) of control:

1) subjects in the field of circulation of medicines and medical devices carrying out retail sales of medicines and having a certificate of good pharmacy practice (GPP);

2) subjects (objects) of control carrying out pharmaceutical activities related to the wholesale and retail sale of medical devices.

10. For subjects (objects) of control classified as high and medium degree of risk according to objective criteria, an inspection for compliance with requirements, preventive control with a visit to the subject (object) of control, preventive control without a visit to the subject (object) of control and an unscheduled inspection shall be conducted.

11. For areas of activity of subjects (objects) of control classified as low degree of risk according to objective criteria, an inspection for compliance with the requirements of preventive control without a visit to the subject (object) of control and an unscheduled inspection shall be conducted.

Paragraph 2. Subjective criteria

12. The determination of subjective criteria in the field of circulation of medicines and medical devices shall be carried out using the following stages:

1) formation of a database and collection of information;

2) analysis of information and risks assessment.

13. Formation of a database and collection of information are necessary to identify subjects (objects) of control.

The following sources of information shall be used to assess the degree of risk:

1) the results of previous inspections and preventive control with visits to subjects (objects) of control;

2) Note of the ILLI!

Subparagraph 2) shall be enforced from 01.12.2024 by joint order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77.

3) Note the ILLI!

Subparagraph 3) shall be enforced from 01.12.2024 by joint order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77.

4) Note of the ILLI!

Subparagraph 4) shall be enforced from 01.12.2024 by joint order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77.

5) Note of the ILLI!

Subparagraph 5) shall be enforced from 01.12.2024 by joint order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77.

The following sources of information shall be used to assess the degree of risk when creating a schedule for requirements compliance:

1) the results of previous inspections and preventive control with visits to subjects (objects) of control;

2) the presence of adverse incidents that arose through the fault of the subject of control;

3) the presence and number of confirmed complaints and appeals;

4) results of preventive control without a visit to the subject (object) of control (final documents issued based on the results of preventive control without a visit to the subject (object) of control);

14. Based on available sources of information, data according to subjective criteria, subject to analysis and assessment shall be formed.

Analysis and assessment of subjective criteria allow us to concentrate the conduct of inspection for compliance with requirements and preventive control of the subject (object) of control in relation to the subject (object) of control with the greatest potential risk.

At the same time, the data of subjective criteria previously taken into account and used in relation to a specific subject (object) of control or data for which the statute of limitations has expired in accordance with the legislation of the Republic of Kazakhstan shall not be used in the analysis and assessment.

In relation to subjects of control who have fully eliminated the violations issued based on the results of the previous preventive control with a visit and (or) inspection for compliance

with the requirements, their inclusion in the formation of schedules and lists for the next period of state control shall not be allowed.

15. The degree of violations of requirements for subjects (objects) of control in the field of circulation of medicines and medical devices for compliance with qualification requirements shall be determined in accordance with Appendix 1 to these Criteria and the Degree of violation of requirements for subjects (objects) of control in the field of circulation of medicines and medical devices for conducting preventive control of subjects (objects) of control by information sources shall be determined in accordance with Appendix 2 to these Criteria.

16. Based on the priority of the sources of information used and the significance of indicators of the subjective criteria, in accordance with the procedure for calculating the risk degree indicator according to subjective criteria determined in the List of subjective criteria for determining the degree of risk according to subjective criteria in the field of circulation of medicines and medical devices in accordance with Article 138 of the Entrepreneurial Code of the Republic of Kazakhstan in relation to all subjects (objects) in accordance with Appendix 3 to these Criteria, the risk degree indicator shall be calculated according to subjective criteria.

17. Inspection for compliance with requirements and preventive control with a visit to the subject (object) shall be carried out depending on the purpose and types of activity of the objects, in accordance with checklists in the field of circulation of medicines and medical devices according to Appendices 16, 17, 18, 19, 20, 21 and 25 to this joint order.

18. For areas of activity of subjects (objects) of control classified as high-risk, inspections for compliance with requirements shall be determined by criteria, but shall be carried out no more than once a year.

For areas of activity of subjects (objects) of control classified as medium risk, inspections for compliance with requirements shall be determined by criteria, but shall be carried out no more than once every two years.

For areas of activity of subjects (objects) of control classified as low risk, the frequency of inspections for compliance with requirements shall be determined by criteria for assessing the degree of risk, but not more than once every three years.

Chapter 3. The procedure for calculating the degree of risk according to subjective criteria

19. The calculation of the risk degree indicator according to subjective criteria (R) shall be carried out in an automated mode by summing up the risk degree indicator for violations based on the results of previous inspections and preventive control with visits to subjects (objects) of control (SP) and the risk degree indicator according to subjective criteria determined in accordance with paragraph 13 of these Criteria (SC), with subsequent normalization of the values given in the range from 0 to 100 points.

Rinterm = SP + SC, where

Rinterm - an intermediate indicator of the degree of risk according to subjective criteria,

SP – an indicator of the degree of risk for violations,

SC - an indicator of the degree of risk according to subjective criteria determined in accordance with paragraph 13 of these Criteria.

The calculation shall be made for each subject (object) of control of a homogeneous group of subjects (objects) of control of each sphere of state control. In this case, the list of assessed subjects (objects) of control, classified as a homogeneous group of subjects (objects) of control of one sphere of state control shall form a sample set (sample) for subsequent normalization of data.

20. Based on the data obtained from the results of previous inspections and preventive control with visits to subjects (objects) of control, an indicator of the degree of risk for violations shall be formed, assessed in points from 0 to 100.

If one gross violation is detected from any of the sources of information specified in paragraph 16 of these Criteria, the subject of control shall be assigned a risk indicator of 100 points and shall be subject to inspection for requirements compliance or preventive control with a visit to the subject (object) of control.

$SP_н$ – показатель незначительных нарушений;

If gross violations are not detected, the risk level indicator for violations shall be calculated by the total indicator for violations of a significant and minor degree.

When determining the indicator of significant violations, a coefficient of 0.7 shall be applied.

This indicator shall be calculated using the following formula:

$SPs = (SP_2 \times 100/SP_1) \times 0,7$, where:

SPs – an indicator of significant violations;

SP_1 – required number of significant violations;

SP_2 – number of significant violations identified;

When determining the indicator of minor violations, a coefficient of 0.3 shall be applied.

This indicator shall be calculated using the following formula:

SPm = (SP2 x 100/SP1) x 0,3, where:

SPm – an indicator of minor violations;

SP1 – required number of minor violations;

SP2 – number of minor violations identified;

The violation risk indicator (SP) shall be calculated on a scale from 0 to 100 points and shall be determined by summing the indicators of significant and minor violations according to the following formula:

SP = SPs + SPm, where:

SP – an indicator of the risk degree for violations;

SPs – an indicator of significant violations;

SPm - an indicator of minor violations.

The resulting value of the risk degree indicator for violations shall be included in the calculation of the risk degree indicator based on subjective criteria.

21. The calculation of the risk degree indicator according to subjective criteria determined in accordance with paragraph 16 of these Criteria shall be made on a scale from 0 to 100 points and shall be carried out using the following formula:

$$SC = \sum_{i=1}^{n} x_i * w_i, \text{где}$$

xi – an indicator of subjective criterion,

wi – specific weight of the subjective criterion indicator xi,

n – number of indicators.

The resulting value of the risk degree indicator according to subjective criteria, determined in accordance with paragraph 13 of these Criteria, shall be included in the calculation of the risk degree indicator according to subjective criteria.

22. The R indicator values calculated for subjects (objects) shall be normalized to a range from 0 to 100 points. Data normalization shall be carried out for each sample set (sample) using the following formula:

$$R = \frac{R_{\text{пром}} - R_{min}}{R_{max} - R_{min}},$$

R – risk degree indicator (final) according to the subjective criteria of an individual subject (object) of control,

Rmax – the maximum possible value on the risk degree scale according to subjective criteria for subjects (objects) included in one sample set (sample) (upper limit of the scale),

Rmin – the minimum possible value on the risk degree scale according to subjective criteria for subjects (objects) included in one sample set (sample) (lower limit of the scale),

Rinterm - an intermediate indicator of the degree of risk according to subjective criteria, calculated in accordance with paragraph 16 of these Criteria.

Appendix 1
to the criteria for assessing
the degree of risk in the area
of circulation of medicines
and medical devices

The degree of violation of requirements for subjects (objects) of control in the sphere of circulation of medicines and medical devices for compliance with qualification requirements

№	Requirements	Degree of violations
1.	Compliance of a premise or building under the right of ownership or lease or trust management of state property with sanitary rules establishing sanitary and epidemiological requirements for facilities in the field of circulation of medicines and medical devices	gross
2.	Availability of equipment and furniture, inventory, instruments and apparatus to ensure quality control and compliance with the conditions of production, manufacturing, storage and sale of medicines and medical devices	gross
3.	Availability of a motor vehicle with appropriate cabinets, refrigeration, and other equipment, if necessary, ensuring compliance with the conditions of storage and sale of medicines and medical devices for a mobile pharmacy for rural settlements	gross
4.	Availability of a staff of employees with appropriate education, work experience, and specialist certificates for organizations on the production of medicines and medical devices: higher pharmaceutical or chemical-technological, chemical education and work experience in the specialty for at least three years for heads of departments directly involved in the production of medicines and medical devices, or technical for heads of departments directly involved in the production of medical devices;	gross

	higher pharmaceutical or chemical, biological education for workers carrying out quality control of medicines and medical devices, or technical education for workers carrying out quality control of medical devices; technical education for a specialist in the maintenance of equipment used in the technological process of production of medicines and medical devices	
5.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for organizations in the field of circulation of medicines and medical devices that manufacture medicines: higher pharmaceutical education and at least three years of work experience in the specialty for the head of a pharmacy engaged in the manufacture of medicines and its production departments, as well as for the employees who carry out quality control of medicines and medical devices; higher or secondary pharmaceutical education for employees involved in the direct manufacture of medicines and the release of manufactured medicines; secondary pharmaceutical education and at least three years of work experience in the specialty for the head of a pharmacy and its production departments in the absence of specialists with higher pharmaceutical education in the regional center and rural settlements	gross
6.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for pharmacies: higher or secondary pharmaceutical education (work experience in the specialty for at least three years) for the head of a pharmacy or its departments; higher or secondary pharmaceutical education for the specialists selling medicines and medical devices;	gross

	when selling medicines via the Internet, the availability of transport on the right of ownership or lease for delivery in a manner that does not allow changes in their properties during storage and transportation	
7.	Availability of a staff of employees with appropriate education, work experience, and a specialist certificate for a pharmacy in healthcare organizations providing primary health care, consultative and diagnostic care: higher or secondary pharmaceutical education (work experience in the specialty for at least three years) for the head of a pharmacy, as well as for the employees involved in the sale of medicines and medical devices. In pharmacies for rural settlements where there are no pharmacies, in the absence of specialists with pharmaceutical education, specialists with medical education who have been trained to sell them shall be allowed to sell medicines and medical products	gross
8.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for a pharmacy warehouse: higher pharmaceutical education and at least three years of work experience for the head of a pharmacy warehouse; higher or secondary pharmaceutical education for the heads of pharmacy warehouse departments and workers involved in the acceptance, storage and release of medicines and medical devices	gross
9.	Availability of a staff of employees with appropriate education, work experience, and a specialist certificate for a mobile pharmacy for rural settlements: higher or secondary pharmaceutical education for the head of a mobile pharmacy, as well as for the employees involved in the sale of medicines and medical products. In the absence of specialists with pharmaceutical education, specialists	gross

	with a medical education who have been trained for their sale shall be allowed to carry out retail sales of medicines and medical devices	
10.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for the manufacture of medical devices and higher or secondary pharmaceutical, medical or technical education	gross
11.	Availability of specialization or improvement and other types of advanced training over the last 5 (five) years in the declared subtypes of pharmaceutical activities	gross
12.	Availability of higher or secondary pharmaceutical education (work experience in the specialty - at least three years) for individuals applying to engage in pharmaceutical activities without forming a legal entity	gross

Appendix 2
to the criteria for assessing
the degree of risk in the area
of circulation of medicines and
medical devices

The degree
of violation of requirements for subjects (objects) of control in the sphere of circulation of medicines and medical devices for conducting preventive control of subjects (objects) of control by information sources

№	Name of criteria	Degree of violation
Section 1. In relation to medical organizations on the issues of drug provision		
1.	Compliance with the prescription of medicines containing narcotic drugs, psychotropic substances and their precursors during outpatient and inpatient treatment in health care organizations by a doctor of a health care organization who has access to work with narcotic drugs and their precursors	gross
	Compliance with the recording in the patient's medical documents of the prescription of medicines containing narcotic drugs, psychotropic substances and precursors of Tables II, III, IV of the List of narcotic	

2.	drugs, psychotropic substances and precursors subject to control in the Republic of Kazakhstan (hereinafter - the List), indicating a single dose, method and frequency of administration (injection), duration of treatment, as well as justification for prescribing medicines	gross
3.	Ensuring the use (taking) of medicines containing narcotic drugs, psychotropic substances of Tables II, III of the List strictly under the supervision of medical personnel at the time of their issuance: 1) oral administration, application of transdermal therapeutic systems (plaster, film); 2) in the presence of a nurse, injections - in the presence of a doctor	significant
4.	Compliance with the rules and procedures for writing prescriptions for medicines containing narcotic drugs, psychotropic substances and precursors	significant
5.	Availability of a person responsible for storing and issuing special prescription forms	significant
6.	Ensuring subject-quantitative accounting of special prescription forms	gross
7.	Availability of a safe or metal cabinet for storing special prescription forms. Upon completion of work, the room shall be sealed and (or) stamped. The keys to the room, the seal and (or) the stamp shall be kept by the responsible person	gross
8.	Ensuring the storage and destruction of unused special prescriptions given by relatives of deceased patients. Recipes are destroyed as prescriptions accumulate, but at least 1 (one) time per month, by burning in the presence of a permanent commission, which includes a representative of the internal affairs body. The fact of destruction of unused special recipes is in a corresponding act	significant

	The destruction of prescriptions shall be carried out as recipes accumulate, but at least 1 (one) time per month, by burning in the presence of a permanent commission, which includes a representative of the internal affairs body. The fact of destruction of unused special prescriptions shall be documented by an appropriate act	
9.	Availability of a list of medicines containing narcotic drugs, psychotropic substances of Table II of the List, determined by order of the head of the healthcare organization, not exceeding a five-day supply, which is used with the permission of the responsible doctor on duty to provide emergency medical care in a healthcare organization providing inpatient care in the evening and at night	gross
10.	Ensuring the collection and destruction of empty ampoules of medicines containing narcotic drugs, psychotropic substances of Table II of the List, the contents of which are not used or partially used, as well as tablets and patches (transdermal therapeutic systems)	gross
11.	Availability of an order for a medical worker responsible for issuing a temporary death certificate, ensuring notification of relatives of a deceased cancer patient about the delivery of unused special prescription forms and medicines containing narcotic and psychotropic substances of Table II of List, as well as the acceptance of special prescription forms and unused medicines, containing narcotic and psychotropic substances of Table II of the List after patients died at home. Availability of acts of acceptance and transfer of medicines containing narcotic drugs, psychotropic substances and their precursors remaining after the death of the patient	gross
	The presence of a permanent commission, which includes representatives of internal affairs	

12.	bodies and the territorial division of the state body in the field of sanitary and epidemiological welfare of the population for the destruction of medicines containing narcotic drugs, psychotropic substances of Table II List with expired expiration dates, handed over by relatives of deceased patients, and also broken, defective, empty ampoules, tablets and patches (transdermal therapeutic systems), as well as ampoules, tablets and patches (transdermal therapeutic systems), the contents of which have been partially used	significant
13.	Availability of acts of destruction of medicines containing narcotic drugs, psychotropic substances and their precursors of Tables II, III, IV of List	significant
14.	Compliance with the rules and procedures for registration and storage of medical documentation, requirements for medicines containing narcotic drugs, psychotropic substances and precursors of Tables II, III, IV of the List	significant
15.	Compliance with prescription regulations	significant
16.	Ensuring accounting and monitoring of prescriptions for free or preferential receipt of medicines	significant
17.	Ensuring that sample signatures of authorized persons entitled to sign prescriptions are sent to the facilities of the pharmaceutical organization	minor
18.	Reflection in the patient's outpatient card of the contents and numbers of prescriptions for free or preferential receipt of medicines	significant
19.	Ensuring the calculation of the need for medicines: 1) in accordance with the medicinal formulary of the medical organization; 2) based on data on the dynamics of morbidity and the epidemiological situation in the region, as well as statistical data on the projected number of patients;	significant

	3) taking into account registers of treated patients; 4) taking into account the actual consumption of medicines for the previous year and the projected balance as of January 1 of the next financial year	
20.	Compliance with the conditions for the purchase of medicines and pharmaceutical services within the framework of the guaranteed volume of free medical care (hereinafter - GVFMC) and medical care in the system of compulsory social health insurance (hereinafter - CSHI)	significant
21.	Ensuring the distribution of medicines depending on the projected number of patients and certain categories of citizens living in populated areas, by types of diseases	significant
22.	Availability in medical organizations providing outpatient care, facilities in the field of circulation of medicines, providing pharmaceutical services within the framework of the guaranteed volume of free medical care, as well as in periodicals distributed in the territory of the relevant administrative-territorial unit, the following information for patients is posted: 1) list and addresses of facilities in the field of circulation of medicines that provide pharmaceutical services within the framework of the guaranteed volume of medical care; 2) addresses of organizations providing outpatient care through which outpatient drug provision is provided; 3) address and telephone number of the customer for the provision of pharmaceutical services	M inor
23.	Compliance with the rational use (prescription) of medicines and the formation of a medicine formulary based on proven clinical effectiveness and safety of medicines	significant
	The presence of a permanent commission that, at least once a quarter, shall conduct analysis of	

24.	medical prescriptions at the inpatient , inpatient replacing and outpatient levels	minor
25.	Ensuring the accounting of medicines within the framework of the guaranteed volume of medical care during the provision of inpatient , inpatient-replacing and outpatient care within the framework of the guaranteed volume of free medical care in total and quantitative terms in medical records or automated programs for recording and use of medicines	gross
26.	Reflection of used medicines in the medical card of an inpatient patient, in the list of medical prescriptions	significant
27.	Ensuring that medicines received for the provision of emergency, inpatient and inpatient-replacing care within the framework of the GVFMC shall be marked with the stamp of a medical organization indicating the name of the medical organization, its address and the mark “Free”	minor
28.	Entering information about side effects, serious side effects and lack of effectiveness in the medical card of an inpatient and (or) outpatient patient, and including maintenance of statistics on identified cases of side effects in a medical organization	significant
29.	Compliance with the requirements for separate storage and accounting of medicines and medical devices purchased for the provision of medical care within the framework of the FVFMC, additional volume of medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of CSHI and paid services	gross
30.	Compliance with maximum prices for the trade name of medicines and medical devices, for the international nonproprietary name of a medicine or the technical characteristics of a medical device within the framework	gross

	of the GVFMC and (or) in the system of CSHI	
31.	In medical organizations providing medical care at all levels within the framework of the SVFMC, an additional volume of medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of CSHI, a stock of medicines and medical devices shall be created: for at least one month, with the exception of providing medical care for HIV infection, where a supply of medicines and medical devices shall be created for at least three months	gross
32.	The provision of medicines, medical devices, specialized medicinal products, immunobiological medicines within the framework of the GVFMC and (or) in the system of CSHI when providing primary health care and specialized medical care in an outpatient conditions shall be carried out in accordance with the list of medicines and medical devices for free and (or) preferential outpatient provision for certain categories of citizens of the Republic of Kazakhstan	gross
33.	The provision of medicines and medical devices on an outpatient basis within the framework of the GVFMC and (or) in the system of CSHI for citizens, fellow countrymen, refugees, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan and serving sentences by court in places of deprivation of liberty, detainees, prisoners in custody and placed in special institutions, registered at the dispensary, shall be carried out at the place of attachment to medical organizations	gross
34.	Providing certain categories of citizens with certain diseases (conditions) with free and (or) preferential medicines and medical devices on an outpatient basis within	gross

	the framework of the GFVMC and (or) in the system of CSHI free of charge with a doctor's prescription	
35.	The issuance of first aid kits for mother and child to newborns shall be carried out upon discharge from obstetric organizations with a note of issue in the development history of a newborn	gross
36.	Compliance with the procedure for generating the need for medicines and medical devices within the framework of the SVFMC and the system of CSHI: 1) compiling a calculation of the need for medicines and medical devices within the framework of the SVFMC, additional volume of medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of CSHI : taking into account the established daily dose for medicines; based on data on actual consumption of medicines and medical devices for the previous financial year; 2) organizing and conducting the purchase of medicines, medical devices and specialized medical products, pharmaceutical services within the framework of the GVFMC, additional volume of medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of CSHI on the issues of drug provision and compliance with price limits; 3) organization and procurement of services for the storage and transportation of medicines and medical devices, services for accounting and sale of medicines and medical devices by a single distributor within the framework of the SVFMC, additional volume of medical care for persons held in pre-trial detention centers and penal (penitentiary) institutions) systems,	gross

	at the expense of budgetary funds and (or) in the system of CSHI on the issues of drug provision; 4) provision of medicines and medical products within the framework of the GVFMC, additional volume of medical care to persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system CSHI; 5) provision of medicines and medical devices in rural areas where there are no pharmacies; 6) ensuring the rational use of medicines and conducting assessments of the rational use of medicines; 7) storage, accounting of medicines and medical devices, when providing medical care within the framework of the GVFMC, additional volume of medical care to persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of CSHI	
37.	Ensuring the availability in medical organizations providing medical care at all levels within the framework of GVFMC, an additional volume of medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the compulsory medical insurance system, of a supply of medicines and medical devices: for at least one month, with the exception of providing medical care for HIV infection, where a supply of medicines and medical devices shall be created for at least three months	gross
38.	Ensuring the redistribution of medicines and medical devices between medical organizations independently in cases of changes in the dynamics of morbidity, transfer or relocation of a patient, changes in the treatment regimen due to intolerance, drug resistance, death,	significant

	liquidation of medical organizations, changes in the profile of medical services at all levels of medical care	
39.	Compliance with the calculation of the projected need in medicines for the provision of medical care in inpatient and inpatient-replacing conditions	significant
40.	Compliance with the ethical conditions for promoting medicines and medical devices in terms of: To participate in daily medical conferences in medical organizations and educational organizations in the field of healthcare, representatives of manufacturers and (or) distributors ten calendar days before planned participation in the daily medical conference they agree in writing on the time and topic of the event with the head of the healthcare organization. Individual contacts of manufacturers, distributors, or authorized representatives, as well as other entities in the field of circulation of medicines and medical devices authorized to promote medicines and medical devices, with medical and pharmaceutical workers during their working hours and at the workplace for the purpose of promoting medicines and medical devices shall be excluded. In the interaction of entities in the field of circulation of medicines and medical devices with members of professional associations, it is excluded that members of professional associations may encourage the adoption of any decisions in the process of carrying out its statutory activities in favor of entities in the field of circulation of medicines and medical devices. Members of professional associations do not allow the facts of financial and other conspiracies in order to obtain benefits when promoting certain medicines and medical devices to the market, but at the same time make efforts to suppress such actions	gross

41.	Preventing ethical violations of the promotion of medicines and medical devices in the interaction of entities in the field of circulation of medicines and medical devices: 1) providing or offering financial remuneration or any other incentives of a material or non-material nature to medical and pharmaceutical workers for prescribing and releasing certain medicines; 2) payment for entertainment, recreation, travel to a place of recreation, with the exception of payments related to the implementation of scientific and educational activities; 3) concluding agreements, organizing promotions for prescribing or recommending medicines and medical devices to patients with the involvement of medical workers, with the aim of obtaining material benefits, with the exception of written official agreements on conducting biomedical, clinical-economic, epidemiological, and other types of researches not prohibited by the legislation of the Republic Kazakhstan, as well as agreements on participation in ongoing marketing researches; 4) providing samples of medicines and medical devices to patients, except for cases not prohibited by the legislation of the Republic of Kazakhstan; 5) encouragement to prescribe medicines and medical devices on prescription forms of an unspecified form, including those containing advertising information, as well as with pre-printed names of medicines and medical devices; 6) organization of programs in accordance with which property and non-property prizes are provided, gifts to heads of pharmacy organizations and pharmaceutical workers for achieving certain sales results	gross

42.	Placement in places of visual information for patients and on the Internet resource of a medical organization of a list of medicines and medical products for free and (or) preferential outpatient care for certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions), as well as the addresses of medical organizations through which outpatient care is provided and the number of a toll-free telephone line (if available) to obtain information on the use of medicines	minor
43.	Compliance with a two-year storage period for prescriptions for medicines released within the framework of SVFMC and (or) CSHI	minor
44.	Availability of a health specialist certificate for each pharmaceutical worker	gross
45.	Availability of a state license for pharmaceutical activities and appendices for subtypes of activity or notification on the start of activity . Compliance with the types and subtypes of activities declared upon receipt of the state license and its appendices	gross
46.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices, operational documents (for medical devices), indicated in the labeling of their packages	gross
47.	Ensuring the safety, storage conditions of various groups of medicines and medical devices and their handling by complying with the requirements for the design, arrangement, composition, size of areas, equipment of premises (areas) for storing medicines and medical	gross

	devices and their operation, ensuring safety	
48.	Compliance with separate storage of medicines and medical devices from other products in order to avoid any impact on them, protection from the negative effects of light, temperature , moisture and other external factors	gross
49.	Keeping records of the expiration dates of medicines and medical devices on paper or electronic media	minor
50.	Carrying out the storage of medicines and medical devices in designated and clearly marked storage areas	significant
51.	Providing the storage room, including the refrigeration room (chamber), with appropriate equipment for monitoring temperature, air humidity (thermometers, hygrometers, other types of instruments), and their location on the internal walls of the premises away from heating devices based on the results of testing zones of temperature fluctuations for cold and warm season	gross
52.	Compliance with separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, physical state, physicochemical properties, exposure to various environmental factors	gross
53.	Availability of an isolated place for storing medicines, the decision on the circulation of which has not yet been made, expired, returned, withdrawn from the category suitable for supply, for which there are suspicions of falsification, recalled and rejected	gross
54.	Ensuring protection from the effects of weather conditions in the areas of acceptance and shipment. Availability of equipment in the areas of acceptance and shipment (ventilation/ air conditioning system, hygrometer, thermometer),	gross

	equipment for cleaning containers. Availability of an equipped control area for the received products	
55.	Separation of zones for acceptance, quarantine, defects, shipment and storage, as well as the availability of a room in which medicines are stored in quarantine, with clear markings and limited access	gross
56.	Availability of common fireproof buildings with insulation by fireproof walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, providing the premises with supply and exhaust ventilation	gross
57.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and at least 1.2 meters high	gross
58.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups	gross
59.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling is not more than 90 percent of the volume. Alcohols in large quantities are stored in metal containers, which are filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)	gross
60.	Compliance with isolated storage of calcium hypochloride, taking into account its properties	gross
61.	Compliance with the storage of flammable liquids with constant	gross

	monitoring of the containers condition, their tightness and serviceability	
62.	Implementation of measures during storage of explosive drugs against contamination by dust.	gross
63.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis.	gross
64.	Ensuring the protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other fatty substances, and their storage in isolated rooms or under canopies	gross
65.	Compliance with the conditions for storing dressings in a dry, ventilated area in cabinets, drawers, on racks, shelves, pallets, in conditions that ensure cleanliness	gross
66.	Compliance with the storage conditions of medical instruments, devices, instruments, equipment in dry heated rooms at room temperature, with a relative air humidity not exceeding 65 percent	gross
67.	Compliance with the requirements for finishing premises (areas) for storing medicines and ensuring the cleanliness of premises and storage equipment	significant
68.	Ensuring protection from insects, rodents or other animals and availability of a preventive pest control program	minor
69.	Separation of rest rooms, dressing rooms, showers and toilets for workers from storage rooms (areas). Food products, drinks, tobacco products, and medicines for personal use shall not be stored in storage rooms (areas). Availability of protective clothing or uniform appropriate for the work performed and personal protective equipment if necessary for employees working in the storage area. Personnel working with dangerous drugs shall undergo special training	significant

70.	Providing with the necessary equipment and inventory on the premises for the medicines storage: 1) racks, pallets, shelves, cabinets for storing medicines and medical devices; 2) technological equipment for creating temperature conditions; 3) devices for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection, and safety of medicines	gross
71.	Availability of a document on calibration (verification) of equipment used to control and monitor storage conditions	gross
72.	Availability of a developed and approved emergency action plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage, emergency situations	significant
73.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The equipment is used in good condition and kept in proper cleanliness	significant
74.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities storing medicines and medical devices	significant
75.	Presence of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use	significant
76.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use	significant
	Availability of secondary package labeling, including the following information:	

	1) trade name of the medicine; 2) international nonproprietary name (if available) in Kazakh, Russian and English; 3) name of the manufacturer of the medicine, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated when it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packager, then the name of the packager, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, his address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of the active pharmaceutical substance (active pharmaceutical substances); 7) the amount of the medicine in the package by weight, volume or number of dosage units, depending on the dosage form and type of packaging; 8) information on the composition of the medicine; 9) for medicinal herbal preparations, which are packaged medicinal plant raw materials, the mass of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain humidity; 10) for medicinal products containing narcotic substances, psychotropic substances, their analogs, and precursors, the names of these substances and their content in weight units or percentages shall be indicated.	
77.	In single-component medicinal products, subject to the authenticity of the medicine name and the active pharmaceutical substance and indication of its dosage, concentration, activity, the	gross

	composition of the active pharmaceutical substance shall not be indicated; 11) list of excipients: 12) for infusion solutions that contain more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of injection (the method of administration shall not be indicated for tablets and capsules intended for oral administration); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: "best before: (date, month, year)" or "(date, month, year)"; The expiration date is indicated as " best before (month, year)" or "(month, year)", while the expiration date is determined up to and including the last day of the specified month; 21) registration number of the medicinal product in the form of the designation "RK-MP-"; 22) barcode (if available); 23) means of identification or a material medium containing means of identification	
	Availability of labeling of primary package indicating the following information: 1) trade name of the medicine, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages;	

78.	3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “ date, month, year” Additional information is placed that is identical to the information printed on the secondary packaging. Intermediate packaging, which does not allow the information on the primary packaging to be read without compromising its integrity, repeats the information indicated on the primary packaging.	gross
79.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices	significant
80.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of report cards through the portal of an authorized organization online containing a mandatory minimum amount of information	significant
81.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection	significant
82.	Absence of facts of purchase, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan	gross
83.	Absence of facts of production, import, storage, use and sale of counterfeit medicines and medical devices	gross
84.	Absence of facts of sales of medicines and medical devices, the quality of which is not confirmed by a conclusion on safety and quality	gross

85.	Absence of facts of storage, use and sale of expired medicines and medical devices	gross
86.	Compliance of the medicine with the requirements of the regulatory document on control of the quality and safety of the medicine and medical device (based on the results of assessing the safety and quality of samples withdrawn as doubt)	gross
87.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unusability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and seized from illegal traffic of narcotic drugs, psychotropic substances, their analogs and precursors do not represent medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan.	gross
88.	Availability of a list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies to conduct the relevant check	gross
89.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day, they shall be	gross

	stamped and (or) sealed. Keys, stamp and (or) seal shall be kept by the responsible person	
90.	Availability of a first aid kit	minor
91.	Availability of a sign indicating the name of the subject of pharmaceutical activity, its organizational and legal form and mode of operation in the state and Russian languages	minor
92.	Availability of information about the telephone numbers and addresses of territorial subdivisions of the state body in the field of circulation of medicines and medical devices in a place convenient for the public to familiarize	minor
93.	Ensuring the traceability of medicines marked with identification means by providing with information on the introduction into circulation, on the sale and (or) transfer, as well as on the withdrawal from circulation of labeled medicines in the territory of the Republic of Kazakhstan by the participants in the circulation of medicines and subjects in the field of circulation of medicines and medical devices	gross
94.	Compliance with the rules for advertising medicines and medical devices: 1) advertising of medicines and medical devices is reliable, recognizable without special knowledge or the use of special means, to exclude comparisons with other pharmaceutical services, medicines and medical devices, not to mislead the consumers by abusing their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of research and testing; 2) advertising of medicines and medical devices is provided in the Kazakh and Russian languages, contains complete and reliable information about the medicine or medical device, complies with the instructions for medical use of the medicine (insert leaflet), instructions	gross

	for medical use or operational document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare	
95.	Prohibition of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of samples of medicines released with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical devices, except for medicines and medical devices for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations not related to their purpose, use and release, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicines and medical devices; 8) the use of medical workers authorized to prescribe medicines and medical devices as distributors of advertising, with the exception of cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license to carry out the relevant type of activity; 10) advertising of pharmaceutical services provided by persons who do not have a certificate as a specialist	gross

	in the field of healthcare, including foreign specialists; 11) indication in advertising for the population of treatment methods for the following diseases: sexually transmitted diseases, cancer, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical devices, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed , and the use of the product is not accompanied by the development of side effects; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicinal product and medical device	
96.	Availability of a document on calibration and (or) verification of a medical device that is a measuring instrument	gross
97.	Compliance that the medical equipment in use, at the time of acceptance, was new, unused, of the latest or serial model, free of defects	gross
98.	Availability of a log of the technical condition of medical equipment to be serviced	gross
99.	Availability of documents confirming current and major repairs	significant
	Availability of documents confirming warranty service (at least	

100.	thirty-seven months from the date of commissioning and frequency recommended by the manufacturer) consisting of periodic monitoring of the technical condition of medical equipment (at least once a year)	gross
101.	Availability at the operated medical equipment of: 1) operational documentation (operation manual and service manual); 2) service manual for medical equipment	gross
102.	Availability of facts of operation of medical equipment that is not provided with service, removed from service, or operation of medical equipment by personnel who do not have special training or have not been trained in the use of medical equipment	gross
103.	Availability of facts of unreasonable downtime of medical equipment (lack of measures to restore serviceable condition)	significant
Section 2. In relation to subjects (objects) of pharmaceutical activities engaged in the production of medicines and medical devices		
104.	Compliance with technological processes for the production of medicines and medical devices according to the registration dossier	gross
105.	Availability of state registration in the Republic of Kazakhstan of medicinal substances used in production, with the exception of those produced under the conditions of Good Manufacturing Practice	gross
106.	Availability of shipping documents for medicines and medical devices	gross
107.	Carrying out activities for the production of medicines or wholesale distribution of medicines by suppliers of substances or intermediate products	gross
108.	Compliance of substances, excipients, consumables and packaging materials with the registration dossier	gross
	Carrying out incoming control of raw materials (substances, auxiliary materials), materials, semi-finished	

109.	products, components; intermediate control during the production process, control of finished pharmaceutical products	gross
110.	Availability of a quality assurance system in production, documentation and control of its effectiveness	gross
111.	Ensuring registration of all technological and auxiliary operations during the production of a separate series of medicines and medical devices	gross
112.	Compliance with the requirements for maintaining documentation of all production processes and materials used in production, the procedure for its storage	gross
113.	Compliance with stability testing, shelf life determination and re-inspection of medicinal products	gross
114.	Ensuring a sufficient number of samples to carry out testing where necessary (arbitration testing)	gross
115.	Availability of markings indicating the status of manufactured products, initial products, packaging materials	gross
116.	Carrying out quality control of materials, intermediate products, finished products	gross
117.	Maintaining a database of side effects of medicines and medical devices	significant
118.	Availability of a certificate of healthcare specialist for each pharmaceutical worker	gross
119.	Availability of a state license for pharmaceutical activities and appendices for subtypes of activity or notification on the start of activity . Compliance with the types and subtypes of activities declared upon receipt of the state license and its appendix	gross
120.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for	gross

	medicines and medical devices, operational documents (for medical devices), indicated in the labeling of their packages	
121.	Ensuring the safety, storage conditions of various groups of medicines and medical devices and their handling by complying with the requirements for the design, arrangement, composition, size of areas, equipment of premises (zones) for storing medicines and medical devices and their operation, ensuring safety	gross
122.	Compliance of separate storage of medicines and medical devices from other products in order to avoid any impact on them, protection from the negative effects of light, temperature , moisture and other external factors	gross
123.	Keeping records of the expiration dates of medicines and medical devices on paper or electronic media	minor
124.	Storage of medicines and medical devices in designated and clearly marked storage areas	significant
125.	Providing the storage room, including the refrigeration room (chamber), with appropriate equipment for monitoring temperature, air humidity (thermometers, hygrometers, other types of instruments) and their location on the internal walls of the premises away from heating devices based on the results of testing zones of temperature fluctuations for cold and warm season	gross
126.	Compliance with separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, physical state, physicochemical properties, exposure to various environmental factors	gross
127.	Availability of an isolated place for storing medicines, the decision on the circulation of which has not yet been made, expired, returned, withdrawn from the category suitable for supply, for which there	gross

	are suspicions of falsification, recalled and rejected	
128.	Ensuring protection from the effects of weather conditions in the areas of acceptance and shipment. Availability of equipment in the areas of acceptance and shipment (ventilation/ air conditioning system, hygrometer, thermometer), equipment for cleaning containers. Availability of an equipped control area for the received products	gross
129.	Separation of zones for acceptance, quarantine, defects, shipment and storage. Availability of a room in which medicines shall be stored in quarantine, clearly marked and with limited access	gross
130.	Availability of common fireproof buildings with insulation by fireproof walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, providing the premises with supply and exhaust ventilation	gross
131.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and at least 1.2 meters high	gross
132.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups	gross
133.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling is not more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, which are filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic	gross

	salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)	
134.	Compliance with isolated storage of calcium hypochloride, taking into account its properties	gross
135.	Compliance with the storage of flammable liquids with constant monitoring of the containers condition, their tightness and serviceability	gross
136.	Implementation of measures during storage of explosive drugs against contamination by dust	gross
137.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis	gross
138.	Ensuring the protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other fatty substances, and their storage in isolated rooms or under canopies	gross
139.	Compliance with the conditions for storing dressings in a dry, ventilated area in cabinets, drawers, on racks, shelves, pallets, in conditions that ensure cleanliness	gross
140.	Compliance with the storage conditions of medical instruments, devices, instruments, equipment in dry heated rooms at room temperature, with a relative air humidity not exceeding 65 percent	gross
141.	Compliance with the requirements for finishing premises (areas) for storing medicines and ensuring the cleanliness of premises and storage equipment	significant
142.	Ensuring protection from insects, rodents or other animals and availability of a preventive pest control program	minor
	Separation of rest rooms, dressing rooms, showers and toilets for workers from storage rooms (zones). Food products, drinks, tobacco products, and medicines for personal use shall not be stored in storage rooms (zones).	

143.	Availability of protective clothing or uniform appropriate for the work performed and personal protective equipment if necessary for employees working in the storage area. Personnel working with dangerous drugs shall undergo special training	significant
144.	Providing with the necessary equipment and inventory in the premises for the storage of medicines: 1) racks, pallets, shelves, cabinets for storing medicines and medical devices; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines	gross
145.	Availability of a document on calibration (verification) of equipment used to control and monitor storage conditions	gross
146.	Availability of a developed and approved emergency action plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage, emergency situations	significant
147.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The equipment is used in good condition and kept in proper cleanliness	significant
148.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities storing medicines and medical devices	significant
	Presence of a commission for the destruction of medicines and medical	

149.	devices unsuitable for sale and medical use	significant
150.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use	significant
	Availability of labeling of secondary packaging, including the following information: 1) trade name of the medicine; 2) international nonproprietary name (if available) in Kazakh, Russian and English; 3) name of the manufacturer of the medicine, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated when it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicine is not its packager, then the name of the packager, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, his address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of the active pharmaceutical substance (active pharmaceutical substances); 7) the amount of the medicine in the package by weight, volume or number of dosage units, depending on the dosage form and type of packaging; 8) information on the composition of the medicine; 9) for medicinal herbal preparations, which are packaged medicinal plant raw materials, the mass of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin is indicated at their certain humidity; 10) for medicines containing narcotic substances, psychotropic substances, their analogs and precursors, the names of these	

151.	substances and their content in weight units or percentages are indicated. In single-component medicines, subject to the authenticity of the name of the medicine and the active pharmaceutical substance and indication of its dosage, concentration, activity, the composition of the active pharmaceutical substance shall not be indicated; 11) list of excipients: for parenteral, ophthalmic drugs and drugs for external use, a list of all excipients shall be indicated; for infusion solutions, the qualitative and quantitative composition of all excipients shall be indicated; for other dosage forms, a list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions that contain more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of injection (the method of administration shall not be indicated for tablets and capsules intended for oral administration); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: "best before: (date, month, year)" or "(date, month, year)"; The expiration date is indicated as " best before (month, year)" or "(month, year)", while the expiration	gross

	date is determined up to and including the last day of the specified month; 21) registration number of the medicinal product in the form of the designation “RK-MP-”; 22) barcode (if available); 23) means of identification or a material medium containing means of identification	
152.	Availability of labeling of primary packaging indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “ date, month, year” Additional information that is identical to the information printed on the secondary packaging shall be placed. Intermediate packaging, which does not allow the information on the primary packaging to be read without compromising its integrity, repeats the information indicated on the primary packaging	gross
153.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices	significant
154.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of report cards through the portal of an authorized organization online containing a mandatory minimum amount of information	significant

155.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection	significant
156.	Absence of facts of purchase, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan	gross
157.	Absence of facts of production, import, storage, use and sale of counterfeit medicines and medical devices	gross
158.	Absence of facts of sales of medicines and medical devices, the quality of which is not confirmed by a conclusion on safety and quality	gross
159.	Absence of facts of storage, use and sale of expired medicines and medical devices	gross
160.	Compliance of the medicine with the requirements of the regulatory document on control of the quality and safety of the medicine and medical device (based on the results of assessing the safety and quality of samples withdrawn as doubt)	gross
161.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unusability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illegal traffic of narcotic drugs, psychotropic substances, their analogs and precursors do not represent medical,	gross

	scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan.	
162.	Availability of a list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies to conduct the relevant inspection	gross
163.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day, they shall be sealed and (or) stamped. Keys, seal and (or) stamp shall be kept by the responsible person	gross
164.	Availability of a first aid kit	minor
165.	Availability of a sign indicating the name of the subject of pharmaceutical activity, its organizational and legal form and mode of operation in the state and Russian languages	minor
166.	Availability of information about the telephone numbers and addresses of territorial subdivisions of the state body in the field of circulation of medicines and medical devices in a place convenient for the public to familiarize themselves	minor
167.	Ensuring traceability of medicines marked with identification means by providing the drug administration and entities in the field of circulation of medicines and medical devices with information on the introduction into circulation, sale and (or) transfer , as well as on the withdrawal from circulation of labeled medicines in the territory of the Republic of Kazakhstan	gross
	Compliance with the rules for advertising medicines and medical devices: 1) advertising of medicines and medical devices shall be reliable, recognizable without special	

168.	knowledge or the use of special means, exclude comparisons with other pharmaceutical services, medicines and medical devices, do not mislead consumers by abusing their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of researches and testings; 2) advertising of medicines and medical devices is provided in the Kazakh and Russian languages, contains complete and reliable information about the medicine or medical device, complies with the instructions for medical use of the medicine (insert leaflet), instructions for medical use or operational document for the medical product; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare	gross
	Prohibition of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription medicines in the media; 3) distribution for advertising purposes of samples of medicines released with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical devices, except for medicines and medical devices for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations not related to their purpose, use and release, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms;	

169.	7) placement of outdoor (visual) advertising of medicines and medical products; 8) the use of medical workers authorized to prescribe medicines and medical devices as distributors of advertising, with the exception of cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license to carry out the relevant type of activity; 10) advertising of pharmaceutical services provided by persons who do not have a certificate as a specialist in the field of healthcare, including foreign specialists; 11) indication in advertising for the population of treatment methods for the following diseases: sexually transmitted diseases, cancer, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising the services, medicines and medical devices, biologically active food additives as unique, the safest, and most effective; 14) assert that the safety and effectiveness of the medicine are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicine, biologically active food additive is guaranteed, and the use of the product is not accompanied by the development of side effects; 16) provide information in advertising that is not directly related	gross	

	to the advertised pharmaceutical service, medicine, or medical device	
170.	Compliance with the manufacturer's maximum price	gross
171.	Availability of a certificate of compliance with the requirements of the Good Manufacturing Practice (GMP) Standard	gross
Section 3. In relation to subjects (objects) of pharmaceutical activities engaged in the manufacture of medicines and medical devices		
172.	Availability of a pharmacist-analyst' s workplace equipped with a standard set of measuring instruments, testing equipment, laboratory glassware, and auxiliary materials	gross
173.	Implementation of preventive (cautionary) measures, acceptance control of raw materials (medicinal substance, excipient), written, organoleptic, random survey control, random physical and chemical control, control during the release of manufactured medicines	gross
174.	Availability and maintenance of checklists for the manufacture of medicines according to prescriptions and requirements of medical organizations	significant
175.	Availability and maintenance of a numbered, laced, sealed, and signed by the head of the pharmacy journal for recording the results of organoleptic, physical, and chemical control	significant
176.	Availability of state registration in the Republic of Kazakhstan for medicinal substances used in manufacturing, with the exception of those produced under the conditions of Good Manufacturing Practice	gross
177.	Carrying out activities by suppliers of substances for the production of medicines or wholesale sales of medicines	gross
178.	Maintaining and monitoring the expiration dates of medicines and medical devices	significant
	Providing technology for the manufacture of a medicinal product, in accordance with the requirements	

179.	of general articles of the State Pharmacopoeia of the Republic of Kazakhstan	gross
180.	Implementation of preventive (precautionary) measures: 1) compliance with the conditions for aseptic manufacturing of medicinal products; 2) ensuring the serviceability and accuracy of weighing instruments, carrying out their annual verification ; 3) ensuring proper conditions for obtaining, collecting, storing purified water, water for injection, correct labeling of the container in the form of indicating the date of receipt, the analysis number, and the signature of the person who performed the analysis on the tag; 4) compliance with the terms and conditions of reagents storage, standard and titrated solutions, and their correct design (on the labels, in addition to the name, the concentration, molarity, date of receipt, expiration date, storage conditions, and by whom it was manufactured shall be indicated); 5) determination of deviations in the tested medicinal products using measuring instruments of the same type (with the same metrological characteristics) as when they were manufactured in pharmacies; 6) proper processing, filling, design of burette installation and rods	gross
	Design of glass stoppered bottles (pharmaceutical containers) as follows: 1) name, country and manufacturing plant, series number of the manufacturing plant, number and validity period of the product conformity certificate, expiration date of the medicinal substance, date of filling, signature of the person who filled the bar and verified the authenticity of the medicinal substance is indicated on the glass stoppered bottles in the storage premises;	

181.	2) the date the glass stoppered bottle was filled out, the signature of the person who filled the glass stoppered bottle and verified the authenticity of the medicinal substance and excipients on the glass stoppered bottles with medicinal substances and excipients, which are contained in the assistant's room is indicated; 3) the highest single and daily doses are additionally indicated on the glass stoppered bottles with narcotic drugs, psychotropic substances, precursors, toxic substances; 4) the number of units of action in one gram of medicinal plant material or in one milliliter of solution is indicated on glass stoppered bottles with medicinal substances containing cardiac glycosides; 5) the inscription: "For sterile medicinal products" is indicated on glass stoppered bottles with medicinal substances intended for the manufacture of medicinal products requiring aseptic manufacturing conditions; 6) the percentage of moisture; on cylinders with liquids (hydrogen peroxide solution, ammonia solution, formaldehyde) the actual content of the active substance is indicated on containers with medicinal substances containing moisture; 7) glass stoppered bottles with solutions, tinctures and liquid semi-finished products are provided with drop meters or pipettes, indicating the number of drops established by weighing in a certain volume	gross
182.	Availability and maintenance of a journal for recording the results of control of medicinal substances for authenticity	significant
183.	Implementation of control over compliance with the technology of manufacturing medicines by the pharmacist-technologist	gross
	Carrying out acceptance control of raw materials (drug substance, excipients) used for the manufacture of medicinal products (bill of lading,	

184.	quality certificate of the manufacturer), compliance of series on samples of medicinal substances and excipients with the series specified in the accompanying documentation, compliance with storage conditions, transportation, as well as identification of medicinal substances and auxiliary materials according to the indicators “ Packaging”, “Labelling” and “ Description”	significant
185.	Carrying out written control of medicinal products manufactured in a pharmacy by filling out a control sheet immediately after the preparation of the medicinal product. The checklist indicates: 1) date of manufacture; 2) number of the prescription or requirement of the medical organization indicating the name of the department; 3) names of the medicinal substances taken, their quantity, total volume or weight, number of doses; 4) signatures of the person who manufactured, packaged and tested the medicinal product. On the control sheet, the names of narcotic drugs, poisonous, psychotropic substances, and precursors are underlined in red pencil, and the letter “D” is placed on medical products for children. The control sheet is filled out in Latin in accordance with the sequence of manufacturing technology. All calculations are written down on the back of the check sheet	gross
186.	Conducting random survey control of medical products manufactured in a pharmacy	gross
187.	Carrying out organoleptic control in terms of appearance, color, smell, uniformity, absence of visible mechanical inclusions in solutions	significant
	Carrying out random physical control by checking the total weight or volume of the medicinal product, the number and weight of individual	

188.	doses included in this medicinal product (but not less than three doses), and the quality of closure. The following shall be subject to selective physical control: 1) each series of packaging of industrial products and in-house pharmaceutical preparations in the amount of three to five packages, including packaging of homeopathic medicines for compliance with the norms of deviations permissible in the manufacture of medicines (including homeopathic) in a pharmacy and the norms of deviations permissible during packaging industrial products; 2) at least three percent of medicinal products manufactured according to prescriptions (requirements) in one working day; 3) the number of homeopathic granules in a certain mass of the sample; 4) each series of medicinal products requiring sterilization, after packaging before sterilization in an amount of at least five vials (bottles) for mechanical inclusions (mobile insoluble substances, except for gas bubbles, accidentally present in solutions)	gross
189.	Carrying out primary and secondary inspection for mechanical inclusions during the manufacturing process of solutions	gross
190.	Carrying out chemical control according to the following indicators : 1) authenticity, purity tests and acceptable limits of impurities (qualitative analysis); 2) quantitative determination (quantitative analysis) of medicinal substances included in its composition	gross
191.	Providing a complete chemical analysis of purified water	gross
	Exercising control during release by checking all manufactured medicinal products, including homeopathic ones, for compliance with:	

192.	1) packaging of medicinal products based on the physical and chemical properties of the medicinal substances included in them; 2) the doses indicated in the prescription, including the highest single doses, the highest daily doses of medicinal products depending on the patient's age; 3) numbers on the prescription and numbers on the label; 4) the patient's name on the receipt, name on the label and prescription; 5) registration of medicinal products	gross
193.	Ensuring registration of the results of control of individual stages of manufacturing solutions for injections and infusions in the logbook for recording the results of control of individual stages of manufacturing solutions for injections and infusions	gross
194.	Availability of a range of concentrates, semi-finished products and in-pharmacy procurement of medicinal products manufactured in a pharmacy, annually approved by an accredited testing laboratory, with which an agreement on control and analytical services has been concluded	gross
195.	Availability of a specialist certificate in the field of healthcare for each pharmaceutical worker	gross
196.	Availability of a state license for pharmaceutical activities and appendices for subtypes of activity or notification of the start of activity. Compliance with the types and subtypes of activities declared upon receipt of the state license and its appendix	gross
197.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices,	gross

	operational documents (for medical devices), indicated in the labeling of their packages	
198.	Ensuring the safety, storage conditions of various groups of medicines and medical devices and their handling by complying with the requirements for the design, arrangement, composition, size of areas, equipment of premises (zones) for storing medicines and medical devices and their operation, ensuring safety	gross
199.	Observance of separate storage of medicines and medical devices from other products in order to avoid any impact on them, protection from the negative effects of light, temperature , moisture and other external factors	gross
200.	Keeping records of the expiration dates of medicines and medical devices on paper or electronic media	minor
201.	Carrying out storage of medicines and medical devices in designated and clearly marked storage zones	significant
202.	Providing the storage room, including the refrigeration room (chamber), with appropriate equipment for monitoring temperature, air humidity (thermometers, hygrometers, other types of instruments), and their location on the internal walls of the premises away from heating devices based on the results of testing zones of temperature fluctuations for cold and warm season	gross
203.	Compliance with separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, physical state, physicochemical properties, exposure to various environmental factors	gross
204.	Availability of an isolated place for storing medicines, the decision on the circulation of which has not yet been made, expired, returned, withdrawn from the category	gross

	suitable for supply, in relation of which there are suspicions of falsification, recalled and rejected	
205.	Ensuring protection from the effects of weather conditions in the zones of acceptance and shipment. Availability of equipment in the zones of acceptance and shipment (ventilation/ air conditioning system, hygrometer, thermometer), equipment for cleaning containers. Availability of an equipped control zone for the received products	gross
206.	Separation of acceptance, quarantine , defective, shipping and storage zones. Availability of a room in which medicines are stored in quarantine, clearly marked and with limited access	gross
207.	Availability of common fireproof buildings with insulation by fireproof walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, providing the premises with supply and exhaust ventilation	gross
208.	Storage of flammable medicines separately from other medicines: provision with fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and at least 1.2 meters high	gross
209.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups	gross
210.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling is not more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, which are filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable	gross

	substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)	
211.	Compliance with isolated storage of calcium hypochloride, taking into account its properties	gross
212.	Compliance with the storage of flammable liquids with constant monitoring of the condition of containers, their tightness and serviceability	gross
213.	Implementation of measures during storage of explosive drugs against contamination by dust	gross
214.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis	gross
215.	Ensuring the protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other fatty substances, and their storage in isolated rooms or under canopies	gross
216.	Compliance with the conditions for storing dressings in a dry, ventilated area in cabinets, drawers, on racks, pallets, shelves, in conditions that ensure cleanliness	gross
217.	Compliance with the storage conditions of medical instruments, devices, instruments, equipment in dry heated rooms at room temperature, with a relative air humidity not exceeding 65 percent	gross
218.	Compliance with the requirements for finishing premises (zones) for storing medicines and ensuring the cleanliness of premises and storage equipment	significant
219.	Ensuring protection from insects, rodents or other animals and availability of a preventive pest control program	minor
	Separation of rest rooms, dressing rooms, showers, and toilets for workers from storage rooms (zones). Food products, drinks, tobacco products, and medicines for personal use shall not be stored in storage rooms (zones). Availability of	

220.	protective clothing or uniform appropriate for the work performed and personal protective equipment if necessary for employees working in the storage zone. Personnel working with dangerous drugs shall undergo special training	significant
221.	Providing with the necessary equipment and inventory in the premises of medicines storage: 1) racks, pallets, shelves, cabinets for storing medicines and medical devices; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection, and safety of medicines	gross
222.	Availability of a document on calibration (verification) of equipment used to control and monitor storage conditions	gross
223.	Availability of a developed and approved emergency action plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage, emergency situations	significant
224.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The equipment shall be used in good condition and kept in proper cleanliness	significant
225.	Availability of a person responsible for ensuring the safety of quality of medicines and medical devices at facilities storing medicines and medical devices	significant
226.	Presence of a commission for the destruction of medicines and medical	significant

	devices unsuitable for sale and medical use	
227.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use	significant
	Availability of secondary package labeling, including the following information: 1) trade name of the medicine; 2) international nonproprietary name (if available) in Kazakh, Russian and English; 3) name of the manufacturer of the medicine, address. The name of the manufacturer and its address are indicated in full or abbreviated (city, country). A trademark shall be indicated when it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packager, then the name of the packager, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, his address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of the active pharmaceutical substance (active pharmaceutical substances); 7) the amount of the medicinal product in the package by weight, volume or number of dosage units, depending on the dosage form and type of packaging; 8) information on the composition of the medicinal product; 9) for medicinal herbal preparations, which are packaged medicinal plant raw materials, the mass of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain humidity; 10) for medicinal products containing narcotic substances, psychotropic substances, their analogs and precursors, the names of	

228.	these substances and their content in weight units or percentages shall be indicated. In single-component medicinal products, subject to the authenticity of the medicinal product name and active pharmaceutical substance and indication of its dosage, concentration, activity, the composition of the active pharmaceutical substance shall not be indicated; 11) list of excipients: for parenteral, ophthalmic drugs and drugs for external use, a list of all excipients shall be indicated; for infusion solutions, the qualitative and quantitative composition of all excipients shall be indicated; for other dosage forms, a list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions that contain more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of injection (the method of administration shall not be indicated for tablets and capsules intended for oral administration); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: "best before: (date, month, year)" or "(date, month, year)"; The expiration date is indicated as " best before (month, year)" or "(month, year)", with the expiration date determined up to and including the last day of the specified month;	gross

	21) registration number of the medicinal product in the form of the designation “RK-MP-”; 22) barcode (if available); 23) means of identification or a material medium containing means of identification	
229.	Availability of primary package labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) name of the organization-manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “ date, month, year” Additional information shall be placed that is identical to the information printed on the secondary packaging. Intermediate packaging, which does not allow the information on the primary packaging to be read without compromising its integrity, repeats the information indicated on the primary packaging	gross
230.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices	significant
231.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of report cards through the portal of an authorized organization online containing a mandatory minimum amount of information	significant
	Compliance with the deadlines for submitting a completed report card	

232.	about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection	significant
233.	Absence of facts of purchase, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan	gross
234.	Absence of facts of production, import, storage, use and sale of counterfeit medicines and medical devices	gross
235.	Absence of facts of sales of medicines and medical devices, the quality of which is not confirmed by a conclusion on safety and quality	gross
236.	Absence of facts of storage, use and sale of expired medicines and medical devices	gross
237.	Compliance of the medicine with the requirements of the regulatory document on control of the quality and safety of the medicine and medical device (based on the results of assessing the safety and quality of samples withdrawn as doubt)	gross
238.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unusability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from the illegal traffic of narcotic drugs, psychotropic substances, their analogs and precursors do not represent medical, scientific or other value and cannot be processed, as well as in other	gross

	cases provided for by the legislation of the Republic of Kazakhstan.	
239.	Availability of a list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies to conduct the relevant inspection	gross
240.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day, they shall be sealed and (or) stamped. Keys, seal and (or) stamp shall be kept by the responsible person	gross
241.	Availability of a first aid kit	minor
242.	Availability of a sign indicating the name of the subject of pharmaceutical activity, its organizational and legal form and mode of operation in the state and Russian languages	minor
243.	Availability of information about the telephone numbers and addresses of territorial divisions of the state body in the field of circulation of medicines and medical devices in a place convenient for the public to familiarize	minor
244.	Ensuring traceability of medicines marked with identification means by providing the drug administration and entities in the field of circulation of medicines and medical devices with information on the introduction into circulation, sale and (or) transfer , as well as on the withdrawal from circulation of labeled medicines in the territory of the Republic of Kazakhstan	gross
	Compliance with the rules for advertising medicines and medical devices: 1) advertising of medicines and medical devices is reliable, recognizable without special knowledge or the use of special means, exclude comparisons with	

245.	other pharmaceutical services, medicines and medical devices, do not mislead consumers by abusing their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of research and testing; 2) advertising of medicines and medical devices is provided in the Kazakh and Russian languages, contains complete and reliable information about the medicine or medical device, complies with the instructions for medical use of the medicine (insert leaflet), instructions for medical use or operational document for the medical product; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare	gross
	Prohibition of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription medicines in the mass media; 3) distribution for advertising purposes of samples of medicines dispensed with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical devices, except for medicines and medical devices for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations not related to their purpose, use and dispensing, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms;	

246.	7) placement of outdoor (visual) advertising of medicines and medical devices; 8) the use of medical workers authorized to prescribe medicines and medical devices as distributors of advertising, with the exception of cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license to carry out the relevant type of activity; 10) advertising of pharmaceutical services provided by persons who do not have a certificate as a specialist in the field of healthcare, including foreign specialists; 11) indication in advertising for the population of treatment methods for the following diseases: sexually transmitted diseases, cancer, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical products, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed , and the use of the product is not accompanied by the development of side effects; 16) provide information in advertising that is not directly related	gross

	to the advertised pharmaceutical service, medicine and medical device	
Section 4. In relation to subjects (objects) of pharmaceutical activities engaged in wholesale sales of medicines and medical devices		
247.	Availability and functioning of a documentation system for tracking the receipt and shipment of medicines and medical devices	gross
248.	Ensuring the provision of a copy of the product conformity certificate upon request of the subject. Certificates of conformity of medicines and medical devices shall be stored for the duration of its validity plus one year and shall be available to consumers and (or) state regulatory bodies	significant
249.	Purchasing medicines and medical devices from entities that have a license for pharmaceutical activities and an appendix to the license for subtypes of activity: production of medicines, wholesale sales of medicines, or who have notified the start of activities for the wholesale sale of medical devices	gross
250.	Implementation of the sale of medicines and medical devices to entities having a license for pharmaceutical or medical activities or who have notified about the start of activities for the sale of medical devices	gross
251.	The sale of medicinal substances shall be carried out to pharmacies that have a license for pharmaceutical activities with the right to manufacture, as well as organizations for the production of medicines that have a license for pharmaceutical activities with the right to produce medicines	gross
252.	Carrying out wholesale sales of medical devices related to measuring instruments, in the availability of a certificate on approval of the type of measuring instruments, or a certificate of metrological certification of medical measuring equipment	gross

253.	Provision of vehicles and equipment used for transportation and compliance with the purposes of their use, to protect products from undesirable effects that lead to loss of quality or violate the integrity of packaging, as well as: 1) the possibility of their identification and safety assessment has not been lost; 2) were not contaminated with other medicines (dosages), substances and did not contaminate themselves; 3) were protected and not exposed to environmental factors. The vehicle and its equipment shall be kept clean and treated with detergents and disinfectants as needed	significant
254.	Compliance with storage conditions during transportation necessary to ensure the quality, safety and effectiveness of medicines, as well as to prevent the risk of counterfeit medicines entering the supply chain	gross
255.	Availability of temperature control devices in vehicles in case of supplies of medicines requiring special transportation conditions. Instrument readings shall be recorded throughout transportation and shall be documented	gross
256.	Ensuring the protection of medicines and medical devices from environmental factors (precipitation, dust, sunlight, mechanical damage). Medicines and medical devices prepared for transportation shall be packaged in group containers (cardboard boxes or stacks) with subsequent packaging in transport packaging (boxes, cartons, wrapping paper) that meets the requirements of the regulatory document	gross
	Ensuring the execution of shipping documents containing the following information for each item, batch (series) of products: name; dosage (for a medicine); packaging; quantity, unit price;	

257.	sum; series; best before date; number and validity period of the certificate of conformity (for a medicine or medical device). Corrections, additions, and blots in shipping documents shall not be allowed.	gross
258.	Compliance with the maximum price for the trade name of a medicine during wholesale sales	gross
259.	Availability of a specialist certificate in the field of healthcare for each pharmaceutical worker	gross
260.	Availability of a state license for pharmaceutical activities and appendices for subtypes of activity or notification on the start of activity . Compliance with the types and subtypes of activities declared upon receipt of the state license and its appendix	gross
261.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices, operational documents (for medical devices), indicated in the labeling of their packages	gross
262.	Ensuring the safety, storage conditions of various groups of medicines and medical devices and their handling by complying with the requirements for the design, arrangement, composition, size of areas, equipment of premises (zones) for storing medicines and medical devices and their operation, ensuring safety	gross
263.	Observance of separate storage of medicines and medical devices from other products in order to avoid any impact on them, protection from the negative effects of light, temperature , moisture and other external factors	gross

264.	Keeping records of the expiration dates of medicines and medical devices on paper or electronic media	minor
265.	Storage of medicines and medical devices in designated and clearly marked storage areas	significant
266.	Providing the storage room, including the refrigeration room (chamber), with appropriate equipment for monitoring temperature, air humidity (thermometers, hygrometers, other types of instruments) and their location on the internal walls of the premises away from heating devices based on the results of testing zones of temperature fluctuations for cold and warm season	gross
267.	Compliance with separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, physical state, physicochemical properties, exposure to various environmental factors	gross
268.	Availability of an isolated place for storing medicines, the decision on the circulation of which has not yet been made, expired, returned, withdrawn from the category suitable for supply, for which there are suspicions of falsification, recalled and rejected	gross
269.	Ensuring protection from the effects of weather conditions in the zones of acceptance and shipment. Availability of equipment in the zones of acceptance and shipment (ventilation/ air conditioning system, hygrometer, thermometer), equipment for cleaning containers. Availability of an equipped control zone for the received products	gross
270.	Separation of acceptance, quarantine , defective, shipping and storage zones. Availability of a room in which medicines shall be stored in quarantine, with clear markings and limited access.	gross
	Availability of common fireproof buildings with insulation by	

271.	fireproof walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, providing the premises with supply and exhaust ventilation	gross
272.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and at least 1.2 meters high	gross
273.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups	gross
274.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling is not more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, which are filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)	gross
275.	Compliance with isolated storage of calcium hypochloride, taking into account its properties	gross
276.	Compliance with the storage of flammable liquids with constant monitoring of the containers condition, their tightness and serviceability	gross
277.	Implementation of measures during storage of explosive drugs against contamination by dust	gross
278.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis	gross
	Ensuring the protection of cylinders with oxygen and flammable gases from heat sources, contact with oil	

279.	and other fatty substances, and their storage in isolated rooms or under canopies	gross
280.	Compliance with the conditions for storing dressings in a dry, ventilated area in cabinets, drawers, on racks, pallets, shelves, in conditions that ensure cleanliness	gross
281.	Compliance with the storage conditions of medical instruments, devices, instruments, equipment in dry heated rooms at room temperature, with a relative air humidity not exceeding 65 percent	gross
282.	Compliance with the requirements for finishing premises (areas) for storing medicines and ensuring the cleanliness of premises and storage equipment	significant
283.	Ensuring protection from insects, rodents or other animals and availability of a preventive pest control program	minor
284.	Separation of rest rooms, dressing rooms, showers and toilets for workers from storage rooms (zones). Food products, drinks, tobacco products, and medicines for personal use shall not be stored in storage rooms (zones). Availability of protective clothing or uniform appropriate for the work performed and personal protective equipment if necessary for employees working in the storage zone. Personnel working with dangerous drugs shall undergo special training	significant
285.	Providing with the necessary equipment and inventory in the premises of medicines storage: 1) racks, pallets, shelves, cabinets for storing medicines and medical devices; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions;	gross

	6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines	
286.	Availability of a document on calibration (verification) of equipment used to control and monitor storage conditions	gross
287.	Availability of a developed and approved emergency action plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage, emergency situations	significant
288.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The equipment shall be used in good condition and kept in proper cleanliness	significant
289.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities carrying out storage of medicines and medical devices	significant
290.	Presence of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use	significant
291.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use	significant
	Availability of secondary package labeling, including the following information: 1) trade name of the medicine; 2) international nonproprietary name (if available) in Kazakh, Russian and English; 3) name of the manufacturer of the medicine, address. Name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated when it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packager, then the	

	name of the packager, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, his address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of the active pharmaceutical substance (active pharmaceutical substances); 7) the amount of the medicinal product in the package by weight, volume or number of dosage units, depending on the dosage form and type of packaging; 8) information on the composition of the medicinal product; 9) for medicinal herbal preparations, which are packaged medicinal plant raw materials, the mass of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain humidity; 10) for medicinal products containing narcotic substances, psychotropic substances, their analogs and precursors, the names of these substances and their content in weight units or percentages shall be indicated. In single-component medicinal products, subject to the authenticity of the name of the medicinal product and the active pharmaceutical substance and the indication of its dosage, concentration, activity, the composition of the active pharmaceutical substance shall not be indicated; 11) list of excipients: for parenteral, ophthalmic medicinal products and drugs for external use, a list of all excipients shall be indicated; for infusion solutions, the qualitative and quantitative composition of all excipients shall be indicated; for other dosage forms, a list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated;	
292.		gross

	12) for infusion solutions that contain more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of injection (the method of administration shall not be indicated for tablets and capsules intended for oral administration); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: "best before: (date, month, year)" or "(date, month, year)"; The expiration date is indicated as " best before (month, year)" or "(month, year)", while the expiration date is determined up to and including the last day of the specified month; 21) registration number of the medicinal product in the form of the designation "RK-MP-"; 22) barcode (if available); 23) means of identification or a material medium containing means of identification	
293.	Availability of primary package labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date "month, year" or " date, month, year"	gross

	Additional information shall be placed that is identical to the information printed on the secondary packaging. Intermediate packaging, which does not allow the information on the primary packaging to be read without compromising its integrity, repeats the information indicated on the primary packaging	
294.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices	significant
295.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of record cards through the portal of an authorized organization online containing a mandatory minimum amount of information	significant
296.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection	significant
297.	Absence of facts of purchase, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan	gross
298.	Absence of facts of production, import, storage, use and sale of counterfeit medicines and medical devices	gross
299.	Absence of facts of sales of medicines and medical devices, the quality of which is not confirmed by a conclusion on safety and quality	gross
300.	Absence of facts of storage, use and sale of expired medicines and medical devices	gross
	Compliance of the medicine with the requirements of the regulatory document on control of the quality	

301.	and safety of the medicine and medical device (based on the results of assessing the safety and quality of samples withdrawn as doubt)	gross
302.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases where: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unusability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illegal traffic of narcotic drugs, psychotropic substances, their analogs and precursors do not represent medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan.	gross
303.	Availability of a list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies to conduct the relevant inspection	gross
304.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day, they are sealed and (or) stamped. Keys, seal and (or) stamp shall be kept by the responsible person	gross
305.	Availability of a first aid kit	minor
	Availability of a sign indicating the name of the subject of pharmaceutical activity, its	

306.	organizational and legal form and mode of operation in the state and Russian languages	minor
307.	Availability of information about the telephone numbers and addresses of territorial divisions of the state body in the field of circulation of medicines and medical devices in a place convenient for the public to familiarize	minor
308.	Ensuring traceability of medicines marked with identification means by providing the drug administration and entities in the field of circulation of medicines and medical devices with information on the introduction into circulation, sale and (or) transfer , as well as on the withdrawal from circulation of labeled medicinal products in the territory of the Republic of Kazakhstan	gross
309.	Compliance with the rules for advertising medicines and medical devices: 1) advertising of medicines and medical products is reliable, recognizable without special knowledge or the use of special means, exclude comparisons with other pharmaceutical services, medicines and medical devices, do not mislead consumers by abusing their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of research and testing; 2) advertising of medicines and medical devices is provided in the Kazakh and Russian languages, contains complete and reliable information about the medicine or medical device, complies with the instructions for medical use of the medicine (insert leaflet), instructions for medical use or operational document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare	gross

310.	Prohibition of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of samples of medicines released with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical devices, except for medicines and medical devices for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations not related to their purpose, use and release, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicines and medical devices; 8) the use of medical workers authorized to prescribe medicines and medical devices as distributors of advertising, with the exception of cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license to carry out the relevant type of activity; 10) advertising of pharmaceutical services provided by persons who do not have a certificate as a specialist in the field of healthcare, including foreign specialists; 11) indication in advertising for the population of methods of treatment for the following diseases: sexually transmitted diseases, cancer, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV	gross

	infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as state officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical devices, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed , and the use of the product is not accompanied by the development of side effects; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicine and medical device	
311.	Availability of a document on calibration and (or) verification of a medical device that is a measuring instrument	gross
312.	Compliance with the fact that the operated medical equipment, at the time of acceptance, was new, unused , of the latest or serial model, without defects	gross
313.	Availability of a log of the technical condition of medical equipment subject to service	gross
314.	Availability of documents confirming current and major repairs	significant
315.	Availability of documents confirming warranty service (at least thirty-seven months from the date of commissioning and frequency recommended by the manufacturer) consisting of periodic monitoring of the technical condition of medical equipment (at least once a year)	gross
	Availability at the operated medical equipment of:	

316.	1) operational documentation (operation manual and service manual); 2) service manual for medical equipment	gross
317.	The presence or absence of facts of medical equipment operation that is not provided with service, removed from service, or operation of medical equipment by personnel who do not have special training, who have not been trained in the use of medical equipment	gross
318.	The presence or absence of facts of unreasonable downtime of medical equipment (lack of measures to restore serviceable condition)	significant
319.	Availability of a certificate of compliance with the requirements of the Good Distribution Practice (GDP) Standard	gross
Section 5. In relation to subjects (objects) of pharmaceutical activities engaged in retail sales of medicines and medical devices		
320.	Ensuring the sale of medical devices related to measuring instruments, in the presence of a certificate of approval of the type of measuring instruments or a certificate of metrological certification of medical measuring equipment	gross
321.	Ensuring the sale of prescription medicines according to a doctor’s prescription	gross
322.	Ensuring that medicines sold without a doctor's prescription are placed on display windows	significant
323.	Registration of invalid prescriptions in the Register of incorrectly written prescriptions and their redemption with the stamp “Prescription is invalid”	minor
324.	Compliance with shelf life of prescriptions: 1) for a medicine containing narcotic drugs, psychotropic substances, precursors and toxic substances – 1 (one) year; 2) for medicines released within the framework of the guaranteed volume	significant

	of free medical care and (or) compulsory social health insurance - 2 (two) years; 3) for other medicines - at least 30 (thirty) calendar days	
325.	Ensuring that reliable information is provided regarding: 1) correct and rational application or use; 2) possible side effects and contraindications; 3) interactions with other drugs, precautions for their use or use; 4) expiration dates and storage rules;	significant
326.	Availability of a document on calibration and (or) verification of a medical device that is a measuring instrument	gross
327.	Compliance with the fact that the operated medical equipment, at the time of acceptance, was new, unused , of the latest or serial model, without defects	gross
328.	Availability of a log of the technical condition of medical equipment subject to service	gross
329.	Availability of documents confirming current and major repairs	significant
330.	Availability of documents confirming warranty service (at least thirty-seven months from the date of commissioning and frequency recommended by the manufacturer) consisting of periodic monitoring of the technical condition of medical equipment (at least once a year)	gross
331.	Availability at the operated medical equipment of: 1) operational documentation (operation manual and service manual); 2) service manual for medical equipment	gross
332.	The presence or absence of facts of operation of medical equipment that is not provided with service, removed from service, or operation of medical equipment by personnel who do not have special training or have not been trained in the use of medical equipment	gross

333.	The presence or absence of facts of unreasonable downtime of medical equipment (lack of measures to restore serviceable condition)	significant
334.	Ensuring the implementation of preventive measures: 1) quality control during acceptance and implementation; 2) compliance with the rules and shelf life of medicines, keeping records of medicines with a limited shelf life; 3) serviceability and accuracy of weighing instruments; 4) checking the correctness of the prescribed prescription, its validity period, the compliance of the prescribed doses with the patient's age, the compatibility of ingredients, and the norms for one-time release; 5) keeping records of the validity periods of safety and quality assessment conclusions	gross
335.	Ensuring acceptance of medicines and medical devices with checking: 1) the compliance of the quantity, completeness, integrity of the container, compliance of packaging, labeling with regulatory documents, availability of instructions for the medical use of a medicine and medical device in the state and Russian languages; availability of an operational document for a medical device; 2) compliance with the name, dosage , packaging, quantity, batch (series) of products specified in the accompanying documents; 3) the presence in the accompanying documents of a certificate of conformity or a reference to it in the invoice for the release of goods	gross
336.	Availability of information on the list of medicines and specialized medicinal products for free provision of certain categories of citizens with certain diseases at the outpatient level in a convenient place for familiarization	minor
	Availability of lists and sample signatures of persons entitled to sign	

337.	prescriptions for free receipt of medicines approved by the head of the relevant healthcare organization in retail sales facilities that have relevant agreements with local government healthcare authorities	minor
338.	Ensuring placement in a place convenient for familiarization of: 1) a copy of the license for pharmaceutical activities and its appendices or a document (including a printed copy of an electronic document) informing about the start or termination of activities or certain actions; 2) books of reviews and suggestions; 3) information about the telephone numbers of the pharmaceutical reference service	minor
339.	Ensuring that the following information is placed in a place visible to visitors: “Medicines cannot be returned or exchanged”; “Medicines are not given to children ”; “The over-the-counter sale of medicines intended for prescription is prohibited”; “Shelf life of drugs prepared in pharmacies”	minor
340.	Compliance with the maximum price for the trade name of a medicine during retail sales	gross
341.	Availability of a specialist certificate in the field of healthcare for each pharmaceutical worker	gross
342.	Availability of a state license for pharmaceutical activities and appendices for subtypes of activity or notification on the start of activity . Compliance with the types and subtypes of activities declared upon receipt of the state license and its appendix	gross
343.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the	gross

	instructions for medical use for medicines and medical devices, operational documents (for medical devices), indicated in the labeling of their packages	
344.	Ensuring the safety, storage conditions of various groups of medicines and medical devices and their handling by complying with the requirements for the design, arrangement, composition, size of areas, equipment of premises (zones) for storing medicines and medical devices and their operation, ensuring safety	gross
345.	Observance of separate storage of medicines and medical devices from other products in order to avoid any impact on them, protection from the negative effects of light, temperature , moisture and other external factors	gross
346.	Keeping records of the expiration dates of medicines and medical devices on paper or electronic media	minor
347.	Carrying out the storage of medicines and medical devices in designated and clearly marked storage zones	significant
348.	Providing the storage room, including the refrigeration room (chamber), with appropriate equipment for monitoring temperature, air humidity (thermometers, hygrometers, other types of instruments) and their location on the internal walls of the premises away from heating devices based on the results of testing zones of temperature fluctuations for cold and warm season	gross
349.	Compliance with separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, physical state, physicochemical properties, exposure to various environmental factors	gross
	Availability of an isolated place for storing medicines, the decision on the circulation of which has not yet been made, expired, returned,	

350.	withdrawn from the category suitable for supply, for which there are suspicions of falsification, recalled and rejected	gross
351.	Providing protection from the effects of weather conditions in the zones of acceptance and shipment. Availability of equipment in the zones of acceptance and shipment (ventilation/ air conditioning system, hygrometer, thermometer), equipment for cleaning containers. Availability of an equipped control zone for the received products	gross
352.	Separation of acceptance, quarantine , defective, shipping and storage zones. Availability of a room in which medicines are stored in quarantine, clearly marked and with limited access	gross
353.	Availability of common fireproof buildings with insulation by fireproof walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, providing the premises with supply and exhaust ventilation	gross
354.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and at least 1.2 meters high	gross
355.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups	gross
356.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling is not more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, which are filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and	gross

	liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)	
357.	Compliance with isolated storage of calcium hypochloride, taking into account its properties	gross
358.	Compliance with the storage of flammable liquids with constant monitoring the condition of containers, their tightness and serviceability	gross
359.	Implementation of measures during storage of explosive drugs against contamination by dust	gross
360.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis	gross
361.	Ensuring the protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other fatty substances, and their storage in isolated rooms or under canopies	gross
362.	Compliance with the conditions for storing dressings in a dry, ventilated area in cabinets, drawers, on racks, pallets, shelves, in conditions that ensure cleanliness	gross
363.	Compliance with the storage conditions of medical instruments, devices, instruments, equipment in dry heated rooms at room temperature, with a relative air humidity not exceeding 65 percent	gross
364.	Compliance with the requirements for finishing premises (areas) for storing medicines and ensuring the cleanliness of premises and storage equipment	significant
365.	Ensuring protection from insects, rodents or other animals and availability of a preventive pest control program	minor
	Separation of rest rooms, dressing rooms, showers and toilets for workers from storage rooms (areas). Food products, drinks, tobacco products, and medicines for personal use shall not be stored in storage	

366.	rooms (areas). Availability of protective clothing or uniform appropriate for the work performed and personal protective equipment if necessary for employees working in the storage area. Personnel working with dangerous drugs shall undergo special training	significant
367.	Providing with the necessary equipment and inventory in drug storage premises: 1) racks, pallets, shelves, cabinets for storing medicines and medical devices; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines	gross
368.	Availability of a document on calibration (verification) of equipment used to control and monitor storage conditions	gross
369.	Availability of a developed and approved emergency action plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage, emergency situations	significant
370.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The equipment shall be used in good condition and kept in proper cleanliness	significant
371.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities carrying out the storage of medicines and medical devices	significant
	Presence of a commission for the destruction of medicines and medical	

372.	devices unsuitable for sale and medical use	significant
373.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use	significant
	Availability of secondary package labeling, including the following information: 1) trade name of the medicine; 2) international nonproprietary name (if available) in Kazakh, Russian and English; 3) name of the manufacturer of the medicine, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated when it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicine is not its packager, then the name of the packager, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, his address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of the active pharmaceutical substance (active pharmaceutical substances); 7) the amount of the medicinal product in the package by weight, volume or number of dosage units, depending on the dosage form and type of packaging; 8) information on the composition of the medicinal product; 9) for medicinal herbal preparations, which are packaged medicinal plant raw materials, the mass of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain humidity; 10) for medicinal products containing narcotic substances, psychotropic substances, their analogs and precursors, the names of	

374.	these substances and their content in weight units or percentages shall be indicated. In single-component medicinal products, subject to the authenticity of the name of the medicinal product and the active pharmaceutical substance and indication of its dosage, concentration, activity, the composition of the active pharmaceutical substance shall not be indicated; 11) list of excipients: for parenteral, ophthalmic drugs and drugs for external use, a list of all excipients shall be indicated; for infusion solutions, the qualitative and quantitative composition of all excipients shall be indicated; for other dosage forms, a list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions that contain more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of injection (the method of administration shall not be indicated for tablets and capsules intended for oral administration); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: "best before: (date, month, year)" or "(date, month, year)"; The expiration date shall be indicated as "best before (month, year)" or "(month, year)", while the	gross

	expiration date shall be determined up to and including the last day of the specified month; 21) registration number of the medicinal product in the form of the designation “RK-MP-”; 22) barcode (if available); 23) means of identification or a material medium containing means of identification	
375.	Availability of primary package labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “ date, month, year” Additional information shall be placed that is identical to the information printed on the secondary packaging. Intermediate packaging, which does not allow the information on the primary packaging to be read without compromising its integrity, repeats the information indicated on the primary packaging	gross
376.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices	significant
377.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of report cards through the portal of an authorized organization online containing a mandatory minimum amount of information	significant

378.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection	significant
379.	Absence of facts of purchase, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan	gross
380.	Absence of facts of production, import, storage, use and sale of counterfeit medicines and medical devices	gross
381.	Absence of facts of sales of medicines and medical devices, the quality of which is not confirmed by a conclusion on safety and quality	gross
382.	Absence of facts of storage, use and sale of expired medicines and medical devices	gross
383.	Compliance of the medicine with the requirements of the regulatory document on control of the quality and safety of the medicine and medical device (based on the results of assessing the safety and quality of samples withdrawn as doubt)	gross
384.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unusability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illegal traffic of narcotic drugs, psychotropic substances, their analogs and precursors do not represent medical,	gross

	scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan.	
385.	Availability of a list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies to conduct the relevant inspection	gross
386.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day, they are sealed and (or) stamped. Keys, seal and (or) stamp shall be kept by the responsible person	gross
387.	Availability of a first aid kit	minor
388.	Availability of a sign indicating the name of the subject of pharmaceutical activity, its organizational and legal form and mode of operation in the state and Russian languages	minor
389.	Availability of information about the telephone numbers and addresses of territorial divisions of the state body in the field of circulation of medicines and medical devices in a place convenient for the public to familiarize	minor
390.	Ensuring traceability of medicines marked with identification means by providing the drug administration and entities in the field of circulation of medicines and medical devices with information on the introduction into circulation, sale and (or) transfer , as well as on the withdrawal from circulation of labeled medicines in the territory of the Republic of Kazakhstan	gross
	Compliance with the rules for advertising medicines and medical devices: 1) advertising of medicines and medical products is reliable, recognizable without special	

391.	knowledge or the use of special means, exclude comparisons with other pharmaceutical services, medicines and medical devices, do not mislead consumers by abusing their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of researches and testings; 2) advertising of medicines and medical devices is provided in the Kazakh and Russian languages, contains complete and reliable information about the medicine or medical device, complies with the instructions for medical use of the medicine (insert leaflet), instructions for medical use or operational document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare	gross
	Prohibition of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of samples of medicines released with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical devices, except for medicines and medical devices for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations not related to their purpose, use and release, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms;	

392.	7) placement of outdoor (visual) advertising of medicines and medical devices; 8) the use of medical workers authorized to prescribe medicines and medical devices as distributors of advertising, with the exception of cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license to carry out the relevant type of activity; 10) advertising of pharmaceutical services provided by persons who do not have a certificate as a specialist in the field of healthcare, including foreign specialists; 11) indication in advertising for the population of methods of treatment for the following diseases: sexually transmitted diseases, cancer, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical devices, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed , and the use of the product is not accompanied by the development of side effects; 16) provide information in advertising that is not directly related	gross

	to the advertised pharmaceutical service, medicine and medical device	
Section 6. In relation to the state expert organization in the field of circulation of medicines and medical devices		
393.	Violation of the rules of state registration, re-registration of a medicine or medical device, amendments to the registration dossier of a medicine or medical device by the State expert organization in the field of circulation of medicines and medical devices	gross
394.	Violation of the procedure for conducting an examination of medicines conducted by a state expert organization in the field of circulation of medicines and medical devices when conducting an examination of the quality and safety of vaccines	gross
Section 7. According to the sources of information provided for in subparagraphs 2) -7) of paragraph 14 of the Criteria		
Criteria for the source of information “Analysis of official Internet resources of state bodies, including authorized bodies in the field of healthcare of countries of the Commonwealth of Independent States (CIS), and the media”		
1.	Availability of facts of non-compliance of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan on the safety, effectiveness and quality of medicines and medical devices, identified based on the results of the analysis of official media, information on helplines, hotlines, information provided by state bodies and organizations, including international ones, as well as websites of authorized bodies in the field of healthcare of countries of the Commonwealth of Independent States (CIS)	gross
Criteria for the source of information “List of identified violations based on the results of laboratory tests conducted by the state expert organization in the field of circulation of medicines and medical devices”		
2.	Availability of test results presented by the state expert organization in the field of circulation of medicines and medical devices, confirming non-compliance with the safety, effectiveness and quality of medicines and medical devices	gross

Criteria for the source of information “The presence of adverse incidents that arose through the fault of the subject of control. Adverse incidents include the probability of causing harm to health, a threat to human life or health, as a result of the production, manufacture, import, storage, sale, application (use) of medicines and medical devices, including those that do not comply with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare”		
3.	The presence of adverse events that have led to a threat to human life or health, caused by the fault of the subject of pharmaceutical activity	gross
Criteria for the source of information “Information from international regulatory authorities in the field of quality and safety of medicines and medical devices, state bodies of countries, including the Eurasian Economic Union”		
4.	Information from international bodies, state bodies of countries, including the Eurasian Economic Union, on facts of non-compliance of medicines and medical devices with legal requirements for safety, effectiveness and quality	gross

Appendix 3
to the criteria for assessment
the degree of risk
in the area of circulation
medicines and medical devices

List of subjective criteria for determining the degree of risk according to subjective criteria in the field of circulation of medicines and medical devices in accordance with Article 138 of the Entrepreneurial Code of the Republic of Kazakhstan in relation to all subjects (objects)

№	Indicator of the subjective criterion	Source of data for the indicator of subjective criterion	Specific weight by significance, points (the total should be 100)	Condition	
				condition 1/value	condition 2/value
For preventive control with a visit					
	The presence of a negative analysis result or non-conformity of medicines and medical devices identified within the framework of the Rules for assessing the quality of medicines and medical devices registered in the Republic of Kazakhstan,	results of the information analysis provided by state bodies and organizations, non-conformity, absence and (or) presence of a negative conclusion obtained based on the results of		no negative result	presence of a negative result

1.	approved by order of the Minister of Healthcare of the Republic of Kazakhstan dated 20.12.2020 № KR HCM-282/ 2020, the Rules for selection from the market, including in medical organizations, medicines and medical devices subject to quality control taking into account a risk-based approach, approved by the order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.12.2020 № KR HCM-323/ 2020	assessing the quality of medicines and medical devices registered in the Republic of Kazakhstan, as well as non-conformity, absence and (or) presence of a negative conclusion obtained by the results of selection from the market, including in medical organizations, of medicines and medical devices subject to quality control taking into account a risk-based approach.	high risk	0%	100%
For the checks for compliance with requirements					
	The fact that there is no re-issuance of the license and (or) an appendix to the license of an individual entrepreneur: 1) changes in the surname, name, patronymic (if any) of the individual licensee; 2) re-registration of an individual entrepreneur-licensee, changing his name or legal address; 3) reorganization of the legal			yes	no

1.	entity-licensee in accordance with the procedure determined by Article 34 of the Law of the Republic of Kazakhstan “On Permits and Notifications” (hereinafter - the Law); 4) changing the address of the object location without physically moving it for a license issued under the class “ permits issued for objects” or for appendices to a license indicating objects; 5) availability of a requirement for re-registration in the laws of the Republic of Kazakhstan	clause 11.8. results of information analysis provided by state bodies and organizations	high risk	0%	100%
	The fact that there is no re-issuance of the license and (or) an appendix to the license of a legal entity: 1) changes in the surname, name, patronymic (if any) of the individual licensee; 2) re-registration of an individual entrepreneur-licensee, changing his name or legal address; 3) reorganization of the legal entity-licensee in accordance with	clause 11.8. results of information		yes	no

2.	the procedure determined by Article 34 of the Law; 4) changing the address of the object location without physically moving it for a license issued under the class “ permits issued for objects” or for appendices to a license indicating objects; 5) availability of a requirement for re-registration in the laws of the Republic of Kazakhstan	analysis provided by state bodies and organizations	high risk	0%	100%

Appendix 16
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan
dated November 15, 2018
№ KR HCM-32 and
the Minister of National
economy of the Republic of Kazakhstan
dated November 15, 2018 № 70

Checklist in the field of circulation of medicines and medical devices for compliance with qualification requirements for subjects (objects) of control

Footnote. Appendix 16 is in the wording of the joint order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

The state body that appointed an inspection/preventive control with a visit
to the subject (object) of control _____

_____

_____

An act on the appointment of an inspection/preventive control with a visit to the subject (object)

of control _____
_____
_____
_____
№, date
Name of the subject (object) of control
_____
_____
(Individual identification number), the business identification number of the subject (object) of control
_____
Location address
_____
_____

№	List of requirements	Meets the requirements	Does not meet the requirements
1.	Compliance of a premise or building under the right of ownership or lease or trust management of state property with sanitary rules establishing sanitary and epidemiological requirements for facilities in the field of circulation of medicines and medical devices		
2.	Availability of equipment and furniture, inventory, instruments and apparatus to ensure quality control and compliance with the conditions of production, manufacturing, storage and sale of medicines and medical devices in accordance with regulatory legal acts		
3.	Availability of a motor vehicle with appropriate cabinets and refrigeration and other equipment, if necessary, ensuring compliance with the conditions of storage and sale of medicines and		

	medical devices for a mobile pharmacy for rural settlements		
4.	Availability of a staff of employees with appropriate education, work experience and specialist certificates for organizations producing medicines and medical devices: higher pharmaceutical or chemical-technological, chemical education and work experience in the specialty for at least three years for heads of departments directly involved in the production of medicines and medical devices, or technical for heads of departments directly involved in the production of medical devices; higher pharmaceutical or chemical, biological education for workers carrying out quality control of medicines and medical devices, or technical education for workers carrying out quality control of medical devices; technical education for a specialist in the maintenance of equipment used in the technological process of production of medicines and medical devices		
	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for organizations in the field of circulation of medicines and medical devices engaged in the manufacture of medicines: higher pharmaceutical education and at least three years of work experience in the specialty for the head		

5.	of a pharmacy that manufactures medicines and its production departments, as well as employees who monitor the quality of medicines and medical devices; higher or secondary pharmaceutical education for employees involved in the direct production of medicinal products and release of manufactured medicinal products; secondary pharmaceutical education and at least three years of work experience in the specialty with the head of a pharmacy and its production departments in the absence of specialists with higher pharmaceutical education in the regional center and rural settlements		
6.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for pharmacies: higher or secondary pharmaceutical education (work experience in the specialty for at least three years) for the head of a pharmacy or its departments; higher or secondary pharmaceutical education for specialists carrying out the sale of medicines and medical devices; when selling medicines via the Internet, the availability of transport on the right of ownership or lease for delivery in a manner that does not allow changes in their properties during storage and transportation		
	Availability of a staff of employees with appropriate education, work experience and a specialist certificate		

7.	for a pharmacy in healthcare organizations providing primary health care, consultative and diagnostic care: higher or secondary pharmaceutical education (work experience in the specialty for at least three years) for the head of a pharmacy, as well as employees involved in the sale of medicines and medical devices. In pharmacies for rural settlements where there are no pharmacies, in the absence of specialists with pharmaceutical education, specialists with medical education who have been trained to sell them shall be allowed to sell medicines and medical devices		
8.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for a pharmacy warehouse: higher pharmaceutical education and at least three years of work experience for the head of a pharmacy warehouse; higher or secondary pharmaceutical education for the heads of pharmacy warehouse departments and workers involved in the acceptance, storage and release of medicines and medical devices		
9.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for a mobile pharmacy for rural settlements: higher or secondary pharmaceutical education for the head of a mobile pharmacy, as well as employees involved in the		

	sale of medicines and medical devices. In the absence of specialists with pharmaceutical education, specialists with a medical education who have been trained for their sale shall be allowed to carry out retail sales of medicines and medical devices		
10.	Availability of a staff of employees with appropriate education, work experience and a specialist certificate for the manufacture of medical devices: higher or secondary pharmaceutical, medical or technical education		
11.	Availability of specialization or improvement and other types of advanced training over the last 5 (five) years in the declared subtypes of pharmaceutical activities		
12.	Availability of higher or secondary pharmaceutical education (work experience in the specialty - at least three years) for individuals applying to engage in pharmaceutical activities without forming a legal entity		

Official(s)

_____

_____

position signature

_____

_____

surname, name, patronymic (if any)

Head of the subject of control

_____

_____

position signature

_____

_____

surname, name, patronymic (if any)

Appendix 17
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 №КР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist in the field of circulation of medicines and medical devices in relation to medical organizations on drug supply issues

Footnote. Appendix 17 – as amended by the joint order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 №87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (effective ten calendar days after the date of its first official publication).

State body that appointed inspection/preventive control with a visit to the control subject (object) _____

_____

_____

Act on appointing inspection / preventive control with a visit to the control subject (object) _____

_____

_____

№, date

Name of the control subject (object)

_____

_____

(Individual Identification Number), Business Identification Number of the control subject (object) _____

_____

Location address

№	List of requirements	Compliance with requirements	Non-compliance with requirements
	Compliance with the prescription of medicines containing narcotic drugs, psychotropic substances		

1.	and their precursors during outpatient and inpatient treatment in health care organizations by a doctor of a health care organization who has access to work with narcotic drugs and their precursors		
2.	Compliance with the recording in the patient's medical documents of the prescription of medications containing narcotic drugs, psychotropic substances and precursors in accordance with Tables II, III, IV of the List of narcotic drugs, psychotropic substances and precursors subject to control in the Republic of Kazakhstan, indicating the single dose, method and frequency of administration , duration of treatment, also substantiation of prescribing the medications		
3.	Ensuring the use (taking) of medicines containing narcotic drugs, psychotropic substances of Tables II, III of the List strictly under the supervision of medical personnel at the time of their dispensing - oral administration, application of transdermal therapeutic systems (patch, film) - in the presence of a nurse, administration of injections - in the presence of a doctor		
4.	Compliance with the rules and procedures for writing prescriptions for medicines containing narcotic drugs, psychotropic substances and precursors (hereinafter -NPP Rules)		
	Presence of a person responsible for storage and		

5.	issuance of special prescription forms		
6.	Ensuring subject-quantitative accounting of special prescription forms		
7.	Availability of a safe or metal cabinet for storing special prescription forms. At the end of the work, the room shall be sealed and (or) stamped. The keys to the room, the seal and (or) the sealer shall be kept by the person in charge		
8.	Ensuring storage and destruction of unused special prescriptions handed in by relatives of deceased patients. Destruction of prescriptions shall be carried out as prescriptions accumulate, but at least once a month, by burning in the presence of a permanent commission, which shall include a representative of the internal affairs body. The fact of destruction of unused special prescriptions shall be formalized by an appropriate report		
9.	Availability of the list of medicines containing narcotic drugs, psychotropic substances of Table II of the List, determined by the order of the head of the healthcare organization, not exceeding a five-day supply, which is used with the permission of the responsible doctor on duty, to provide emergency medical care in a healthcare organization providing inpatient care in the evening and nighttime.		
	Ensuring collection and destruction of empty		

10.	ampoules from medicines containing narcotic drugs, psychotropic substances of Table II of the List, the contents of which are unused or partially used, as well as tablets and patches (transdermal therapeutic systems)		
11.	Availability of an order for a medical worker responsible for issuing a temporary death certificate, ensuring notification of relatives of a deceased cancer patient about handing over unused special prescription forms and medicines containing narcotic and psychotropic substances of Table II of List, as well as acceptance of special prescription forms and unused medicines, containing narcotic and psychotropic substances of Table II of the List after patients died at home. Availability of acts of acceptance and transfer of medicines containing narcotic drugs, psychotropic substances and their precursors remaining after the death of the patient		
12.	Presence of a permanent commission, which includes representatives of internal affairs bodies and the territorial division of the state body in the field of sanitary and epidemiological welfare of the population for destruction of medicines containing narcotic drugs, psychotropic substances of Table II List with expired dates, handed over by relatives of deceased patients, and also broken, defective, empty ampoules, tablets and patches (		

	transdermal therapeutic systems), also ampoules, tablets and patches (transdermal therapeutic systems), the contents of which have been partially used		
13.	Availability of acts of destruction of medicines containing narcotic drugs, psychotropic substances and their precursors of Tables II, III, IV of List		
14.	Compliance with the rules and procedures for registration and storage of medical documentation, requirements for medicines containing narcotic drugs, psychotropic substances and precursors of Tables II, III, IV of the List, approved by the NPP Rules		
15.	Compliance with prescription regulations		
16.	Ensuring registration and monitoring of prescriptions for free or discounted medications		
17.	Ensuring that the specimen signatures of authorized persons entitled to sign prescriptions are sent to the facilities of the pharmaceutical organization		
18.	Reflection in the patient's outpatient record of the contents and numbers of prescriptions for free or discounted medications		
19.	Ensuring the calculation of the need for medicines: 1) in accordance with the medicinal medical organization's drug formulary; 2) based on data on the dynamics of morbidity and the epidemiological situation in the region, as well as statistical data on		

	the projected number of patients; 3) taking into account registers of treated patients; 4) taking into account the actual consumption of medicines for the previous year and the projected balance as of January 1 of the next financial year		
20.	Compliance with the conditions for the procurement of medicines and pharmaceutical services within the framework of the guaranteed volume of free medical care (hereinafter - GVFMC) and medical care in the system of compulsory social health insurance (hereinafter - CSHI)		
21.	Ensuring the distribution of medicines depending on the projected number of patients and certain categories of citizens living in populated areas, by type of diseases		
22.	The following information for patients shall be placed in medical organizations providing outpatient and polyclinic care, facilities in the sphere of drug circulation that provide pharmaceutical services within the framework of the SGBMP, as well as in periodic printed publications distributed on the territory of the respective administrative-territorial unit: 1) the list and addresses of facilities in the sphere of circulation of medicines that provide pharmaceutical services within the GVFMC frames;		

	2) addresses of organizations providing outpatient and polyclinic care through which outpatient pharmaceutical services are provided; 3) address and telephone number of the customer for provision of pharmaceutical services		
23.	Compliance with the rational use (prescription) of medicines and the formation of a drug formulary based on proven clinical effectiveness and safety of medicines		
24.	Presence of a permanent commission that, at least once a quarter, analyzes medical prescriptions at the inpatient, hospital-replacement and outpatient levels		
25.	Ensuring the accounting of medicines within the GVFMC framework during the provision of inpatient, hospital-replacement and outpatient care within the GVFMC framework in total and quantitative terms in medical records or automated programs for accounting and use of medicines		
26.	Reflection of used medications in the medical record of an inpatient patient, in the list of medical prescriptions		
27.	Ensuring provision of medicines received for emergency, inpatient and hospital substitution care within the GVFMC framework with a stamp of a medical organization indicating the name of the medical organization, its address and “Free of charge” mark		

28.	Entering information about side effects, serious side effects and lack of efficacy in the medical record of an inpatient and (or) outpatient patient, including statistics on identified cases of side effects in the medical organization		
29.	Compliance with the requirements for separate storage and accounting of medicines and medical devices procured for the provision of medical care within the GVFMC framework, additional medical care to persons held in pre-trial detention centers and penal (penitentiary) institutions at the expense of budget funds and (or) in the CSHI system and paid services		
30.	Compliance with maximum prices for the trade name of medicines and medical devices, for the international nonproprietary name of a medicine or the technical characteristics of a medical product within the GVFMC framework and (or) in the CSHI system		
31.	In medical organizations providing medical care at all levels within the GVFMC framework, additional medical care to persons held in pre-trial detention facilities and penal (penitentiary) institutions, at the expense of budgetary funds and (or) in the CSHI system, a stock of medicines and medical devices shall be created: for at least one month, except for medical care for HIV infection, where the stock of medicines and		

	medical devices is created for at least three months		
32.	Provision with medicines, medical devices, specialized therapeutic products, immune-biological medicines within the GVFMC framework and (or) in the CSHI system when providing primary medical and sanitary and specialized medical care in outpatient conditions shall be carried out according to the list of medicines and medical devices for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan.		
33.	Provision with medicines and medical devices in outpatient conditions within the GVFMC framework and (or) in the CSHI system of citizens, Kandas, refugees, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan and serving a sentence under a court verdict in liberty deprivation places, detained, imprisoned and placed in special institutions, who are on dispensary registration, shall be carried out at the place of attachment to medical organizations.		
34.	Certain categories of citizens with certain diseases (conditions) shall be provided with free and (or) discounted medicines and medical devices in outpatient conditions within the GVFMC framework and (or) in the CSHI system free of charge		

	according to a doctor's prescription		
35.	Mother and child first aid kits shall be issued for newborns upon discharge from obstetric organizations with a note of issuance in the development history of the newborn		
	Compliance with the procedure for forming the need for medicines and medical devices within the GVFMC framework and the CSHI system: 1) calculation of the need for medicines and medical devices within the GVFMC framework, additional medical care for persons held in pre-trial detention centers and institutions of the penal (penitentiary) system at the expense of budget funds and (or) in the CSHI system: - taking into account the established daily dose for medicines; - based on data on actual consumption of medicines and medical devices for the previous financial year; 2) organizing and conducting the purchase of medicines, medical devices and specialized medical products, pharmaceutical services within the GVFMC framework, additional volume of medical care for persons held in pre-trial detention centers and institutions of the penitentiary (penal) system, at the expense of budgetary funds and (or) in the CSHI system on issues of drug provision and compliance with price limits;		

36.	3) organization and procurement of services for the storage and transportation of medicines and medical devices, services for accounting and sale of medicines and medical devices by a single distributor within the GVFMC framework, additional volume of medical care for persons held in pre-trial detention centers and penitentiary (penal) institutions, at the expense of budgetary funds and (or) in the compulsory medical insurance system on drug supply issues; 4) provision of medicines and medical devices within the GVFMC framework, additional medical care to persons held in pre-trial detention centers and penal (penitentiary) institutions at the expense of budget funds and (or) in the CSHI system; 5) provision of medicines and medical products in rural areas that have no pharmacies; 6) ensuring rational use of medicines and conducting assessments of the rational use of medicines; 7) storage, accounting of medicines and medical devices, when providing medical care within the GVFMC framework, additional medical care to persons held in pre-trial detention centers and penal (penitentiary) institutions, at the expense of budget funds and (or) in the CSHI system		
	Ensuring availability in medical organizations providing medical care at all levels within the GVFMC framework, of an		

37.	additional volume of medical care for persons held in pre-trial detention centers and penal (penitentiary)institutions, at the expense of budgetary funds and (or) in the CSHI system, a supply of medicines and medical products: for at least one month, with the exception of providing medical care for HIV infection, where the stock of medicines and medical products is created for at least three months		
38.	Ensuring redistribution of medicines and medical devices between medical organizations independently in cases of changes in the dynamics of morbidity, transfer or relocation of a patient, changes in the treatment regimen due to intolerance, drug resistance, death, liquidation of medical organizations, changes in the profile of medical services at all levels of medical care		
39.	Compliance with the calculation of the forecast need for medicines for the provision of medical care in inpatient and hospital-replacement conditions		
	Observance of ethics conditions of promoting medicinal products and medical devices specifically: To participate in daily physician conferences in medical and health education organizations, representatives of manufacturers and (or) distributors ten calendar days prior to the planned participation in the daily		

40.	physician conference shall coordinate in writing the time and topic of the event with the head of the health care organization. Individual contacts of manufacturers, distributors or authorized representatives, as well as other entities in the sphere of circulation of medicinal products and medical devices, empowered to promote medicinal products and medical devices, with medical and pharmaceutical workers during their working hours and at their workplace for the purpose of promotion of medicinal products and medical devices shall be excluded. In the interaction of entities in the field of circulation of medicines and medical devices with members of professional associations, the members of professional associations may not encourage adoption of any decisions in the process of its statutory activities in favor of entities in the field of circulation of medicines and medical devices. Members of professional associations shall exclude financial and other collusions for the purpose of obtaining benefits when promoting certain drugs and medical devices on the market, but at the same time shall make efforts to suppress such actions		
	Preventing breaching of ethics in the promotion of medicines and medical devices in the interaction of entities in the field of circulation of medicines and medical devices:		

41.	1) providing or offering financial remuneration or any other material or non-material incentives to medical and pharmaceutical professionals for prescribing and dispensing certain remedies; 2) payment for entertainment, recreation, travel to a place of recreation, with the exception of payments related to the pursuit of scientific and educational activities; 3) conclusion of agreements, organization of actions for prescribing or recommending medicines and medical devices to patients with involvement of medical professionals with the aim of obtaining material benefits, except for written official agreements on conducting biomedical, clinical and economic, epidemiological and other types of research not prohibited by the legislation of the Republic of Kazakhstan, as well as agreements on participation in ongoing marketing research; 4) providing samples of medicines and medical devices to patients, except for cases not prohibited by the legislation of the Republic of Kazakhstan; 5) encouragement to prescribe medicines and medical devices on prescription forms not of the established pattern, including those containing advertising information, as well as with pre-printed names of medicines and medical devices;			

	6) organization of programs that provide property and non-property prizes, gifts to pharmacy managers and pharmacy employees for achieving certain sales results.		
42.	Placement in places of visual information for patients and on the Internet resource of a medical organization of the list of medicines and medical devices for free and (or) preferential outpatient provision of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions), as well as addresses of medical organizations through which outpatient drug provision is carried out and toll-free telephone number (if available) to obtain information on the use of medicines		
43.	Compliance with the two-year storage period of prescriptions for medicines dispensed under the GVFMC and (or) the CSHI system		
44.	Holding by each pharmacy worker of a health specialist certificate		
45.	Availability of a state license for pharmaceutical activities and of attachments for subtypes of activity or notification of the commencement of activity. Compliance with the types and subtypes of activities declared upon receipt of the state license and attachment to it		
	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the		

46.	regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices, operational documents (for the medical device), indicated in the labeling of their packages		
47.	Ensuring safety, storage conditions and handling of various groups of medicines and medical devices by complying with the requirements for design , arrangement, composition , size of areas, equipment of premises (areas) for storage of medicines and medical devices and their operation, ensuring the safety		
48.	Storage of medicines and medical devices separate from other products to avoid any impact on them, protection from negative impact of light, temperature, moisture and other external factors		
49.	Keeping records of the expiry dates of medicines and medical devices on paper or electronic media		
50.	Storage of medicines and medical devices in designated and clearly marked storage areas		
51.	Provision of storage premises, including a refrigerating room (chamber) with appropriate equipment for control of temperature, air humidity (thermometers, hygrometers , other types of devices) and their location on the internal walls of the premises away from heating devices based on the results of testing of temperature fluctuation		

	zones for cold and warm seasons		
52.	Observance of separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, aggregate state, physicochemical properties, exposure to various environmental factors		
53.	Availability of isolated storage space for pending, expired, returned, withdrawn, presumably counterfeit, recalled and rejected medicinal products		
54.	Provision of weather protection in the receiving and discharge areas. Availability of equipment in receiving and discharge areas (ventilation/air conditioning system, hygrometer, thermometer), container cleaning equipment. Availability of an equipped area for inspection of received products		
55.	Separation of receiving, quarantine, defective, discharge and storage areas. Availability of a clearly labeled and restricted access quarantine room where medicines are stored.		
56.	Availability of common non-combustible buildings with insulation by non-combustible walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, provision of premises with supply and exhaust ventilation		

57.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and 1.2 meters high		
58.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups		
59.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling must be no more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)		
60.	Compliance with isolated storage of calcium hypochloride, taking into account its properties		
61.	Compliance with the storage of flammable liquids with constant monitoring of the condition of containers, their tightness and serviceability		
	Implementation of measures in the storage of		

62.	explosive medicines against contamination by dust		
63.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis		
64.	Ensuring protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other greasy substances, and their storage in isolated rooms or under sheds		
65.	Observance of conditions of storage of dressings in a dry ventilated area in cabinets, drawers, on racks, pallets, trays, in conditions ensuring cleanliness		
66.	Compliance with the conditions of storage of medical instruments, devices, appliances, equipment in dry heated rooms at room temperature, with relative humidity not exceeding 65 percent		
67.	Compliance with the requirements for interior finishing of premises (areas) for storing medicines and ensuring cleanliness of storage premises and equipment		
68.	Providing protection against the entry of insects, rodents or other animals, and presence of preventive pest control program		
69.	Separation of rest rooms, dressing rooms, showers and toilets for employees from storage rooms (areas). Food, beverages, tobacco products, as well as medicines for personal use shall not be stored in storage rooms (areas). Employees working in the storage area shall have		

	protective or work clothing appropriate to the work performed and personal protective equipment if necessary. Personnel working with hazardous medicinal products shall undergo special instruction		
70.	Provision of the necessary equipment and inventory in drug storage areas: 1) racks, pallets, shelves, cabinets for storing medicines and medical products; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) mechanization means for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines		
71.	Availability of a document on calibration (verification) of equipment used for control and monitoring of storage conditions		
72.	Availability of a developed and approved emergency plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage , emergency situations		
73.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The used equipment shall		

	be in good condition and kept in proper cleanliness		
74.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities storing medicines and medical devices		
75.	Availability of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use		
76.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use		
	Availability of secondary package labeling including the following information: 1) trade name of the medicinal product; 2) international non-proprietary name (if any) in Kazakh, Russian and English languages; 3) name of the manufacturer of the medicinal product, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packer, the name of the packer, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, its address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if		

77.	applicable) of active pharmaceutical substance(s); 7) quantity of the medicinal product in the package by weight, volume or number of dosage units depending on the dosage form and type of package; 8) information on the composition of the medicinal product; 9) for herbal medicinal products which are prepackaged medicinal plant raw materials, the weight of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain moisture content; 10) for medicinal preparations containing in their composition substances subject to control in accordance with the Law of the Republic of Kazakhstan "On narcotic drugs, psychotropic substances, their analogs and precursors and measures to counteract their illicit trafficking and abuse", the names of these substances and their content in weight units or percent shall be indicated. In single-component medicinal preparations, provided that the name of the medicinal product and active pharmaceutical substance are authentic and its dosage, concentration, activity are indicated, the composition of the active pharmaceutical substance shall not be indicated; 11) list of auxiliary substances: for parenteral, ophthalmic drugs and preparations for external use, the list of all			

	auxiliary substances shall be indicated; for infusion solutions the qualitative and quantitative composition of all auxiliary substances shall be indicated; for other dosage forms the list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions containing more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of administration (the method of administration for tablets and capsules intended for oral administration shall not be indicated); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: " expiration date: (date, month, year)" or "(date, month, year)"; The expiration date "best before (month, year)" or "(month, year)" shall be indicated, whereby the expiration date shall be			

	determined up to and including the last day of the indicated month; 21) registration number of the medicinal product in the form of the designation “RK-LS-”; 22) bar code (if any); 23) means of identification or material medium containing means of identification		
78.	Availability of primary packaging labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “day, month, year” Additional information identical to that on the secondary package is placed. An intermediate package that does not allow the information on the primary packaging to be read without compromising its integrity repeats the information on the primary packaging		
79.	Organization of work to monitor adverse reactions and (or) lack of efficacy of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices		

80.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of efficacy of medicines and medical devices. Transmission of message cards through the portal of an authorized organization online containing a mandatory minimum amount of information		
81.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection		
82.	Absence of facts of procurement, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan		
83.	Absence of facts of production, importation, storage, use and sale of counterfeit medicines and medical devices		
84.	Absence of facts of sale of medicines and medical devices, the quality of which is not confirmed by the conclusion on safety and quality		
85.	Absence of facts of storage , use and sale of expired medicines and medical devices		
86.	Compliance of the medicinal product with the requirements of the regulatory document on quality and safety control of the medicinal product and medical device (based on the results of safety and		

	quality assessment of samples withdrawn as doubtful)		
87.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unsuitability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illicit circulation of narcotic drugs, psychotropic substances, their analogs and precursors that do not have medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan		
88.	Availability of the list of persons who have conclusions from psychiatrists and narcologists on the absence of drug addiction, substance abuse, chronic alcoholism, also on suitability for carrying out activities related to narcotic drugs, psychotropic substances and their		

	precursors and the conclusion of the internal affairs bodies on conducting the relevant check		
89.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day they shall be sealed and (or) stamped. Keys, seal and (or) sealer shall be kept by the responsible person		
90.	Availability of a first aid kit		
91.	Availability of a signboard indicating the name of the pharmaceutical activity subject, its organizational and legal form and operation mode in the state and Russian languages		
92.	Availability of information on telephone numbers and addresses of territorial subdivisions of the state body in the sphere of circulation of medicines and medical devices in a place convenient for the population's viewing		
93.	Ensuring traceability of medicinal products labeled with identification means by providing by participants of circulation of medicinal products and entities in the sphere of circulation of medicinal products and medical devices of information on launch into circulation, on sale and (or) transfer, as well as on withdrawal of labeled medicinal products from circulation on the territory of the Republic of Kazakhstan		
	Compliance with the rules of advertising of medicinal products and medical devices:		

94.	1) advertising of medicinal products and medical devices shall be reliable, recognizable without special knowledge or application of special means, exclude comparisons with other pharmaceutical services, medicinal products and medical devices, not to mislead consumers through abuse of their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of research and testing; 2) advertising of medicinal products and medical devices shall be in Kazakh and Russian languages, contain complete and reliable information on the medicinal product or medical device, comply with the instruction for medical use of the medicinal product (leaflet-insert), instruction for medical use or operating document for the medical device; 3) availability of the conclusion on compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare		
	Non-admission of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of		

95.	samples of medicines dispensed with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical products, except for medicines and medical products for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations unrelated to their purpose, use and dispensing, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicinal products and medical devices; 8) use of medical professionals authorized to prescribe medicines and medical devices as distributors of advertisements, except for cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license for the relevant type of activity ; 10) advertising of pharmaceutical services provided by persons who do not have a certificate of a health care specialist,			

	including foreign specialists; 11) indication in advertising to the public of treatment methods for the following diseases: sexually transmitted diseases, oncology, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical products, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the efficacy of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed, and the use of the product is not accompanied by the development of side effects ; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicinal product and medical device		
96.	Availability of a document on calibration and (or)		

	verification of a medical device that is a measuring instrument		
97.	Compliance with the requirement that the medical equipment in use, at the time of acceptance, was new, unused, the latest or a serial model, free of defects		
98.	Availability of a log of the technical condition of medical equipment subject to service		
99.	Availability of documents confirming current and major repairs		
100.	Availability of documents confirming warranty service (not less than thirty-seven months from the date of commissioning and periodicity recommended by the manufacturer) consisting of periodic inspection of the technical condition of medical equipment (at least once a year).		
101.	Availability in operated medical equipment: 1) of operational documentation (operation manual and service manual); 2) of service manual for medical equipment		
102.	Presence of facts of operation of medical equipment not provided with service maintenance, removed from service maintenance, or operation of medical equipment by personnel without special training, not trained in the use of medical equipment.		
103.	Presence of facts of unjustified idling of medical equipment (		

	absence of measures for restoration of serviceable condition)		

Designated person (s)

_____

_____

position, signature

_____

_____

surname, name, patronymic (if any)

The head of the control subject

_____

_____

position, signature

_____

____

surname, name, patronymic (if any)

Appendix 18
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist in the field of circulation of medicines and medical devices regarding subjects (objects) of pharmaceutical activities engaged in the production of medicines and medical devices

Footnote. Appendix 18 – as amended by the joint order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 №87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (effective ten calendar days after the date of its first official publication).

State body that appointed inspection/preventive control with a visit to the control subject (object) _____

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_____

Act on appointing inspection / preventive control with a visit to control subject (object) _____

_____

_____

_____

№, date

Name of the control subject (object)

_____

_____

(Individual Identification Number), Business Identification Number of the control subject (object) _____

_____

Location address

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1.	Compliance with all production processes of medicines and medical devices (GMP)		
2.	Availability of state registration in the Republic of Kazakhstan of medicinal substances used in production, with the exception of those produced under Good Manufacturing Practice conditions		
3.	Availability of forwarding documents for medicines and medical productsв		
4.	Carrying out activities for the production of medicines or wholesale distribution of medicines by suppliers of substances or intermediate products		
5.	Compliance of substances, excipients, consumables and packaging materials with the registration dossier		
6.	Incoming control of raw materials (substances, auxiliary materials), materials, semi-finished products, components; intermediate control during the production process, control of finished pharmaceutical products		

7.	Availability of a quality assurance system, documentation and control of its efficacy in production		
8.	Ensuring registration of all technological and auxiliary operations during the production of a separate series of medicines and medical devices		
9.	Compliance with the requirements for maintaining documentation of all production processes and materials used in production, its storage order		
10.	Compliance with stability testing, shelf-life establishment, and revalidation of medications .		
11.	Ensuring that the number of samples is sufficient for testing when necessary (arbitration tests)		
12.	Availability of markings indicating the status of manufactured products, initial products, packaging materials		
13.	Quality control of materials , intermediate products, finished products.		
14.	Maintaining of database of side effects of medicines and medical devices		
15.	Availability of a health specialist certificate for each pharmacy worker		
16.	Availability of a state license for pharmaceutical activities and of attachments for subtypes of activity or notification of the commencement of activity. Compliance with the types and subtypes of activities declared upon receipt of the state license and attachment to it		

17.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices, operational documents (for the medical device), indicated in the labeling of their packages		
18.	Ensuring safety, storage conditions and handling of various groups of medicines and medical devices by complying with the requirements for design , arrangement, composition , size of the areas, equipment of premises (areas) for storage of medicines and medical devices and their operation, ensuring the safety		
19.	Observance of storing medicines and medical devices separate from other products to avoid any impact on them, protection from negative impact of light, temperature, moisture and other external factors		
20.	Keeping records of the expiry dates of medicines and medical devices on paper or electronic media		
21.	Storage of medicines and medical devices in designated and clearly marked storage areas		
22.	Provision of storage premises, including a refrigerating room (chamber) with appropriate equipment for control of temperature, air humidity (thermometers, hygrometers , other types of devices) and their location on the		

	internal walls of the premises away from heating devices based on the results of testing of temperature fluctuation zones for cold and warm seasons		
23.	Observance of separation during storage of all medicines and medical devices depending on the pharmacological group, administration method, aggregate state, physicochemical properties, exposure to various environmental factors		
24.	Availability of isolated storage space for pending, expired, returned, withdrawn, presumably counterfeit, recalled and rejected medicinal products		
25.	Provision of weather protection in the receiving and discharge areas. Availability of equipment in receiving and discharge areas (ventilation/air conditioning system, hygrometer, thermometer), container cleaning equipment. Availability of an equipped area for inspection of received products		
26.	Separation of acceptance, quarantine, defective, discharge and storage areas. Availability of a room in which medicines are stored in quarantine, clearly marked and with limited access		
27.	Availability of common non-combustible buildings with insulation by non-combustible walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable		

	substances, provision of premises with supply and exhaust ventilation		
28.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and 1.2 meters high		
29.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups		
30.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling must be no more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)		
31.	Compliance with isolated storage of calcium hypochloride, taking into account its properties		
32.	Compliance with the storage of flammable liquids with constant monitoring of the condition		

	of containers, their tightness and serviceability		
33.	Implementation of measures in the storage of explosive medicines against their contamination by dust		
34.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis		
35.	Ensuring protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other greasy substances, and their storage in isolated rooms or under sheds		
36.	Observance of conditions of storing dressings in a dry ventilated area in cabinets, drawers, on racks, pallets, trays, in conditions ensuring cleanliness		
37.	Compliance with the conditions of storing medical instruments, devices, appliances, equipment in dry heated rooms at room temperature, with relative humidity not exceeding 65 percent		
38.	Compliance with the requirements for interior finishing of premises (areas) for storing medicines and ensuring cleanliness of storage premises and equipment		
39.	Providing protection against the entry of insects, rodents or other animals, and presence of preventive pest control program		
	Separation of rest rooms, dressing rooms, showers and toilets for employees from storage rooms (areas). Food, beverages, tobacco products, as well as medicines for personal use		

40.	shall not be stored in storage rooms (areas). Employees working in the storage area shall have protective or work clothing appropriate to the work performed and personal protective equipment if necessary. Personnel working with hazardous medicinal products shall undergo special instruction		
41.	Provision of the necessary equipment and inventory in drug storage areas: 1) racks, pallets, shelves, cabinets for storing medicines and medical products; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines		
42.	Availability of a document on calibration (verification) of equipment used for control and monitoring of storage conditions		
43.	Availability of a developed and approved emergency plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage , emergency situations		
	Availability of developed and approved instructions		

44.	for cleaning and disinfection of equipment. The used equipment shall be in good condition and kept in proper cleanliness		
45.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at the facilities storing medicines and medical devices.		
46.	Availability of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use.		
47.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use.		
	Availability of secondary package labeling including the following information: 1) trade name of the medicinal product; 2) international non-proprietary name (if any) in Kazakh, Russian and English languages; 3) name of the manufacturer of the medicinal product, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packer, the name of the packer, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, its address (city, country); 5) dosage form;		

48.	6) dosage, and (or) activity, and (or) concentration (if applicable) of active pharmaceutical substance(s); 7) quantity of the medicinal product in the package by weight, volume or number of dosage units depending on the dosage form and type of package; 8) information on the composition of the medicinal product; 9) for herbal medicinal products which are prepackaged medicinal plant raw materials, the weight of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain moisture content; 10) for medicinal preparations containing in their composition substances subject to control in accordance with the Law of the Republic of Kazakhstan "On narcotic drugs, psychotropic substances, their analogs and precursors and measures to counteract their illicit trafficking and abuse", the names of these substances and their content in weight units or percent shall be indicated. In single-component medicinal preparations, provided that the name of the medicinal product and active pharmaceutical substance are authentic and its dosage, concentration, activity are indicated, the composition of the active pharmaceutical substance shall not be indicated; 11) list of auxiliary substances:			

	for parenteral, ophthalmic drugs and preparations for external use, the list of all auxiliary substances shall be indicated; for infusion solutions the qualitative and quantitative composition of all auxiliary substances shall be indicated; for other dosage forms the list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions containing more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of administration (the method of administration for tablets and capsules intended for oral administration shall not be indicated); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: " expiration date: (date, month, year)" or "(date, month, year)"; The expiration date "best before (month, year)" or "(month, year)" shall be indicated, whereby the			

	expiration date shall be determined up to and including the last day of the indicated month; 21) registration number of the medicinal product in the form of the designation “RK-LS-”; 22) bar code (if any); 23) means of identification or material medium containing means of identification		
49.	Availability of primary packaging labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “day, month, year” Additional information identical to that on the secondary package is placed. An intermediate package that does not allow the information on the primary packaging to be read without compromising its integrity repeats the information on the primary packaging		
50.	Organization of work to monitor adverse reactions and (or) lack of efficacy of medicines and medical devices, appointment of responsible persons for		

	monitoring side effects of medicines and medical devices		
51.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of efficacy of medicines and medical devices. Transmission of message cards through the portal of an authorized organization online containing a mandatory minimum amount of information		
52.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) efficacy to the authorized organization in cases of detection		
53.	Absence of facts of procurement, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan		
54.	Absence of facts of production, importation, storage, use and sale of counterfeit medicines and medical devices		
55.	Absence of facts of sale of medicines and medical devices, the quality of which is not confirmed by the conclusion on safety and quality		
56.	Absence of facts of storage , use and sale of expired medicines and medical devices		
57.	Compliance of the medicinal product with the requirements of the regulatory document on quality and safety control of the medicinal product		

	and medical device (based on the results of safety and quality assessment of samples withdrawn as doubtful)		
58.	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unsuitability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illicit circulation of narcotic drugs, psychotropic substances, their analogs and precursors that do not have medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan		
59.	Availability of a list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities		

	related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies on conducting the relevant check		
60.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day they shall be sealed and (or) stamped. Keys, seal and (or) sealer shall be kept with the responsible person		
61.	Availability of a first aid kit		
62.	Availability of a signboard indicating the name of the pharmaceutical activity subject, its organizational and legal form and operation mode in the state and Russian languages		
63.	Availability of information on telephone numbers and addresses of territorial subdivisions of the state body in the sphere of circulation of medicines and medical devices in a place convenient for the population's viewing		
64.	Ensuring traceability of medicinal products labeled with identification means by providing by participants of circulation of medicinal products and entities in the sphere of circulation of medicinal products and medical devices of information on launch into circulation, on sale and (or) transfer, as well as on withdrawal of labeled medicinal products from circulation on the territory of the Republic of Kazakhstan		
	Compliance with the rules of advertising medicinal		

65.	products and medical devices: 1) advertising of medicinal products and medical devices shall be reliable, recognizable without special knowledge or application of special means, exclude comparisons with other pharmaceutical services, medicinal products and medical devices, not to mislead consumers through abuse of their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of research and testing; 2) advertising of medicinal products and medical devices shall be in Kazakh and Russian languages, contain complete and reliable information on the medicinal product or medical device, comply with the instruction for medical use of the medicinal product (leaflet-insert), instruction for medical use or operating document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare		
	Non-admission of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media;		

66.	3) distribution for advertising purposes of samples of medicines dispensed with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical products, except for medicines and medical products for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations unrelated to their purpose, use and dispensing, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicinal products and medical devices; 8) use of medical professionals authorized to prescribe medicines and medical devices as distributors of advertisements, except for cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license for the relevant type of activity ; 10) advertising of pharmaceutical services provided by persons who			

	do not have a certificate of a health care specialist, including foreign specialists; 11) indication in advertising to the public of treatment methods for the following diseases: sexually transmitted diseases, oncology, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical products, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and efficacy of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed, and the use of the product is not accompanied by the development of side effects ; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicinal product and medical device		
67.	Compliance with manufacturer's price limits		

68.	Availability of a certificate of compliance with the requirements of the Good Manufacturing Practice (GMP) Standard		

Designated person (s)

_____

_____

position, signature

_____

_____

surname, name, patronymic (if any)

The head of the control subject

_____

_____

position, signature

_____

_____

surname, name, patronymic (if any).

Appendix 19
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist in the field of circulation of medicines and medical devices regarding subjects (objects) of pharmaceutical activity, engaged in manufacturing of medicines and medical devices

Footnote. Appendix 19 as amended by the joint order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 №87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (effective ten calendar days after the date of its first official publication).

State body that appointed inspection/preventive control with a visit to the control subject (object) _____

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_____

_____

Act on appointing inspection / preventive control with a visit to

control subject (object) _____
_____

_____

_____

№, date

Name of the control subject (object)

_____

_____

(Individual Identification Number), Business Identification Number of the control subject (object) _____

_____

Location address

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1.	Availability of a workplace of a pharmacist-analyst equipped with a standard set of measuring instruments, testing equipment, laboratory utensils, auxiliary materials		
2.	Implementation of preventive (precautionary) measures, acceptance control of starting materials (drug substance, excipient), written, organoleptic, random questioning control , random physical and chemical control, control at dispensing of manufactured medicinal products		
3.	Availability and maintenance of checklists when manufacturing medicines according to prescriptions and requirements of medical organizations		
4.	Availability and maintenance of the logbook of organoleptic, physical and chemical control results numbered, laced, sealed and signed by the head of the pharmacy.		
	Presence of state registration in the Republic		

5.	of Kazakhstan for medicinal substances used in manufacturing, except for those produced under Good Manufacturing Practice conditions		
6.	Implementation by substance suppliers of activities in the manufacture of medicines or in the wholesale distribution of medicines		
7.	Maintaining and monitoring of the expiration dates of medicines and medical devices		
8.	Ensuring technology for the manufacture of a medicinal product, in accordance with the requirements of the general articles of the State Pharmacopoeia of the Republic of Kazakhstan		
9.	Implementation of preventive (precautionary) measures: 1) compliance with the conditions of aseptic manufacturing of medicinal products; 2) ensuring the serviceability and accuracy of weighing instruments, carrying out their annual verification; 3) ensuring proper conditions for obtaining, collecting, storing purified water, water for injection, correct labeling of the container in the form of indicating on the tag the date of receipt, the analysis number and the signature of the person who performed the analysis; 4) compliance with the terms and conditions of storage of reagents, reference and titrated solutions and their correct		

	design (the labels shall indicate, in addition to the name, the concentration, molarity, date of receipt, expiration date, storage conditions, and by whom it was manufactured); 5) determination of deviations in the tested medicinal products using measuring instruments of the same type (with the same metrological characteristics) as when they were manufactured in pharmacies; 6) proper handling, filling, design of burette set and glass stoppered bottles		
	Design of glass stoppered bottle (pharmacy containers) as follows: 1) on the containers in the storage premises, the name, country and manufacturing plant shall be indicated, series number of the manufacturing plant, number and validity term of the product conformity certificate, expiration date of the medicinal substance, date of filling, signature of the person who filled the container and verified the authenticity of the medicinal substance; 2) on the containers with medicinal substances and excipients, which are kept in the assistant's room, the date the bottle container was filled, the signature of the person who filled the container and verified the authenticity of the medicinal substance and excipients shall be indicated; 3) on containers with narcotic drugs, psychotropic substances, precursors, toxic substances, the highest		

10.	single and daily doses shall be additionally indicated; 4) on containers with medicinal substances containing cardiac glycosides, the number of units of action in one gram of medicinal plant material or in one milliliter of solution shall be indicated; 5) on containers with medicinal substances intended for the manufacture of medicinal products requiring aseptic manufacturing conditions, the inscription: “For sterile medicinal products” shall be indicated; 6) on containers with medicinal substances containing moisture, the percentage of moisture; on cylinders with liquids (hydrogen peroxide solution , ammonia solution, formaldehyde) the actual content of the active substance shall be indicated; 7) containers with solutions , tinctures and liquid semi-finished products shall be provided with droppers or pipettes, indicating the number of drops established by weighing in a certain volume		
11.	Presence and maintenance of the Logbook of registration of the results of control of medicinal substances for authenticity		
12.	Monitoring compliance with drug manufacturing technology by a pharmacy technician		
	Acceptance control of starting materials (drug substance, auxiliary substance) used for manufacturing of medicinal		

13.	products (delivery note, quality certificate of the manufacturing plant), compliance of series on samples of drug substances and auxiliary substances with the series specified in the accompanying documentation, compliance with storage and transportation conditions, as well as identification of drug substances and auxiliary materials according to the indicators “Packaging”, “Labeling” and “Description”.		
14.	Performing a written control of medications manufactured by the pharmacy by completing a checklist immediately after manufacturing the medication. The checklist shall contain: 1) date of manufacture;; 2) number of the prescription or of the requirement of the medical organization with indication of the name of the department; 3) names of the medicinal substances taken, their quantity, total volume or weight, number of doses; 4) signatures of the person who made, packaged and checked the drug substance . The names of narcotic drugs, poisonous, psychotropic substances, precursors shall be underlined with a red pencil in the checklist, the letter “D” shall be put on medicinal products for children. The checklist shall be filled out in Latin in accordance with the sequence of manufacturing technology.		

	All calculations shall be written on the back of the checklist		
15.	Conducting random survey control of medications manufactured in the pharmacy		
16.	Organoleptic control of appearance, color, odor, homogeneity, absence of visible mechanical inclusions in solutions		
	Random physical control by checking the total mass or volume of the medicinal product, the number and mass of individual doses included in the given medicinal product (but no less than three doses) and the quality of capping. The following are subject to selective physical control: 1) each series of packaging of industrial products and in-house pharmaceutical preparations in the amount		

17.	of three to five packages, including packaging of homeopathic medicines for compliance with the norms of deviations permissible in the manufacture of medicines (including homeopathic) in a pharmacy and the norms of deviations permissible during packaging of industrial products; 2) at least three percent of medicinal products manufactured according to prescriptions (requirements) in one working day; 3) the number of homeopathic granules in a certain mass of the sample; 4) each series of medicinal products requiring sterilization, after packaging before sterilization in the amount of at least five vials (bottles) for mechanical inclusions (mobile insoluble substances, except for gas bubbles, accidentally present in solutions)	The following are subject		

		to selective physical control:	
18.	Primary and secondary control for mechanical inclusions in the process of manufacturing solutions		
19.	Chemical control for the following indicators: 1) authenticity, purity tests and permissible limits of impurities (qualitative analysis); 2) quantitative determination (quantitative analysis) of medicinal substances included in its composition		
20.	Complete chemical analysis of purified water		
21.	Control over dispensing by checking all manufactured medicinal products, including homeopathic medicinal products for compliance of: 1) packaging of medicinal preparations with physical and chemical properties of the medicinal substances included in them; 2) doses indicated in the prescription, including the highest single doses, highest daily doses of medicinal products to the patient's age; 3) the number on the prescription and the number on the label; 4) the patient's surname on the receipt, surname on the label and prescription; 5) design of medicines		
22.	Ensuring that the results of control of individual stages of manufacturing solutions for injections and infusions are recorded in the log of control results of individual stages of manufacturing solutions for injections and infusions		

23.	Availability of a nomenclature of concentrates, semi-finished products and intra-pharmacy preparation of medicinal products manufactured in the pharmacy, annually approved by an accredited testing laboratory with which a contract on control and analytical services has been concluded		
24.	Holding by each pharmacy worker of a health specialist certificate		
25.	Availability of a state license for pharmaceutical activities and of attachments for subtypes of activity or notification of the commencement of activity. Compliance with the types and subtypes of activities declared upon receipt of the state license and attachment to it		
26.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices, operational documents (for the medical device), indicated in the labeling of their packages		
27.	Ensuring safety, storage conditions and handling of various groups of medicines and medical devices by complying with the requirements for design , arrangement, composition , size of areas, equipment of premises (areas) for storage of medicines and medical devices and their		

	operation, ensuring the safety		
28.	Storage of medicines and medical devices separate from other products to avoid any impact on them, protection from negative impact of light, temperature, moisture and other external factors		
29.	Keeping records of the expiry dates of medicines and medical devices on paper or electronic medium		
30.	Storage of medicines and medical devices in designated and clearly marked storage areas		
31.	Provision of storage premises, including a refrigerating room (chamber) with appropriate equipment for control of temperature, air humidity (thermometers, hygrometers , other types of devices) and their location on the internal walls of the premises away from heating devices based on the results of testing of temperature fluctuation zones for cold and warm seasons		
32.	Observance of separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, aggregate state, physicochemical properties , exposure to various environmental factors		
33.	Availability of isolated storage space for pending, expired, returned, withdrawn, presumably counterfeit, recalled and rejected medicinal products		
	Provision of weather protection in the receiving		

34.	and discharge areas. Availability of equipment in receiving and discharge areas (ventilation/air conditioning system, hygrometer, thermometer), container cleaning equipment. Availability of an equipped area for inspection of received products		
35.	Separation of receiving, quarantine, defective, discharge and storage areas . Availability of a clearly labeled and restricted access quarantine room where medicines are stored .		
36.	Availability of common non-combustible buildings with insulation by non-combustible walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, provision of premises with supply and exhaust ventilation		
37.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and 1.2 meters high		
38.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups		
	Compliance with the storage of flammable and combustible liquid medicines that should not be stored:		

39.	1) in a completely filled container, the degree of filling must be no more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)		
40.	Compliance with isolated storage of calcium hypochloride, taking into account its properties		
41.	Compliance with the storage of flammable liquids with constant monitoring of the condition of containers, their tightness and serviceability		
42.	Implementation of measures in the storage of explosive medicines against their contamination by dust		
43.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis		
44.	Ensuring protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other greasy substances, and their storage in isolated rooms or under sheds		
45.	Observance of storage conditions of dressings in a dry ventilated area in cabinets, drawers, on racks, pallets, trays, in conditions ensuring cleanliness		

46.	Compliance with the storage conditions of medical instruments, devices, appliances, equipment in dry heated rooms at room temperature, with relative humidity not exceeding 65 percent		
47.	Compliance with the requirements for interior finishing of premises (areas) for storing medicines and ensuring cleanliness of storage premises and equipment		
48.	Providing protection against the entry of insects, rodents or other animals, and presence of preventive pest control program		
49.	Separation of rest rooms, dressing rooms, showers and toilets for employees from storage rooms (areas). Food, beverages, tobacco products, as well as medicines for personal use shall not be stored in storage rooms (areas). Employees working in the storage area shall have protective or work clothing appropriate to the work performed and personal protective equipment if necessary. Personnel working with hazardous medicinal products shall undergo special instruction		
50.	Provision of the necessary equipment and inventory in drug storage premises: - racks, pallets, poles, cabinets for storing medicines and medical products; - technological equipment for creating temperature conditions; - instruments for recording temperature and humidity;		

	- means of mechanization for loading and unloading operations; - disinfectants and cleaning equipment to ensure sanitary conditions; - other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines		
51.	Availability of a document on calibration (verification) of equipment used for control and monitoring of storage conditions		
52.	Availability of a developed and approved emergency plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage , emergency situations		
53.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The used equipment shall be in good condition and kept in proper cleanliness		
54.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities storing medicines and medical devices		
55.	Availability of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use		
56.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use		

	Availability of secondary package labeling including the following information: 1) trade name of the medicinal product; 2) international non-proprietary name (if any) in Kazakh, Russian and English languages; 3) name of the manufacturer of the medicinal product, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packer, the name of the packer, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, its address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of active pharmaceutical substance(s); 7) quantity of the medicinal product in the package by weight, volume or number of dosage units depending on the dosage form and type of package; 8) information on the composition of the medicinal product; 9) for herbal medicinal products which are prepackaged medicinal plant raw materials, the weight of medicinal plant raw materials and (or) active pharmaceutical			

57.	substance of plant origin shall be indicated at their certain moisture content; 10) for medicinal preparations containing in their composition substances subject to control in accordance with the Law of the Republic of Kazakhstan “On narcotic drugs, psychotropic substances, their analogs and precursors and measures to counteract their illicit trafficking and abuse”, the names of these substances and their content in weight units or percent shall be indicated. In single-component medicinal preparations, provided that the name of the medicinal product and active pharmaceutical substance are authentic and its dosage, concentration, activity are indicated, the composition of the active pharmaceutical substance shall not be indicated; 11) list of auxiliary substances: for parenteral, ophthalmic drugs and preparations for external use, the list of all auxiliary substances shall be indicated; for infusion solutions the qualitative and quantitative composition of all auxiliary substances shall be indicated; for other dosage forms the list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions containing more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated;			

	13) method of administration and, depending on the dosage form, route of administration (the method of administration for tablets and capsules intended for oral administration shall not be indicated); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: " expiration date: (date, month, year)" or "(date, month, year)"; The expiration date "best before (month, year)" or "(month, year)" shall be indicated, whereby the expiration date shall be determined up to and including the last day of the indicated month; 21) registration number of the medicinal product in the form of the designation "RK-LS-"; 22) bar code (if any); 23) means of identification or material medium containing means of identification		
	Availability of primary packaging labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration;		

58.	2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “day, month, year” Additional information identical to that on the secondary package is placed. An intermediate package that does not allow the information on the primary packaging to be read without compromising its integrity repeats the information on the primary packaging		
59.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices		
60.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of message cards through the portal of an authorized organization online containing a mandatory minimum amount of information		
61.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or)		

	effectiveness to the authorized organization in cases of detection		
62.	Absence of facts of procurement, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan		
63.	Absence of facts of production, importation, storage, use and sale of counterfeit medicines and medical devices		
64.	Absence of facts of sale of medicines and medical devices, the quality of which is not confirmed by the conclusion on safety and quality		
65.	Absence of facts of storage , use and sale of expired medicines and medical devices		
66.	Compliance of the medicinal product with the requirements of the regulatory document on quality and safety control of the medicinal product and medical device (based on the results of safety and quality assessment of samples withdrawn as doubtful)		
	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic		

67.	substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unsuitability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illicit circulation of narcotic drugs, psychotropic substances, their analogs and precursors do not have medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan		
68.	Availability of the list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies on conducting the relevant check		
69.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day they shall be sealed and (or) stamped. Keys, seal and (or) sealer shall be kept with the responsible person		
70.	Availability of a first aid kit		
	Availability of a signboard indicating the name of the pharmaceutical activity		

71.	subject, its organizational and legal form and operation mode in the state and Russian languages		
72.	Availability of information on telephone numbers and addresses of territorial subdivisions of the state body in the sphere of circulation of medicines and medical devices in a place convenient for the population's viewing		
73.	Ensuring traceability of medicinal products labeled with identification means by providing by participants of circulation of medicinal products and entities in the sphere of circulation of medicinal products and medical devices of information on launch into circulation, on sale and (or) transfer, as well as on withdrawal of labeled medicinal products from circulation on the territory of the Republic of Kazakhstan		
	Compliance with the rules of advertising medicinal products and medical devices: 1) advertising of medicinal products and medical devices shall be reliable, recognizable without special knowledge or application of special means, exclude comparisons with other pharmaceutical services, medicinal products and medical devices, not to mislead consumers through abuse of their trust, including with regard to characteristics, composition, consumer properties, cost (price),		

74.	expected results of use, results of research and testing; 2) advertising of medicinal products and medical devices shall be in Kazakh and Russian languages, contain complete and reliable information on the medicinal product or medical device, comply with the instruction for medical use of the medicinal product (leaflet-insert), instruction for medical use or operating document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare		
	Non-admission of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of samples of medicines dispensed with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical products, except for medicines and medical products for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations unrelated to their purpose, use and dispensing, with the		

75.	exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicinal products and medical devices; 8) use of medical professionals authorized to prescribe medicines and medical devices as distributors of advertisements, except for cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license for the relevant type of activity ; 10) advertising of pharmaceutical services provided by persons who do not have a certificate of a health care specialist, including foreign specialists; 11) indication in advertising to the public of treatment methods for the following diseases: sexually transmitted diseases, oncology, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as		

	government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical products, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed, and the use of the product is not accompanied by the development of side effects ; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicinal product and medical device		

Designated person (s)

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position, signature

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surname, name, patronymic (if any)

The head of the control subject

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position, signature

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surname, name, patronymic (if any).

Appendix 20
to the joint order

of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist in the field of circulation of medicines and medical devices regarding subjects (objects) of pharmaceutical activity, engaged in wholesale sale of medicines and medical devices

Footnote. Appendix 20 – as amended by the joint order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 №87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (effective ten calendar days after the date of its first official publication).

State body that appointed inspection/preventive control with a visit to the control subject (object) _____

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Act on appointing inspection / preventive control with a visit to the control subject (object) _____

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_____

№, date

Name of the control subject (object)

_____

_____

(Individual Identification Number), Business Identification Number of the control subject (object) _____

_____

Location address

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1.	Availability and operation of a documentation system to track receipt and dispatch of medicines and medical devices		
	Ensuring provision of a copy of the product conformity certificate upon request of the subject.		

2.	Certificates of conformity of medicinal products and medical devices shall be kept for the period of its validity plus one year and shall be available for consumers and (or) state regulatory authorities		
3.	Procurement of medicines and medical devices from entities that have a license for pharmaceutical activities and attachment to the license for subtypes of activity: production of medicines, wholesale sales of medicines, or who have notified about the commencement of activities for the wholesale sale of medical products		
4.	Sales of medicines and medical devices to entities licensed for pharmaceutical or medical activities or have notified about the commencement of activities for the sale of medical products		
5.	The sale of medicinal substances is carried out to pharmacies licensed for pharmaceutical activities with the right to manufacture, as well as to drug manufacturing organizations licensed for pharmaceutical activities with the right to manufacture medicines		
6.	Wholesale sales of medical devices related to measuring instruments, in the presence of a certificate of approval of the type of measuring instruments, or a certificate of metrological attestation of medical measuring equipment		
	Ensuring the vehicles and equipment used for transportation and conformity with the		

7.	purpose of their use, to protect products from undesirable effects that result in loss of quality or compromise the integrity of the packaging, and in order that: 1) the possibility of their identification and safety assessment is not lost; 2) they are not contaminated by other medicinal products (dosage forms), substances and so that they themselves do not contaminate them; 3) they are protected and not exposed to environmental factors. The vehicle and its equipment shall be kept clean and treated with detergents and disinfectants as necessary		
8.	Compliance with storage conditions during transportation necessary to ensure the quality, safety and efficacy of medicines, also to prevent the risk of counterfeit medicines entering the supply chain		
9.	Availability of temperature control devices in vehicles in case of supplies of medicines requiring special transportation conditions. Instrument readings shall be recorded and documented throughout transportation		
10.	Ensuring protection of medicinal products and medical devices from environmental factors (precipitation, dust, sunlight , mechanical damage). Medicinal products and medical devices prepared for transportation are packed in group containers (cardboard boxes or stacks) with subsequent packing in transport packaging (crates,		

	boxes, wrapping paper) complying with the requirements of the regulatory document		
11.	Ensuring the execution of discharge documents containing the following information for each item, batch (series) of products: name; dosage (for a medicine); packaging; quantity, per unit price; sum; series; best before date; number and validity term of the certificate of conformity (for a medicinal product or medical device). Corrections, additions, and blots in discharge documents shall not be allowed.		
12.	Compliance with the maximum price for the trade name of a medicinal product in the wholesale sales		
13.	Holding by each pharmacy worker of a healthcare specialist certificate		
14.	Availability of a state license for pharmaceutical activities and of attachments for subtypes of activity or notification of the commencement of activity. Compliance with the types and subtypes of activities declared upon receipt of the state license and attachment to it		
15.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the		

	instructions for medical use for medicines and medical devices, operational documents (for the medical device), indicated in the labeling of their packages		
16.	Ensuring safety, storage conditions and handling of various groups of medicines and medical devices by complying with the requirements for design , arrangement, composition , size of the areas, equipment of premises (areas) for storage of medicines and medical devices and their operation, ensuring the safety		
17.	Storage of medicines and medical devices separate from other products to avoid any impact on them, protection from negative impact of light, temperature, moisture and other external factors		
18.	Keeping records of the expiry dates of medicines and medical devices on paper or electronic media		
19.	Storage of medicines and medical devices in designated and clearly marked storage areas		
20.	Provision of storage premises, including a refrigerating room (chamber) with appropriate equipment for control of temperature, air humidity (thermometers, hygrometers , other types of devices) and their location on the internal walls of the premises away from heating devices based on the results of testing of temperature fluctuation zones for cold and warm seasons		

21.	Observance of separation during storage of all medicines and medical devices depending on the pharmacological group, administration method, aggregate state, physicochemical properties, exposure to various environmental factors		
22.	Availability of isolated storage space for pending, expired, returned, withdrawn, presumably counterfeit, recalled and rejected medicinal products		
23.	Provision of weather protection in the receiving and dispatching areas. Availability of equipment in receiving and shipping areas (ventilation/air conditioning system, hygrometer, thermometer), container cleaning equipment. Availability of an equipped area for inspection of received products		
24.	Separation of acceptance, quarantine, defective, dispatch and storage areas. Availability of a room in which medicines are stored in quarantine, clearly marked and with limited access		
25.	Availability of common non-combustible buildings with insulation by non-combustible walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, provision of premises with supply and exhaust ventilation		
	Storage of flammable medicines separately from other medicines: provision of fireproof and stable		

26.	racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and 1.2 meters high		
27.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups		
28.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling must not more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, which are filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)		
29.	Compliance with isolated storage of calcium hypochloride, taking into account its properties		
30.	Compliance with the storage of flammable liquids with constant monitoring of the condition of containers, their tightness and serviceability		
31.	Implementation of measures in the storage of explosive medicines against their contamination by dust		

32.	Separate storage of explosive and flammable medicines containing acids and alkalis		
33.	Ensuring protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other greasy substances, and their storage in isolated rooms or under sheds		
34.	Observance of conditions of storing dressings in a dry ventilated area in cabinets, drawers, on racks, pallets, trays, in conditions ensuring cleanliness		
35.	Compliance with the storage conditions of medical instruments, devices, appliances, equipment in dry heated rooms at room temperature, with relative humidity not exceeding 65 percent		
36.	Compliance with the requirements for interior finishing of premises (areas) for storing medicines and ensuring cleanliness of storage premises and equipment		
37.	Providing protection against the entry of insects, rodents or other animals, and presence of preventive pest control program		
38.	Separation of rest rooms, dressing rooms, showers and toilets for employees from storage rooms (areas). Food, beverages, tobacco products, as well as medicines for personal use shall not be stored in storage rooms (areas). Employees working in the storage area shall have protective or work clothing appropriate to the work performed and personal		

	protective equipment if necessary. Personnel working with hazardous medicinal products shall undergo special instruction		
39.	Provision of the necessary equipment and inventory in drug storage areas: 1) racks, trays, poles, cabinets for storing medicines and medical products; 2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines		
40.	Availability of a document on calibration (verification) of equipment used for control and monitoring of storage conditions		
41.	Availability of a developed and approved emergency plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage , emergency situations		
42.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The used equipment shall be in good condition and kept in proper cleanliness		
	Availability of a person responsible for ensuring		

43.	the safety of the quality of medicines and medical devices at facilities storing medicines and medical devices.		
44.	Availability of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use.		
45.	Presence of acts on the destruction of medicines and medical devices unsuitable for sale and medical use.		
	Availability of secondary package labeling including the following information: 1) trade name of the medicinal product; 2) international non-proprietary name (if any) in Kazakh, Russian and English languages; 3) name of the manufacturer of the medicinal product, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packer, the name of the packer, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, its address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of active pharmaceutical substance(s); 7) quantity of the medicinal product in the package by		

46.		weight, volume or number of dosage units depending on the dosage form and type of package; 8) information on the composition of the medicinal product; 9) for herbal medicinal products which are prepackaged medicinal plant raw materials, the weight of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain moisture content; 10) for medicinal preparations containing in their composition substances subject to control in accordance with the Law of the Republic of Kazakhstan "On narcotic drugs, psychotropic substances, their analogs and precursors and measures to counteract their illicit trafficking and abuse", the names of these substances and their content in weight units or percent shall be indicated. In single-component medicinal preparations, provided that the name of the medicinal product and active pharmaceutical substance are authentic and its dosage, concentration, activity are indicated, the composition of the active pharmaceutical substance shall not be indicated; 11) list of auxiliary substances: for parenteral, ophthalmic drugs and preparations for external use, the list of all auxiliary substances shall be indicated; for infusion solutions the qualitative and quantitative composition of all auxiliary		

	substances shall be indicated; for other dosage forms the list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions containing more than one active pharmaceutical substance, the value of osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of administration (the method of administration for tablets and capsules intended for oral administration shall not be indicated); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: " expiration date: (date, month, year)" or "(date, month, year)"; The expiration date "best before (month, year)" or "(month, year)" shall be indicated, whereby the expiration date shall be determined up to and including the last day of the indicated month; 21) registration number of the medicinal product in the form of the designation "RK-LS-";			

	22) bar code (if any); 23) means of identification or material medium containing means of identification		
47.	Availability of primary packaging labeling indicating the following information: 1) trade name of the medicinal product, indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “day, month, year” Additional information identical to that on the secondary package is placed. An intermediate package that does not allow the information on the primary packaging to be read without compromising its integrity repeats the information on the primary packaging		
48.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices		
49.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices.		

	Transmission of message cards through the portal of an authorized organization online containing a mandatory minimum amount of information		
50.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or) effectiveness to the authorized organization in cases of detection		
51.	Absence of facts of procurement, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan		
52.	Absence of facts of production, importation, storage, use and sale of counterfeit medicines and medical devices		
53.	Absence of facts of sale of medicines and medical devices, the quality of which is not confirmed by the conclusion on safety and quality		
54.	Absence of facts of storage , use and sale of expired medicines and medical devices		
55.	Compliance of the medicinal product with the requirements of the regulatory document on quality and safety control of the medicinal product and medical device (based on the results of safety and quality assessment of samples withdrawn as doubtful)		
	Compliance with the requirements for storage, accounting, destruction of medicines containing		

56.	narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in the following cases: 1) the shelf life of the narcotic drug, psychotropic substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unsuitability, excluding the possibility of their restoration or processing; 3) when confiscated, discovered and withdrawn from illicit circulation narcotic drugs, psychotropic substances, their analogs and precursors do not have medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan.		
57.	Availability of the list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies on conducting the relevant check		

58.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day they shall be sealed and (or) stamped. Keys, seal and (or) sealer shall be kept with the responsible person		
59.	Availability of a first aid kit		
60.	Availability of a signboard indicating the name of the pharmaceutical activity subject, its organizational and legal form and operation mode in the state and Russian languages		
61.	Availability of information on telephone numbers and addresses of territorial subdivisions of the state body in the sphere of circulation of medicines and medical devices in a place convenient for the population's viewing		
62.	Ensuring traceability of medicinal products labeled with identification means by providing by participants of circulation of medicinal products and entities in the sphere of circulation of medicinal products and medical devices of information on launch into circulation, on sale and (or) transfer, as well as on withdrawal of labeled medicinal products from circulation on the territory of the Republic of Kazakhstan		
	Compliance with the rules of advertising medicinal products and medical devices: 1) advertising of medicinal products and medical devices shall be reliable, recognizable without special knowledge or application of special		

63.	means, exclude comparisons with other pharmaceutical services, medicinal products and medical devices, not to mislead consumers through abuse of their trust, including with regard to characteristics, composition, consumer properties, cost (price), expected results of use, results of research and testing; 2) advertising of medicinal products and medical devices shall be in Kazakh and Russian languages, contain complete and reliable information on the medicinal product or medical device, comply with the instruction for medical use of the medicinal product (leaflet-insert), instruction for medical use or operating document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare		
	Non-admission of advertising medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of samples of medicines dispensed with a doctor’s prescription; 4) the use of children, their images and voices in advertising of medicines		

64.	and medical products, except for medicines and medical products for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations unrelated to their purpose, use and dispensing, with the exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicinal products and medical devices; 8) use of medical professionals authorized to prescribe medicines and medical devices as distributors of advertisements, except for cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license for the relevant type of activity ; 10) advertising of pharmaceutical services provided by persons who do not have a certificate of a health care specialist, including foreign specialists; 11) indication in advertising to the public of treatment methods for the following diseases:			

	sexually transmitted diseases, oncology, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical products, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed, and the use of the product is not accompanied by the development of side effects ; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicinal product and medical device		
65.	Availability of a document on calibration and (or) verification of a medical device that is a measuring instrument		
66.	Making sure that the used medical equipment, at the time of acceptance is new, unused, newest or serial model, free of defects.		

67.	Availability of a log of the technical condition of medical equipment subject to service		
68.	Availability of documents confirming current and major repairs		
69.	Availability of documents confirming warranty service (not less than thirty-seven months from the date of commissioning and periodicity recommended by the manufacturer) consisting of periodic inspection of the technical condition of medical equipment (at least once a year).		
70.	Availability in operated medical equipment: 1) of operational documentation (operation manual and service manual); 2) of service manual for medical equipment		
71.	Presence or absence of facts of operation of medical equipment not provided with service maintenance, removed from service maintenance, or operation of medical equipment by personnel without special training, not trained in the use of medical equipment.		
72.	Presence or absence of facts of unjustified idling of medical equipment (absence of measures for restoration of serviceable condition)		
73.	Availability of a certificate of compliance with the requirements of the Good Distribution Practice (GDP) Standard		

Designated person (s)

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position, signature

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surname, name, patronymic (if any)

The head of the control subject

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position, signature

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surname, name, patronymic (if any).

Appendix 21
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist in the field of circulation of medicines and medical devices regarding subjects (objects) of pharmaceutical activity, engaged in retail sale of medicines and medical devices

Footnote. Appendix 21 – as amended by the joint order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 №87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77 (effective ten calendar days after the date of its first official publication).

State body that appointed inspection/preventive control with a visit to the control subject (object) _____

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Act on appointing inspection / preventive control with a visit to control subject (object) _____

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№, date

Name of the control subject (object)

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(Individual Identification Number), Business Identification Number of the control subject (object) _____

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Location address

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1.	Ensuring the sale of medical products related to measuring instruments, in the presence of a certificate of approval of the type of measuring instruments or a certificate of metrological certification of medical measuring equipment		
2.	Ensuring the sale of prescription drugs on a doctor’s prescription		
3.	Ensuring that medicines sold without a doctor's prescription are placed on display cases		
4.	Registration of invalid prescriptions in the Register of invalid prescriptions with the stamp “Prescription invalid ”.		
5.	Compliance with the validity term of recipes: 1) for a medicinal product containing narcotic drugs, psychotropic substances, precursors and toxic substances – 1 (one) year; 2) for medicines dispensed within the guaranteed scope of free medical care and (or) compulsory social health insurance – 2 (two) years; 3) for other medicinal products - not less than 30 (thirty) calendar days		
	Ensuring provision of reliable information		

6.	regarding: 1) correct and rational application or use; 2) possible side effects and contraindications; 3) interaction with other medicinal products, precautions in their application or use; 4) expiration dates and rules of storage at home; 5) rules of operation, completeness of medical products		
7.	Availability of a document on calibration and (or) verification of a medical device that is a measuring instrument		
8.	Making sure that the used medical equipment, at the time of acceptance was new, unused, newest or serial model, free of defects.		
9.	Availability of a log of the technical condition of medical equipment subject to service		
10.	Availability of documents confirming current and major repairs		
11.	Availability of documents confirming warranty service (not less than thirty-seven months from the date of commissioning and periodicity recommended by the manufacturer) consisting of periodic inspection of the technical condition of medical equipment (at least once a year).		
12.	Availability in operated medical equipment: 1) of operational documentation (operation manual and service manual); 2) of service manual for medical equipment		
	Presence or absence of facts of operation of		

13.	medical equipment not provided with service maintenance, removed from service maintenance, or operation of medical equipment by personnel without special training, not trained in the use of the medical equipment.		
14.	Presence or absence of facts of unjustified idling of medical equipment (absence of measures for restoration of serviceable condition)		
15.	Ensuring implementation of preventive measures: 1) quality control during acceptance and sales; 2) compliance with the rules and shelf life of medicines, keeping records of medicines with a limited shelf life; 3) serviceability and accuracy of weighing instruments; 4) checking the correctness of the prescription, its validity period, compliance of the prescribed doses with the patient's age, compatibility of ingredients, and the norms for one-time dispensing; 5) keeping records of the validity periods of safety and quality assessment conclusions		
16.	Ensuring acceptance of medicines and medical devices with verification of : 1) compliance of quantity, completeness, integrity of containers, compliance of packaging, labeling with regulatory documents, availability of instructions for medical use of medicines and medical devices in the state and Russian languages; availability of an operational document for a		

	medical device; 2) compliance with the name, dosage, packaging, quantity, batch (series) of products specified in the accompanying documents; 3) presence in the accompanying documents of a certificate of conformity or a reference to it in the invoice for the release of goods		
17.	Availability in a place convenient for viewing of information on the list of medicines and specialized medicinal products for free provision of certain categories of citizens with certain diseases at the outpatient level		
18.	Availability of lists and specimen signatures of persons entitled to sign prescriptions for free receipt of medicines approved by the head of the relevant healthcare organization in retail sales facilities that have relevant agreements with local government healthcare authorities		
19.	Ensuring the placement in a place convenient for familiarization of: 1) a copy of the license for pharmaceutical activities and its attachment or a document (including a printed copy of an electronic document) informing about the beginning or termination of activities or certain actions; 2) a book of feedback and suggestions; 3) information on telephone numbers of the pharmaceutical reference service		
	Ensuring that information of the following nature is		

20.	placed in a place visible to visitors: "Medicines may not be returned and exchanged"; "Medicines are not dispensed to children"; "Over-the-counter sale of medicines dispensed on prescription is prohibited"; "Shelf life of medicines manufactured in a pharmacy"		
21.	Compliance with the maximum price for the trade name of a medicinal product in retail sales		
22.	Holding by each pharmacy worker of a health specialist certificate		
23.	Availability of a state license for pharmaceutical activities and of attachments for subtypes of activity or notification of the commencement of activity. Compliance with the types and subtypes of activities declared upon receipt of the state license and attachment to it		
24.	Ensuring storage and transportation in accordance with the conditions established by the manufacturer in the regulatory and technical document on monitoring the quality and safety of medicines, in the instructions for medical use for medicines and medical devices, operational documents (for the medical device), indicated in the labeling of their packages		
25.	Ensuring safety, storage conditions and handling of various groups of medicines and medical devices by complying with the requirements for design , arrangement, composition , size of areas, equipment		

	of premises (areas) for storage of medicines and medical devices and their operation, ensuring the safety		
26.	Maintaining separate storage of medicines and medical devices from other products to avoid any impact on them, protection from negative impact of light, temperature, moisture and other external factors		
27.	Keeping records of the expiry dates of medicines and medical devices on paper or electronic media		
28.	Storage of medicines and medical devices in designated and clearly marked storage areas		
29.	Provision of storage premises, including a refrigerating room (chamber) with appropriate equipment for control of temperature, air humidity (thermometers, hygrometers , other types of devices) and their location on the internal walls of the premises away from heating devices based on the results of testing of temperature fluctuation zones for cold and warm seasons		
30.	Observance of separation during storage of all medicines and medical devices depending on the pharmacological group, method of administration, aggregate state, physicochemical properties , exposure to various environmental factors		
31.	Availability of isolated storage space for pending, expired, returned,		

	withdrawn, presumably counterfeit, recalled and rejected medicinal products		
32.	Provision of weather protection in the receiving and discharge areas. Availability of equipment in receiving and shipping areas (ventilation/air conditioning system, hygrometer, thermometer), container cleaning equipment. Availability of an equipped area for inspection of received products		
33.	Separation of receiving, quarantine, defective, discharge and storage areas . Availability of a clearly labeled and restricted access quarantine room where medicines are stored .		
34.	Availability of common non-combustible buildings with insulation by non-combustible walls from neighboring premises that meet fire safety requirements in the absence of separate storage facilities for flammable substances, provision of premises with supply and exhaust ventilation		
35.	Storage of flammable medicines separately from other medicines: provision of fireproof and stable racks and pallets, storage of flammable and combustible liquids in built-in fireproof cabinets with doors at least 0.7 meters wide and 1.2 meters high		
36.	Storage of flammable liquids isolated in separate rooms in glass or metal containers from other groups		

37.	Compliance with the storage of flammable and combustible liquid medicines that should not be stored: 1) in a completely filled container, the degree of filling must be no more than 90 percent of the volume. Alcohols in large quantities shall be stored in metal containers, filled to no more than 95 percent of the volume; 2) with mineral acids (sulfuric, nitric and other acids), compressed and liquefied gases, flammable substances, as well as with inorganic salts that produce explosive mixtures with organic substances (potassium chlorate, potassium permanganate)		
38.	Compliance with isolated storage of calcium hypochloride, taking into account its properties		
39.	Compliance with the storage of flammable liquids with constant monitoring of the condition of containers, their tightness and serviceability		
40.	Implementation of measures in the storage of explosive medicines against their contamination by dust		
41.	Compliance with separate storage of explosive and flammable medicines containing acids and alkalis		
42.	Ensuring protection of cylinders with oxygen and flammable gases from heat sources, contact with oil and other greasy substances, and their storage in isolated rooms or under sheds		

43.	Observance of conditions of storing dressings in a dry ventilated area in cabinets, drawers, on racks, pallets, trays, in conditions ensuring cleanliness		
44.	Compliance with the conditions of storing medical instruments, devices, appliances, equipment in dry heated rooms at room temperature, with relative humidity not exceeding 65 percent		
45.	Compliance with the requirements for interior finishing of premises (areas) for storing medicines and ensuring cleanliness of storage premises and equipment		
46.	Providing protection against the entry of insects, rodents or other animals, and presence of preventive pest control program		
47.	Separation of rest rooms, dressing rooms, showers and toilets for employees from storage rooms (areas). Food, beverages, tobacco products, as well as medicines for personal use shall not be stored in storage rooms (areas). Employees working in the storage area shall have protective or work clothing appropriate to the work performed and personal protective equipment if necessary. Personnel working with hazardous medicinal products shall undergo special instruction		
	Provision of the necessary equipment and inventory in drug storage areas: 1) racks, trays, shelves, cabinets for storing medicines and medical products;		

48.	2) technological equipment for creating temperature conditions; 3) instruments for recording temperature and humidity; 4) means of mechanization for loading and unloading operations; 5) disinfectants and cleaning equipment to ensure sanitary conditions; 6) other equipment and inventory ensuring sanitary and hygienic conditions, labor protection, safety precautions, fire safety, environmental protection and safety of medicines		
49.	Availability of a document on calibration (verification) of equipment used for control and monitoring of storage conditions		
50.	Availability of a developed and approved emergency plan in case of malfunction of the refrigeration room (chamber), refrigeration equipment or power outage , emergency situations		
51.	Availability of developed and approved instructions for cleaning and disinfection of equipment. The equipment used shall be in good condition and kept in proper cleanliness		
52.	Availability of a person responsible for ensuring the safety of the quality of medicines and medical devices at facilities storing medicines and medical devices		
53.	Availability of a commission for the destruction of medicines and medical devices unsuitable for sale and medical use		

54.	Availability of acts on the destruction of medicines and medical devices unsuitable for sale and medical use		
	Availability of secondary package labeling including the following information: 1) trade name of the medicinal product; 2) international non-proprietary name (if any) in Kazakh, Russian and English languages; 3) name of the manufacturer of the medicinal product, address. The name of the manufacturer and its address shall be indicated in full or abbreviated (city, country). A trademark shall be indicated if it is granted legal protection in the Republic of Kazakhstan. If the manufacturer of the medicinal product is not its packer, the name of the packer, date and time of packaging shall be indicated; 4) name of the holder of the registration certificate, its address (city, country); 5) dosage form; 6) dosage, and (or) activity, and (or) concentration (if applicable) of active pharmaceutical substance(s); 7) quantity of the medicinal product in the package by weight, volume or number of dosage units depending on the dosage form and type of package; 8) information on the composition of the medicinal product; 9) for herbal medicinal products which are prepackaged medicinal plant raw materials, the		

55.	weight of medicinal plant raw materials and (or) active pharmaceutical substance of plant origin shall be indicated at their certain moisture content; 10) for medicinal preparations containing in their composition substances subject to control in accordance with the Law of the Republic of Kazakhstan "On narcotic drugs, psychotropic substances, their analogs and precursors and measures to counteract their illicit trafficking and abuse", the names of these substances and their content in weight units or percent shall be indicated. In single-component medicinal preparations, provided that the name of the medicinal product and active pharmaceutical substance are authentic and its dosage, concentration, activity are indicated, the composition of the active pharmaceutical substance shall not be indicated; 11) list of auxiliary substances: for parenteral, ophthalmic drugs and preparations for external use, the list of all auxiliary substances shall be indicated; for infusion solutions the qualitative and quantitative composition of all auxiliary substances shall be indicated; for other dosage forms the list of antimicrobial preservatives, dyes, as well as sugars and ethanol shall be indicated; 12) for infusion solutions containing more than one active pharmaceutical substance, the value of			

	osmolarity and (or) osmolality shall be indicated; 13) method of administration and, depending on the dosage form, route of administration (the method of administration for tablets and capsules intended for oral administration shall not be indicated); 14) precautions; 15) warning notices; 16) storage conditions, storage features and transportation conditions; 17) conditions of release (with a prescription or without a doctor's prescription); 18) series number; 19) production date (if not entered in the batch number); 20) expiration date: " expiration date: (date, month, year)" or "(date, month, year)"; The expiration date "best before (month, year)" or "(month, year)" shall be indicated, whereby the expiration date shall be determined up to and including the last day of the indicated month; 21) registration number of the medicinal product in the form of the designation "RK-LS-"; 22) bar code (if any); 23) means of identification or material medium containing means of identification		
	Availability of primary packaging labeling indicating the following information: 1) trade name of the medicinal product,		

56.	indicating the dosage, activity or concentration; 2) international nonproprietary name (if available) in the state, Russian and English languages; 3) the name of the manufacturer of the medicinal product and (or) its trademark; 4) series number; 5) expiration date “month, year” or “day, month, year” Additional information identical to that on the secondary package is placed. An intermediate package that does not allow the information on the primary packaging to be read without compromising its integrity repeats the information on the primary packaging		
57.	Organization of work to monitor adverse reactions and (or) lack of effectiveness of medicines and medical devices, appointment of responsible persons for monitoring side effects of medicines and medical devices		
58.	Provision by the responsible person to the authorized organization of information about side effects and (or) lack of effectiveness of medicines and medical devices. Transmission of message cards through the portal of an authorized organization online containing a mandatory minimum amount of information		
59.	Compliance with the deadlines for submitting a completed report card about adverse reactions (actions) and (or)		

	effectiveness to the authorized organization in cases of detection		
60.	Absence of facts of procurement, production, storage, advertising, use, provision and sale of medicines and medical devices that have not passed state registration in the Republic of Kazakhstan		
61.	Absence of facts of production, importation, storage, use and sale of counterfeit medicines and medical devices		
62.	Absence of facts of sale of medicines and medical devices, the quality of which is not confirmed by the conclusion on safety and quality		
63.	Absence of facts of storage , use and sale of expired medicines and medical devices		
64.	Compliance of the medicinal product with the requirements of the regulatory document on quality and safety control of the medicinal product and medical device (based on the results of safety and quality assessment of samples withdrawn as doubtful)		
	Compliance with the requirements for storage, accounting, destruction of medicines containing narcotic drugs, psychotropic substances and precursors (including substances): The destruction of narcotic drugs, psychotropic substances, their analogues and precursors can be carried out in cases when: 1) the shelf life of the narcotic drug, psychotropic		

65.	substance and precursors has expired; 2) narcotic drugs, psychotropic substances, precursors have been subjected to chemical or physical influence, resulting in their unsuitability, excluding the possibility of their restoration or processing; 3) confiscated, discovered and withdrawn from illicit circulation of narcotic drugs, psychotropic substances, their analogs and precursors do not have medical, scientific or other value and cannot be processed, as well as in other cases provided for by the legislation of the Republic of Kazakhstan		
66.	Availability of the list of persons who have conclusions from psychiatrists and narcologists about the absence of drug addiction, substance abuse, chronic alcoholism, as well as about suitability for carrying out activities related to narcotic drugs, psychotropic substances and their precursors and the conclusion of the internal affairs bodies on conducting the relevant check		
67.	Storage rooms, safes and cabinets shall be kept closed. After the end of the working day they shall be sealed and (or) stamped. Keys, seal and (or) sealer shall be kept with the responsible person		
68.	Availability of a first aid kit		
	Availability of a signboard indicating the name of the pharmaceutical activity		

69.	subject, its organizational and legal form and operation mode in the state and Russian languages		
70.	Availability of information on telephone numbers and addresses of territorial subdivisions of the state body in the sphere of circulation of medicines and medical devices in a place convenient for the population's viewing		
71.	Ensuring traceability of medicinal products labeled with identification means by providing by participants of circulation of medicinal products and entities in the sphere of circulation of medicinal products and medical devices of information on launch into circulation, on sale and (or) transfer, as well as on withdrawal of labeled medicinal products from circulation on the territory of the Republic of Kazakhstan		
	Compliance with the rules of advertising of medicinal products and medical devices: 1) advertising of medicinal products and medical devices shall be reliable, recognizable without special knowledge or application of special means, exclude comparisons with other pharmaceutical services, medicinal products and medical devices, not to mislead consumers through abuse of their trust, including with regard to characteristics, composition, consumer properties, cost (price),		

72.	expected results of use, results of research and testing; 2) advertising of medicinal products and medical devices shall be in Kazakh and Russian languages, contain complete and reliable information on the medicinal product or medical device, comply with the instruction for medical use of the medicinal product (leaflet-insert), instruction for medical use or operating document for the medical device; 3) availability of a conclusion on the compliance of advertising of medicines and medical devices with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare		
	Non-admission of advertising of medicines and medical devices: 1) not registered in the Republic of Kazakhstan; 2) prescription drugs in the media; 3) distribution for advertising purposes of samples of medicines dispensed with a doctor's prescription; 4) the use of children, their images and voices in advertising of medicines and medical products, except for medicines and medical products for children; 5) distribution and placement of advertising of medicines and medical devices in public transport, organizations unrelated to their purpose, use and dispensing, with the		

73.	exception of advertising of medicines at medical, pharmaceutical conferences, congresses, symposiums and other scientific meetings; 6) placement of advertising information on industrial products, prescription forms; 7) placement of outdoor (visual) advertising of medicinal products and medical devices; 8) use of medical professionals authorized to prescribe medicines and medical devices as distributors of advertisements, except for cases of providing reliable information about medicines and medical devices for scientific or educational purposes, as well as for the purpose of informing patients; 9) advertising of pharmaceutical services in the absence of a license for the relevant type of activity ; 10) advertising of pharmaceutical services provided by persons who do not have a certificate of a health care specialist, including foreign specialists; 11) indication in advertising to the public of treatment methods for the following diseases: sexually transmitted diseases, oncology, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, tuberculosis, diabetes mellitus; 12) refer in advertising to the recommendations of scientists, healthcare professionals, as well as		

	government officials who may encourage the use and (or) prescription of medicines and medical devices; 13) present in advertising services, medicines and medical products, biologically active food additives as unique, the safest and most effective; 14) assert that the safety and effectiveness of the medicinal product are due to its natural origin; 15) cause assumptions that the effectiveness of the service provided, treatment with an advertised medicinal product, biologically active food supplement is guaranteed, and the use of the product is not accompanied by the development of side effects ; 16) provide information in advertising that is not directly related to the advertised pharmaceutical service, medicinal product and medical device		

Designated person (s)

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_____

position, signature

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_____

surname, name, patronymic (if any)

The head of the control subject

_____

_____

position, signature

_____

_____

surname, name, patronymic (if any).

to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist

Footnote. Appendix 22 as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2023 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2023 № 91(effective ten calendar days after the date of its first official publication).

In the field of medical services quality

_____

pursuant to Article 138

_____

of Entrepreneur Code of the Republic of Kazakhstan regarding

_____

subjects (objects), providing pathoanatomical diagnostics
name of homogeneous group of control subjects (objects)

_____

State body that appointed inspection/preventive control
with a visit to the control subject (object)

_____

_____

Act on appointing inspection/ preventive control with a visit to
control subject (object) _____

_____ №, date

Name of control subject (object) _____

_____

(Individual Identification Number), Business Identification Number
of control subject (object) _____

_____

Location address _____

_____

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1	2	3	4

1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
2	Compliance with the requirement to register a refusal to accept biological material, attached to a copy of the referral for examination of biological material in the pathology department in a separate folder (“Rejected samples”), as well as in a separate journal (“Rejected samples ”)		
3	Compliance of the pathologist with the requirement for participation of the laboratory technician in the work based on the act of excision, macroscopic examination and macroscopic description of biological material. If it is necessary to obtain additional clinical information at the stage of macroscopic examination of biological material, the specialist physician who sent the material for examination is involved		
4	Compliance with the requirement that the thickness of tissue fragments is 5 millimeters (hereinafter - mm), average diameter - no more than 24 mm		
5	Presence of microscopic description in the protocol of pathological examination of biopsy (surgical) and autopsy material		
	Compliance with the requirement to issue the		

6	pathological examination results with entries in the logs of established form by a medical registrar or laboratory technician		
7	Availability of supporting documentation on compliance with the requirement for storing tissue samples in paraffin blocks in a single archive organized according to end-to-end numbering principle		
8	Availability of supporting documentation on compliance with the requirement for storing tissue specimens in paraffin blocks in a specially equipped dry and cool room, using specialized archival systems and adapted containers, as well as storage of micro-slides in specialized archival systems.		
9	Compliance with the requirement to place micro specimens in boxes in such a way that the slides related to one case are arranged in one indivisible block		
10	Compliance with the requirement for a laboratory technician to sort and prepare biological and medical waste for disposal		
11	Presence of written consent of the spouse or one of the close relatives, or legal representative in pathological diagnostics if the immediate cause of death is unknown		
12	Compliance with the requirement for an independent expert (s) to perform a pathological autopsy of a deceased		

	person at the request of a spouse, close relatives or legal representative		
13	Compliance with the requirement to issue a medical certificate of death (preliminary, final) by a doctor with specialization in “pathological anatomy (adult, pediatric)” on the day of the pathological autopsy.		
14	Compliance with the requirement to document the autopsy results in the form of autopsy report		
15	Compliance with the requirement to stop the autopsy if signs of violent death are detected during a pathological examination of the corpse, the head of the medical organization shall report the incident in writing to the judicial investigative authorities to address the issue of transferring the corpse for a forensic medical examination. A doctor specializing in pathological anatomy (adult, pediatric) shall take measures to preserve the body, organs and tissues of the corpse for further forensic medical examination. A report is drawn up for the completed part of the pathological examination, at the end of which the ground for further forensic medical examination is indicated. The pathologist shall notify in writing the head of the department, the administration of the health care organization where the death occurred, immediately after the interruption of the autopsy,		

	about each case of an interrupted pathological autopsy.		
16	Compliance with the requirement to send an emergency notification to the state body in the field of sanitary and epidemiological well-being of the population by a doctor specializing in " pathological anatomy (adult, pediatric)" in case of initial detection during autopsy of signs of acute infectious disease, food or industrial poisoning, unusual reaction to vaccination		
17	Compliance with the requirement for pathological autopsy of all newborn children who died in medical organizations, including obstetric organizations (regardless of how long after birth they showed signs of life) and stillborn fetuses weighing 500 grams or more at a gestational age of 22 weeks or more, including after termination of pregnancy (spontaneous, for medical and social reasons) with mandatory histological examination of the placenta and issuance of a medical certificate of perinatal death		
18	Compliance with the requirement of the head of the pathology department to ensure that autopsies are performed on dead newborns and stillborns with mandatory histological examination of tissue and organ fragments and their inclusion in the pathological examination report.		

19	Compliance with the requirement of the heads of health care organizations and heads of the pathology department of the organization for the necessary virological and bacteriological examination of autopsy materials of deceased newborns, stillborns and placentas, using for this purpose the appropriate laboratories of health care organizations or state bodies and organizations in the field of sanitary and epidemiological welfare of the population		
20	Compliance with the requirement for a doctor specializing in “ pathological anatomy (adult, pediatric)” to issue a medical certificate of perinatal death on the day of the pathological autopsy (preliminary, final, instead of preliminary)		
21	Compliance with the requirement by a doctor specializing in “ pathological anatomy (adult, pediatric)” when drawing up a pathological diagnosis based on the pathological autopsy results to indicate: 1) the underlying disease; 2) complication of the underlying disease; 3) cause of death; 4) concomitant disease; 5) combined underlying disease: competing diseases, polypathia, background disease		
22	Compliance with the requirements for registration and maintenance of primary medical documentation		

23	Availability of supporting documentation on compliance with the requirements for recording pathological examination materials (biopsy, surgical and autopsy material): 1) the accounting unit of a pathological examination of biological material is one object (one fragment of tissue obtained as a result of a single diagnostic or therapeutic manipulation or operation, embedded in one paraffin or frozen block), processed with one stain or reaction; 2) a registration number is assigned to each object. Each histological specimen shall bear a registration number identical to the registration number of the corresponding block. If it is necessary to perform several stains (reactions) from one block, additional alphabetic or numeric identifiers of stains (reactions) are added to the registration number of the microslide corresponding to the block number; 3) biological material shall be registered in the log of recording the receipt of biopsy (surgical) material and issuance of morphological studies results			
24	Compliance with the requirement not to issue the pathological examination report to the spouse, close relatives, legal representatives or other persons for familiarization. Issuing a pathological anatomical report on the cause of death and diagnosis of the disease to the spouse, close relatives or legal representatives,			

	and in their absence other relatives, as well as at the request of law enforcement bodies and (or) the court, a state body in the field of medical services (assistance)		
25	Compliance with the requirement to issue originals or copies of pathological examination reports at the request of inquiry and preliminary investigation bodies , prosecutor, lawyer and (or) court in connection with the investigation or trial, as well as at the request of state bodies in the field of medical services (assistance)		
26	Compliance with the requirements for cytological examinations, including: 1) macroscopic evaluation and processing of delivered biological material obtained by various methods (exfoliation, puncture, imprint, washout, biological fluids); 2) preparation and staining of microslides with subsequent microscopy; 3) evaluating the results of the study and establishing a cytological conclusion; 4) correlation of cytological and histological findings		
27	Availability of supporting documentation on compliance with the requirement for the laboratory technician of accepting, initially sorting and registration of the biological material received in the cytology laboratory, macroscopic examination, description of biological material,		

	processing of biological material (preparation, fixation, staining, conclusion, sorting of cytological microslides).		
28	Availability of documentation on compliance with the requirement for a microscopic examination at the first stage by a laboratory technician, then by a cytologist		
29	Compliance with the requirement to involve a physician (specialized expert) when it is necessary to obtain additional clinical information at the stage of microscopic examination of biological material, who sent the material for examination. The final microscopic examination of smears and drawing up a protocol of the results of the study shall be performed by a cytologist		
30	Compliance with the requirement for a doctor specializing in " pathological anatomy (adult, pediatric)" to establish the category and reasons for the discrepancy between the final clinical and pathological diagnoses		

Designated person (s) _____ _____
position, signature

_____

surname, name, patronymic (if any)
The head of the control subject _____ _____
position, signature

_____

surname, name, patronymic (if any)

Appendix 23
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated

November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist

Footnote. Appendix 23 – as amended by the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2023 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2023 № 91(effective ten calendar days after the date of its first official publication).

In the field of medical services quality

_____

pursuant to Article 138

_____

of Entrepreneur Code of the Republic of Kazakhstan regarding

_____

subjects (objects), irrespective of activity

_____

name of homogeneous group of control subjects (objects)

_____

State body that appointed inspection/preventive control
with a visit to the control subject (object)

_____

_____

Act on appointing inspection/ preventive control with a visit to
control subject (object) _____

_____ №, date

Name of control subject (object) _____

_____

(Individual Identification Number), Business Identification Number
of control subject (object) _____

_____

Location address _____

_____

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1	2	3	4
1	Availability of a specialist certificate for admission to clinical practice		

2	Availability of a license and (or) attachment to the license		
3	Compliance of the premises or building on the right of ownership or lease agreement, or contract of gratuitous use of real estate (loan), or trust management of property, or public-private partnership agreement with the standards for organizing medical care of specialized services on the subtypes of medical activity provided, as well as compliance with the corresponding sanitary rules establishing sanitary and epidemiological requirements for health care facilities		
4	Availability of functioning medical and (or) special equipment, apparatus and instruments, devices, furniture, inventory, vehicles and other means (if necessary), approved in the standards of organizing medical care of profile services on the subtypes of medical activities provided and minimum standards of equipping health care organizations with medical products		
5	Availability of specialists for the activities provided		
6	Availability of specialization or upgrades and other types of advanced training over the last 5 (five) years on the provided subtypes of medical activity (except for the graduates of internship, residency, secondary educational institution who have completed their training no later than 5 (five) years at the time of inspection).		

Designated person (s) _____ _____
position, signature

_____
surname, name, patronymic (if any)
The head of the control subject _____ _____
position, signature

_____
surname, name, patronymic (if any)

Appendix 24
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy
of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist

Footnote. The joint order as supplemented by Appendix 24 pursuant to the joint order of the Minister of Healthcare of the Republic of Kazakhstan dated 29.05.2023 № 90 and the Minister of National Economy of the Republic of Kazakhstan dated 29.05.2023 № 91(effective ten calendar days after the date of its first official publication).

In the field of medical services quality

_____
pursuant to Article 138

_____
of Entrepreneur Code of the Republic of Kazakhstan regarding

_____
subjects (objects), providing assistance in nuclear medicine
name of homogeneous group of control subjects (objects)

_____
State body that appointed inspection/preventive control
with a visit to the control subject (object)

_____

_____
Act on appointing inspection/ preventive control with a visit to
control subject (object) _____
_____ №, date
Name of control subject (object) _____

_____

(Individual Identification Number), Business Identification Number of control subject (object) _____

_____

Location address _____

_____

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1	2	3	4
1	Availability of supporting documentation on the provision of medical care included in the guaranteed volume of free medical care and (or) the system of compulsory social health insurance on a free basis		
2	Availability of supporting documentation on compliance of treatment and diagnostic measures with the recommendations of clinical protocols		
3	Availability of documentation confirming the status of the Nuclear Medicine Center (hereinafter -the Center) as a structural unit of a multidisciplinary hospital or an independent medical organization providing medical care to the population of the Republic of Kazakhstan according to RND and (or) RNT. The structure of the Center, depending on the functions assigned to it, includes: department of production and quality control of RFMP; RND department; RNT department; Department of Radiation Safety and Medical Physics ; department of engineering and technical support.		

4	Availability of supporting documentation on the main tasks and activities of organizations providing medical care in nuclear medicine and compliance with the main tasks: 1) provision of specialized medical care by profile specialists in outpatient, hospital replacing and inpatient conditions at secondary and tertiary levels of medical care; 2) carrying out radioisotope (radionuclide) research methods; 3) conducting RNT using RFMP; 4) production and quality control of manufactured RFMPs for compliance with the requirements of pharmacopoeia articles, technical regulations and good manufacturing practice; 5) ensuring patient satisfaction with the level and quality of medical care ; 6) development, mastering and implementation of modern innovative methods of RND and RNT; 7) development, mastering and manufacturing application of new RFMP; 8) ensuring radiation safety of patients and production and medical personnel, exercising control over the production of radiopharmaceuticals, rational use of RND and RNT methods; 9) residency training in nuclear medicine; 10) participation in the development of regulations , standards, instructions, recommendations in the field of nuclear medicine;			

	11) providing organizational, methodological, and advisory assistance to healthcare organizations on nuclear medicine issues; 12) conducting consultations when planning nuclear medicine centers.		
5	Availability of supporting documentation on the provision of medical care using nuclear medicine methods within the guaranteed scope of free medical care, voluntary medical insurance and on a paid basis.		
6	Availability of supporting documentation on the provision of specialized medical care in nuclear medicine in outpatient, hospital replacing, inpatient conditions in a planned form: in outpatient conditions that do not provide round-the-clock medical supervision and treatment; in hospital replacing conditions that do not require round-the-clock medical observation and treatment and provide for medical observation and treatment during the day with the provision of a bed; in inpatient conditions, providing round-the-clock medical observation, treatment, care, as well as provision of a bed with meals, including in cases of "one-day" therapy, providing round-the-clock observation during the first day after the start of treatment.		
	Availability of supporting documentation on the referral of patients for PET/		

7	CT, PET/MRI, SPECT, SPECT/CT examinations to the RND department by profile specialists		
8	Availability of supporting documentation on the conduct of radioisotope (radionuclide) studies according to clinical protocols, documented procedures, the applied specific diagnostic method, with mandatory compliance with radiation safety measures for the patient and personnel as indicated		
9	Presence of a signed informed consent of the patient for radioisotope (radionuclide) examination before undergoing this examination, indicating the activity of the RFMP used, after which the patient is examined by a doctor and a nurse.		
10	Availability of supporting documentation on interpretation of the results of the study by a nuclear medicine physician after completion of the diagnostic procedure. In complicated cases, with the mandatory "double–read ", double dependent reading (the picture is read twice; on the second reading, the result of the first reading is available), PET, PET/CT, PET/MRI, SPECT, SPECT /CT scans are performed by specialists in the field of nuclear medicine and a final diagnostic conclusion is drawn up.		
	Availability of supporting documentation on the referral of patients to the RNT department after preliminary examination and resolution of the issue		

11	on the basis of clinical data on the need for RNT with the participation of the head of the department or a nuclear medicine physician in accordance with the list of diseases for RNT. For inpatient medical care for oncology diseases, a referral is issued by a multidisciplinary group established in health care organizations providing oncology care; in the case of non-oncology diseases, a whole-body scintigraphy with the diagnostic activity of the radiopharmaceutical drug “Sodium iodide I-131 ” 185 MBq is prescribed according to clinical indications by the medical consultative board of the medical organization.		
12	Availability of supporting documentation of RNT in inpatient settings in “active ” wards and/or beds. After receiving RFMP, the patient is a source of beta-gamma radiation, and therefore, daily rounds of the doctor shall be made by means of audio and video communication. The radiation safety engineer (dosimetrist) records the dose rate from patients daily through a dose rate monitor and stationary dose rate measurement system.		
	Availability of supporting documentation on delivery of the cadaver of a patient with administered RFLP of “active” wards to a specially allocated freezing chamber located in the radionuclide support unit of the RNT unit (in the radioactive waste storage facility) in case of lethal outcome. The corpse is		

13	kept in the freezer until an acceptable level of radioactive decay (at a distance of 1 meter from the body surface - 20 mcSv /h) and then the corpse is transported. For urgent pathologic examination, the RNT dosimetrist calculates the duration of the autopsy procedure according to the radiation exposure standards for Group B personnel.		
	Availability of documentation (internal orders, regulations, protocols, questionnaires, analytical briefs) of the clinical audit by Patient Support Services and internal expertise and its evaluation according to the following criteria: 1) quality of history taking, which is assessed according to the following criteria: absence of history taking; completeness of history taking; availability of data on past, chronic and hereditary diseases, hemotransfusions, tolerance of medicines, allergological status; development of complications as a result of tactical errors made in the course of treatment and diagnostic measures due to poor quality of anamnesis collection; 2) completeness and validity of diagnostic tests, which shall be evaluated according to the following criteria: absence of diagnostic measures; incorrect conclusion or lack of conclusion based on		

	the results of diagnostic tests, which led to incorrect diagnosis and errors in treatment tactics; performance of diagnostic tests stipulated by clinical protocols; performance of diagnostic tests with high, unjustified risk for the patient's health condition, justification of diagnostic tests not included in clinical protocols; diagnostic tests that are uninformative for making a correct diagnosis and resulted in an unjustified increase in treatment time and the cost of treatment; 3) correctness, timeliness and validity of the clinical diagnosis, taking into account the results of the conducted examinations (in case of planned hospitalization, the examinations conducted at the pre-hospital stage are also taken into account), which are evaluated according to the following criteria: the diagnosis is absent, incomplete or incorrect, does not correspond to the international classification of diseases; the leading pathological syndrome determining the severity of the course of the disease has not been identified, concomitant diseases and complications have not been recognized; the diagnosis is correct but incomplete, the leading pathological syndrome is not highlighted with the highlighted complications, concomitant diseases affecting the outcome were not diagnosed;			

14		the diagnosis of the main disease is correct, but concomitant diseases affecting the outcome of treatment are not diagnosed. Objective reasons for incorrect and (or) untimely diagnosis (atypical course of the main disease, asymptomatic course of the associated disease, rare complications and associated diseases) are reflected in the examination results. The impact of incorrect and (or) untimely diagnosis on the subsequent stages of medical services (care) is assessed; 4) timeliness and quality of consultations of profile specialists, which are evaluated according to the following criteria: lack of consultation, which led to erroneous interpretation of symptoms and syndromes that negatively affected the outcome of the disease; timely consultation, failure to take into account the consultant's opinion when making a diagnosis partially affected the outcome of the disease; timely consultation, consultant's opinion was taken into account when making the diagnosis, failure to implement the consultant's treatment recommendation partially affected the outcome of the disease; consultant's opinion was erroneous and affected the outcome of the disease. Availability of supporting documentation on the assessment of objectivity of the reasons for late		

	consultation and the impact of late diagnosis on the subsequent stages of medical services (care); 5) scope, quality and validity of treatment measures, which shall be assessed by the following criteria: absence of treatment in the presence of indications; prescription of treatment in the absence of indications; prescription of ineffective treatment measures disregarding specifics of the course of the disease, concomitant diseases and complications; performance of therapeutic measures disregarding the functional state of organs and systems, prescription of drugs without proven clinical efficacy; unjustified deviation from the requirements of clinical protocols, presence of polypragmasy, which led to development of a new pathological syndrome and worsening of the patient's condition; 6) absence or development of complications after medical interventions, all complications that have occurred, including those caused by surgical interventions (delayed surgical intervention, inadequate scope and method, technical defects) and diagnostic procedures are evaluated; 7) the achieved result, which shall be evaluated according to the following criteria: achievement of the expected clinical effect in compliance with the technology of medical services (assistance);			

	absence of clinical effect of therapeutic and preventive measures due to poor quality anamnesis collection and diagnostic tests; absence of expected clinical effect due to ineffective therapeutic and preventive measures disregarding the specifics of the course of the disease, concomitant diseases, complications, prescription of drugs without proven clinical efficacy; the presence of polypragmasy, which caused development of undesirable consequences; 8) the quality of medical documentation, which is assessed by the availability, completeness and quality of records in the primary medical documentation intended for recording data on the patients' health condition, reflecting the nature, scope and quality of medical care provided		
15	Availability of supporting documentation of record-keeping and accounting records		

Designated person (s) _____ _____
position, signature

_____
surname, name, patronymic (if any)
The head of the control subject _____ _____
position, signature

_____
surname, name, patronymic (if any)

Appendix 25
to the joint order
of the Minister of Healthcare
of the Republic of Kazakhstan dated
November 15, 2018 № ҚР ДСМ-32
and the Minister of National Economy

of the Republic of Kazakhstan
dated November 15, 2018 №70

Checklist in the field of circulation of medicines and medical devices regarding the state expert organization in the sphere of circulation of medicines and medical devices

Footnote. The joint order as supplemented by Appendix 25 pursuant to the joint order of the acting Minister of Healthcare of the Republic of Kazakhstan dated 24.05.2023 № 87 and the Minister of National Economy of the Republic of Kazakhstan dated 24.05.2023 № 77(effective ten calendar days after the date of its first official publication).

State body that appointed inspection/preventive control with a visit to
to control subject (object) _____
____
_____
_____

Act on appointing inspection/ preventive control with a visit to control subject (object)
_____
_____
_____

№, date
Name of control subject (object)
_____
_____

(Individual Identification Number), Business Identification Number of the control subject (object) _____
____

Location address
_____
_____

№	List of requirements	Compliance with requirements	Non-compliance with requirements
1.	Violation of the rules of state registration, re-registration of a medicinal product or medical device, introduction of amendments to the registration dossier of a medicinal product or medical device by the State Expert Organization in the field of circulation of		

	medicinal products and medical devices		
2.	Violation of the procedure for expert examination of medicines conducted by a state expert organization in the sphere of circulation of medicines and medical devices when conducting an expert examination of the quality and safety of vaccines		

Designated person (s) _____ _____
position, signature

_____
surname, name, patronymic (if any)
The head of the control subject _____ _____
position, signature

_____
surname, name, patronymic (if any)