

On approval of the rules for the provision of medicines and medical products within the guaranteed volume of free medical care, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance, as well as rules and methods for the formation of the need for medicines and medical devices within the guaranteed scope of free medical care, additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated August 20, 2021 No. RK HM-89. Registered with the Ministry of Justice of the Republic of Kazakhstan on August 23, 2021 No. 24069.

Unofficial translation

Footnote. The title is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

In accordance with subparagraphs 49) and 92) of Article 7 of the Code of the Republic of Kazakhstan “On the health of the people and the healthcare system”, **DECREE:**

1. Approve:

1) rules for the provision of medicines and medical products within the guaranteed volume of free medical care, additional medical care to persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance in accordance with Appendix 1 to this order;

2) the rules and methodology for the formation of the need for medicines and medical products within the guaranteed volume of free medical care, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance in accordance with Annex 2 to this by order.

Footnote. Paragraph 1 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing

medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

2. Recognize as invalid some orders of the Ministry of Health of the Republic of Kazakhstan in accordance with Appendix 3 to this order.

3. The Department of Drug Policy of the Ministry of Health of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, shall ensure:

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

2) placement of this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

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

4. To impose control over the execution of this order on the supervising Vice Minister of Health of the Republic of Kazakhstan.

5. This order shall be enforced ten calendar days after the day of its first official publication.

*Minister of Health
of the Republic of Kazakhstan*

A. Tsoy

Appendix 1
to the order of
the Minister of Health
of the Republic of Kazakhstan
dated August 20, 2021
№ RK HM-89

Rules for the provision of medicines and medical products within the guaranteed volume of free medical care, additional 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 compulsory social health insurance

Footnote. The title is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

Chapter 1. General Provisions

1. These rules for the provision of medicines and medical products within the guaranteed volume of free medical care for additional medical care to persons held in pre-trial detention

facilities and institutions of the penal (penitentiary) system at the expense of budgetary funds and (or) in the system of compulsory social medical insurance have been developed in accordance with subparagraph 49) of Article 7 of the Code of the Republic Kazakhstan "On the health of the people and the healthcare system" (hereinafter – The Code) and determine the procedure for providing medicines and medical products within the guaranteed volume of free medical care, additional 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 compulsory social health insurance (hereinafter – the Rules).

Footnote. Paragraph 1 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

2. The following concepts are used in these Rules:

1) the Social health Insurance Fund (hereinafter referred to as the SHIF) is a non-profit organization that accumulates deductions and contributions, as well as purchases and pays for services of healthcare entities providing medical care in the amounts and on the terms provided for by the contract for the purchase of medical services, and other functions defined by the laws of the Republic of Kazakhstan;

2) a list of medicines and medical devices for free and (or) preferential outpatient care for certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions) – the list of medicines, medical devices and specialized medical products purchased at the expense of budgetary funds and (or) assets of the social health insurance fund within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in the provision of primary health care and specialized medical care in outpatient settings, including names and characteristics medicines, medical devices and specialized medical products in the context of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions) (hereinafter – the List);

3) co-payment – payment of the difference in the cost of medicines, medical devices and the established marginal price of their reimbursement within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance at the outpatient level, carried out on a voluntary basis;

4) a single distributor is a legal entity operating within the guaranteed scope of free medical care and (or) in the system of compulsory social health insurance in accordance with Article 247 of the Code;

5) medicinal product – a product that is or contains a substance or a combination of substances that comes into contact with the human body, intended for the treatment,

prevention of human diseases or restoration, correction or modification of its physiological functions through pharmacological, immunological or metabolic effects, or for the diagnosis of diseases and human condition;

6) facilities in the field of circulation of medicines and medical products – a pharmacy, including one that sells via the Internet, a pharmacy in healthcare organizations, a mobile pharmacy for remote rural areas organized from a pharmacy, a pharmacy (distributor) warehouse, a temporary storage warehouse for medicines, medical products, an optics store, a medical store medical products, warehouse of medical products, organizations for the production of medicines and medical products;

7) subjects in the field of circulation of medicines and medical devices – individuals or legal entities engaged in pharmaceutical activities;

8) the authorized body in the field of healthcare (hereinafter referred to as the authorized body) is the central executive body responsible for management and intersectoral coordination in the field of health protection of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical products, quality of medical services (assistance);

9) medicinal form of a healthcare organization – a list of medicines for the provision of medical care within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, formed on the basis of the Kazakh national Medicinal form and approved by the head of the healthcare organization in accordance with the procedure determined by the authorized body;

10) clinical protocol – scientifically proven recommendations for prevention, diagnosis, treatment, medical rehabilitation and palliative care for a particular disease or condition of the patient;

11) The Kazakhstan national Medicinal formulary is a list of medicines with proven clinical safety and efficacy, as well as orphan (rare) medicines, which is an obligatory basis for the development of medicinal formularies of medical organizations and the formation of lists for the purchase of medicines within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

12) medical devices – medical devices and medical equipment;

13) medical devices – materials, products, solutions, reagents, kits, kits used to provide medical care in accordance with the functional purpose and manufacturer's instructions;

14) medical organization – a healthcare organization whose main activity is the provision of medical care;

15) compulsory social health insurance (hereinafter referred to as CSHI) is a set of legal, economic and organizational measures to provide medical care to consumers of medical services at the expense of the assets of the social health insurance fund;

16) guaranteed volume of free medical care (hereinafter referred to as GVFCM) – the volume of medical care provided at the expense of budgetary funds;

17) pharmaceutical service – the activities of entities in the field of circulation of medicines and medical devices related to outpatient drug provision of the population, including the purchase, transportation, storage, accounting and sale of medicines and medical devices, within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

Footnote. Paragraph 2 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

Chapter 2. The procedure for providing medicines and medical products within the guaranteed volume of free medical care, additional medical care to persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance

Footnote. The title of Chapter 2 is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of standards for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced in effective from 01.01.2023).

3. The procedure for providing medicines and medical products includes:

1) determination of the need in accordance with the rules and methodology for the formation of the need for medicines and medical products within the framework of the GVFCM, additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system approved by the authorized body in accordance with subparagraph 92) of Article 7 of the Code;

2) organizing and conducting the purchase of medicines, medical devices and specialized medical products within the framework of the GVFCM, additional 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 CSHI system, pharmaceutical services, in accordance with the Rules of Organization and conducting the purchase of medicines, medical devices and specialized medical products within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, pharmaceutical services, approved by Decree of the Government of the Republic of Kazakhstan dated June 4, 2021 № 375;

3) organization and procurement of services for the storage and transportation of medicines and medical products, services for the registration and sale of medicines and medical products by a single distributor within the framework of the GVFMC, additional 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 CSHI system in accordance with the Rules for the Purchase of services for the storage and transportation of Medicines and Medical devices, services for the registration and sale of medicines and medical products by a single distributor within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, approved by Decree of the Government of the Republic of Kazakhstan dated February 9, 2021 № 47;

4) provision of medicines and medical products within the framework of the GVFMC, additional medical care to persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system;

5) ensuring by local public health authorities the availability of medicines and medical products, including to the rural population in all conditions of medical care;

6) rational use of medicines in accordance with the rules for the implementation of the formulary system, approved by Order of the Minister of Health of the Republic of Kazakhstan dated April 6, 2021 № KR DSM-28 "On approval of the rules for the implementation of the formulary system" (registered in the Register of State Registration of Regulatory Legal Acts under № 22513) and with the rules for assessing rational use medicines, approved by the Order of the Minister of Health of the Republic of Kazakhstan dated November 3, 2020 № KR DSM-179/2020 "On Approval of the Rules for evaluating the rational use of medicines" (registered in the Register of State Registration of Regulatory Legal Acts under № 21586);

7) storage, accounting of medicines and medical devices in the provision of medical care within the framework of the GVFMC, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system in accordance with the Rules for the storage and Transportation of medicines and medical devices, approved by the Order of the Minister of Health of the Republic of Kazakhstan dated February 16, 2021 № KR DSM-19 (registered in the Register of State Registration of Regulatory Legal Acts under № 22230);

8) payment of the cost of medicines and medical products, pharmaceutical services within the framework of the GVFMC and (or) in the CSHI system in accordance with the Rules for paying the cost of pharmaceutical services within the guaranteed volume of free medical care and (or) medical care in the system of compulsory social health insurance to subjects in the field of circulation of medicines and medical products, approved by the Order of the Minister of Health of the Republic of Kazakhstan dated November 27, 2020 № KR DSM-210/2020 (registered in the Register of State Registration of Regulatory Legal Acts under № 21715);

9) compliance with the conditions of ethics for the promotion of medicines and medical products in accordance with the Rules of Ethics for the Promotion of Medicines and Medical

Products approved by Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 № KR DSM-294/2020 (registered in the Register of State Registration of Regulatory Legal Acts under № 21870).

Footnote. Paragraph 3 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

4. In medical organizations providing medical care at all levels within the framework of the GVFCM, an additional amount of medical care is provided to persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system, a stock of medicines and medical devices is created: at least for one month, except for the provision of medical care for HIV infection, where a supply of medicines and medical devices is created for at least three months.

Footnote. Paragraph 4 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

5. In cases of changes in the dynamics of the incidence, transfer or relocation of the patient, changes in the treatment regimen due to intolerance, drug resistance, death, liquidation of medical organizations, changes in the profile of the provision of medical services at all levels of medical care, the redistribution of medicines and medical devices between medical organizations independently, in the manner prescribed by legislation in the field of accounting for material assets.

Paragraph 1. The procedure for providing medicines and medical devices on an outpatient basis

6. The provision of medicines, medical devices, specialized medical products, immunobiological medicines within the framework of the guaranteed volume of medical care and (or) in the compulsory health insurance system in the provision of primary health care and specialized medical care on an outpatient basis is carried out in accordance with the list of medicines and medical devices for free and (or) preferential outpatient care for certain categories of citizens of the Republic of Kazakhstan with certain diseases, approved by order of the Minister of Health of the Republic of Kazakhstan dated August 5, 2021 № RK HM-75 (registered in the Register of State Registration of Regulatory Legal Acts under № 23885).

7. Provision of certain categories of citizens with certain diseases (conditions) with free and (or) subsidized medicines and medical products on an outpatient basis within the framework of the State Compulsory Commissariat of Compulsory Health Care and (or) in the CSHI system is carried out free of charge on a doctor's prescription issued in accordance with

the Rules for prescribing, registration and storage of prescriptions, approved by the order of the Minister of Health of the Republic of Kazakhstan dated October 2, 2020 № RK HM-112/2020 “On approval of the Rules for prescribing, accounting and storing prescriptions” (registered in the Register of State Registration of Regulatory Legal Acts under № 21493).

8. Medicines intended for the provision of outpatient drug provision within the framework of the guaranteed volume of medical care and (or) in the compulsory health insurance system are marked with the stamp of a medical organization indicating the name of the medical organization, its address and the mark “Free of charge” when dispensed.

9. When providing medicines and medical devices, co-payment is possible, in accordance with the rules approved by the order of the Minister of Health of the Republic of Kazakhstan dated July 16, 2021 № RK HM-61 "On approval of the rules for co-payment" (registered in the Register of State Registration of Regulatory Legal Acts under № 23589).

10. In settlements remote from the district center, in the absence of pharmacies, drugstores and mobile drugstores, the provision of medicines and medical products within the framework of the guaranteed volume of free medical care and (or) in the compulsory health insurance system is carried out through medical organizations providing primary health care.

11. The provision of medicines containing narcotic drugs, psychotropic substances and their precursors is carried out by legal entities licensed in the field of circulation of narcotic drugs, psychotropic substances and precursors, in accordance with the Law of the Republic of Kazakhstan "On Permits and Notifications".

12. Excluded by Order of the Minister of Health of the Republic of Kazakhstan dated 11.07.2023 № 129 (effective ten calendar days after the date of its first official publication).

13. Patients with tuberculosis during outpatient treatment are provided with medicines through the offices of chemists of medical organizations providing primary health care.

14. The provision of antiretroviral drugs for the treatment and prevention of HIV infection is carried out through medical organizations providing specialized medical care.

In settlements remote from the regional center, in the absence of medical organizations providing specialized medical care, antiretroviral drugs for the treatment and prevention of HIV infection are provided through medical organizations providing primary health care.

14-1. Patients undergoing maintenance therapy with opioid agonists (hereinafter referred to as PTOA) are provided with medicines for PTOA through medical organizations providing specialized medical care in the field of mental health.

Footnote. The rules were supplemented by paragraph 14-1 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced effective from 01.01.2023).

15. The provision of targeted drugs to patients with oncological diseases is carried out by medical organizations providing oncological care.

16. The provision of immunological (immunobiological) medicinal products in an injectable (infusion) dosage form is carried out through treatment rooms or outpatient chemotherapy rooms of medical organizations providing primary health care or specialized medical care on an outpatient or inpatient basis under the supervision of a medical worker. The drug is opened in the presence of the patient, which is recorded in the relevant information system of the authorized body, including the batch and expiration date of the drug, and an SMS notification is sent to the patient to confirm receipt of the drug.

17. The provision of antiseptic and disinfectant preparations indicated for the treatment of epidermolysis bullosa is carried out as part of the provision of a set of primary health care services and specialized medical care on an outpatient basis.

18. The provision of specialized medical products, including adapted breast milk substitutes, is carried out as part of the provision of a set of services for primary health care and specialized medical care on an outpatient basis.

19. The provision of medicines to newly identified patients begins with a reproduced medicinal product (generic) or a biosimilar medicinal product (biosimilar, biosimilar drug, biosimilar), except in cases of absence, registered reproduced medicinal products (generic) or biosimilar medicinal products (biosimilar, biosimilar drug, biosimilar) or individual drug intolerance. The transfer of patients from an original drug to a reproduced medicinal product (generic) or a biosimilar medicinal product (biosimilar, biosimilar), or from one reproduced medicinal product (generic) to another, is carried out as prescribed by a doctor in accordance with clinical protocols and a formulary.

Footnote. Paragraph 19 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

20. Provision of medicines and medical devices on an outpatient basis within the framework of the State Compulsory Commissariat of Compulsory Health Care and (or) in the compulsory health insurance system for citizens, kandas, refugees, foreigners and stateless persons permanently residing in the territory of the Republic of Kazakhstan and serving sentences by a court verdict in places of deprivation of liberty , detained, taken into custody and placed in special institutions, registered in the dispensary, is carried out by attaching to medical organizations at the place of serving the sentence.

21. Medical organizations providing primary health care and specialized medical care on an outpatient basis, place in places of visual information for patients and on the Internet resource of a medical organization a list of medicines and medical devices for free and (or) preferential outpatient provision of certain categories of citizens Republic of Kazakhstan with

certain diseases (conditions), as well as the addresses of medical organizations through which outpatient drug provision is carried out and the free telephone number 8-800-080-88-87 for obtaining information on the use of medicines.

22. The calculation of the need for medicines containing narcotic drugs and psychotropic substances is carried out in accordance with the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated January 26, 2015 № 32 "On approval of the Rules for the Use of narcotic drugs, psychotropic Substances and their precursors subject to control in the Republic of Kazakhstan" (registered in The Register of State registration of normative legal acts under № 10404).

Footnote. The rules were supplemented by paragraph 22 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 11.07.2023 № 129 (effective ten calendar days after the date of its first official publication).

23. Monitoring of drug supply is carried out by local government health authorities of regions, cities of republican significance and the capital, including using the information systems of the authorized body.

Paragraph 2. The procedure for providing medicines and medical devices in the provision of emergency medical care, as well as specialized care, including high-tech medical services, in inpatient and inpatient-replacing conditions

24 When providing emergency medical care, medical care in inpatient, hospital-replacing conditions within the framework of the guaranteed volume of medical care and (or) in the compulsory health insurance system, the provision of medicines is carried out in accordance with the medicinal formularies of healthcare organizations developed on the basis of the Kazakhstan national medicinal formulary , in accordance with the Rules for the formation of the Kazakhstan national medicinal formulary, as well as the rules for the development of medicinal formularies of healthcare organizations, approved by order of the Acting Minister of Health of the Republic of Kazakhstan dated December 24, 2020 № RK HM-326/2020 “On approval of the rules for the formation of the Kazakhstan national medicinal formulary, as well as the rules for the development of medicinal formularies of organizations health care” (registered in the Register of State Registration of Regulatory Legal Acts under № 21913).

24-1. In medical organizations located in institutions of the penal enforcement (penitentiary) system, when providing medical care, the provision of medicines and medical products is carried out in accordance with these Rules within the framework of additional medical care for persons held in pre-trial detention facilities and institutions of the penal enforcement (penitentiary) system, at the expense of budgetary funds.

Footnote. The rules were supplemented by paragraph 24-1 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of

the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced effective from 01.01.2023).

25. The provision of medicines and medical products in the provision of emergency medical care, including with the involvement of medical aviation, is carried out in accordance with the Rules for the provision of emergency medical care, including with the involvement of medical aviation, approved by order of the Minister of Health of the Republic of Kazakhstan dated November 30 2020 № KR HM-225/2020 “On approval of the rules for the provision of emergency medical care, including with the involvement of medical aviation” (registered in the Register of State Registration of Regulatory Legal Acts under № 21713).

26. The provision of medicines and medical products in medical organizations providing medical care in inpatient and inpatient conditions is carried out in accordance with the prescriptions entered by the doctor in the list of medical prescriptions in accordance with the form, in accordance with the forms of accounting documentation in the field of healthcare, approved by order of the executing duties of the Minister of Health of the Republic of Kazakhstan dated October 30, 2020 № KR HM-175/2020 “On approval of the forms of accounting documentation in the field of healthcare” (hereinafter - Order № KR HM-175/2020) (registered in the Register of State Registration of Regulatory Legal Acts under № 21579).

The sheet of medical appointments is attached to the medical record of the inpatient (health resort card) in the medical information system.

27. Medicines and medical devices intended for the provision of emergency medical care, medical care in inpatient, hospital-substituting conditions within the framework of the GVFMC, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system, are marked when receipt with a stamp of a medical organization indicating the name of the medical organization, its address and a mark "Free of charge".

Footnote. Paragraph 27 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 08/05/2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

28. Medicines and medical devices in the provision of emergency medical care, medical care in inpatient, hospital-substituting conditions within the framework of the GVFMC, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system are subject to accounting in the sum and quantitative expressions in medical documentation and (or) automated accounting programs (medical information systems) for the use of medicines and medical devices.

For the purpose of rational use (prescription) of medicines and medical devices, analysis of data for providing citizens, local public health authorities of regions, cities of republican significance and the capital monitor the operation of medical information systems, including drug provision, and ensure the timeliness of data entry and their reliability.

Footnote. Paragraph 28 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

29. Medicines and medical devices purchased for the provision of medical care within the framework of the GVFCM, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of CSHI and paid services, are subject to separate storage and accounting.

Footnote. Paragraph 29 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

30. First-aid kits for mother and child are issued to newborns upon discharge from obstetric organizations. A note on the issuance of first-aid kits to the mother and child is entered in the history of the development of the newborn in the form, in accordance with the forms of accounting documentation in the field of healthcare, approved by Order № RK HM-175/2020.

31. An inventory of medicines and medical devices stored in medical organizations is carried out at least once a year.

Appendix 2
to the order of the Minister of Health
Of the Republic of Kazakhstan
dated August 20, 2021 № KR DSM-89

Footnote. The text in the upper right corner is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which effective from 01.01.2023).

Rules and methodology for the formation of the need for medicines and medical products within the guaranteed volume of free medical care, additional 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 compulsory social health insurance

Footnote. The title is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

Chapter 1. General provisions

1. These rules and methods of forming the need for medicines and medical products within the guaranteed volume of free medical care, additional 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 compulsory social health insurance (hereinafter – the Rules) have been developed in accordance with subparagraph 92) of Article 7 of the Code of the Republic of Kazakhstan "On the Health of the people and the healthcare system" (hereinafter – The Code) and define the procedure and methodology for the formation of the need for medicines and medical products within the guaranteed volume of free medical care, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance.

Footnote. Paragraph 1 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

2. The following concepts are used in these Rules:

1) social health insurance fund - a non-profit organization that accumulates deductions and contributions, as well as purchases and pays for the services of healthcare entities that provide medical care in the volume and on the terms that are provided for by the contract for the purchase of medical services, and other functions defined by the laws of the Republic Kazakhstan (hereinafter referred to as the Fund);

2) Single distributor - a legal entity operating within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in accordance with Article 247 of this Code;

3) a 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) (hereinafter - the List) - a list of medicines, medical devices and specialized medical products purchased at the expense of budgetary funds and (or) the assets of the social health insurance fund within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in the provision of primary health care and specialized medical care on an outpatient basis, including the names and characteristics of

medicines, medical devices and specialized medical products in the context of certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions);

4) the established daily dose is the value corresponding to the average daily dose of the drug when used for basic indications, set for each active ingredient and dosage form;

5) medicinal formulary of a healthcare organization - a list of medicines for the provision of medical care within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, formed on the basis of the Kazakhstan national medicinal formulary and approved by the head of a healthcare organization in the manner determined by the authorized body;

6) the authorized body in the field of healthcare (hereinafter referred to as the authorized body) - the central executive body that manages and intersectoral coordination in the field of protecting the health of citizens of the Republic of Kazakhstan, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical devices, the quality of medical services (assistance);

7) Kazakhstan national medicinal formulary - a list of medicines with proven clinical safety and efficacy, as well as orphan (rare) medicines, which is a mandatory basis for the development of medicinal formularies of medical organizations and the formation of lists for the purchase of medicines within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance;

8) medical organization - a healthcare organization, the main activity of which is the provision of medical care;

9) marginal price for an international nonproprietary name of a medicinal product or a technical characteristic of a medical device within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance - the price for an international nonproprietary name of a medicinal product or a technical characteristic of a medical device, above which be purchased within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

Footnote. Paragraph 2 as amended by Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of standards for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced in effective from 01.01.2023).

Chapter 2. The procedure for the formation of the need for medicines and medical products within the guaranteed volume of free medical care, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance

Footnote. The title of Chapter 2 is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of standards for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced in effective from 01.01.2023).

3. The need for medicines and medical products within the guaranteed volume of free medical care (hereinafter – GVFCM), additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance (hereinafter – CSHI) is formed by medical organizations:

1) in the provision of emergency medical care, as well as specialized medical care, including high-tech, in inpatient and hospital-substituting conditions in accordance with drug formulas;

2) when providing primary health care and specialized medical care on an outpatient basis in accordance with the list.

Footnote. Paragraph 3 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

4. The need for medicines and medical products within the framework of the GVFCM, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system is formed for a three-year period.

Footnote. Paragraph 4 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

5. The calculation of the need for medicines and medical devices within the framework of the GVFCM, the additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system is carried out in accordance with the methodology for the formation of the need for medicines and medical devices within the GVFCM, additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal enforcement (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system specified in Chapter 3 of these Rules, taking into account the following information:

1) data on the dynamics of morbidity and (or) the epidemiological situation in the region;

2) statistical data of the information systems "Electronic Register of dispensary patients" (hereinafter – IS ERDP), "Electronic Register of inpatient patients" (hereinafter – IS ERDP), "Electronic Register of cancer patients" (hereinafter – IS ERCP) to determine the predicted number of patients and (or) bed days;

3) the values of the established daily dose (hereinafter – EDD) and the duration of administration (number of days) for medicines according to the data of the Collaborating Center of the World Health Organization on the Methodology of Drug Statistics (www.whooc.no) (hereinafter referred to as WHO).

In the absence of EDD values calculated by WHO, the calculation of EDD is carried out taking into account the treatment regimens and dosages recommended by the clinical protocols of the Republic of Kazakhstan and (or) according to the instructions for medical use of the drug;

4) the average course duration of the use of medicines and medical devices, taking into account the treatment regimens and dosages recommended by the clinical protocols of the Republic of Kazakhstan and (or) according to the instructions for the medical use of the drug (for patients with chronic diseases who need constant use of medicines and medical devices is equal to the number of days per year);

5) the maximum price for an international nonproprietary name of a medicinal product or a technical characteristic of a medical device and (or) for a trade name of a medicinal product or medical device within the framework of the GVFMC and (or) in the CSHI system, approved by the authorized body.

Footnote. Paragraph 5 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

Paragraph 1. The procedure for the formation of the need for medicines and medical products within the guaranteed volume of free medical care for additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance when providing medical care in inpatient and stationary substituting conditions

Footnote. The title of paragraph 1 is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of standards for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced in effective from 01.01.2023).

6. A medical organization forms a need by March 1 of the current financial year:

1) in medicines and medical devices included in the list of medicines and medical devices purchased from a Single Distributor (hereinafter referred to as the list of a Single Distributor) for a three-year period;

2) in medicines and medical devices that are not included in the list of a Single Distributor for a three-year period;

3) in medicines and medical devices as part of the additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system.

Footnote. Paragraph 6 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

6-1. The need for medicines and medical devices as part of the additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system, is sent for approval to local public health authorities of oblasts, cities of republican significance and the capital.

Local public health authorities of oblasts, cities of republican significance and the capital consider the need for the validity of the volumes of medicines and medical devices based on data on the dynamics of morbidity and (or) epidemiological situation, actual consumption over the previous year, the reliability of statistical data and the projected number of patients.

Local public health authorities of regions, cities of republican significance and the capital form the general demand for medicines and medical devices and send them to the local executive body of the relevant region, city of republican significance and the capital by March 15 of the current financial year.

Footnote. The rules were supplemented by paragraph 6-1 in accordance with the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced effective from 01.01.2023).

7. The formed need for medicines and medical devices is agreed upon by the formulary commission of the medical organization.

Paragraph 2. The procedure for the formation of the need for medicines and medical products within the guaranteed volume of free medical care, additional medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the system of compulsory social health insurance when providing medical care in outpatient settings conditions

Footnote. The title of paragraph 2 is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of standards for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced in effective from 01.01.2023).

8. A medical organization forms a need for a three-year period before March 15 of the current financial year:

1) in medicines and medical devices included in the list of medicines and medical devices purchased under the GVFMC and (or) in the CSHI system;

2) in medicines and medical devices, as part of the additional volume of GVFMC purchased at the expense of the local budget.

Footnote. Paragraph 8 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

9. The formed need for medicines and medical devices is agreed upon by the formulary commission of the medical organization.

10. The medical organization forms the need for medicines and medical devices specified in subparagraph 2) of paragraph 8 of these Rules, in the form of an application signed by an authorized official of the medical organization, or by a person replacing him, and sends it to the local health authority of regions, cities of republican significance and the capital to be financed from the local budget within the framework of the additional volume of the guaranteed volume of medical care.

11. The need for medicines and medical devices specified in subparagraph 1) of paragraph 8 of these Rules is drawn up in the form of an application in the information system of the Single Distributor "Unified Pharmaceutical Information System" on paper and (or) in the form of an electronic document signed by an electronic digital signature (hereinafter - EDS) of an authorized official of a medical organization, or a person replacing him.

12. By March 20 of the current financial year, the formed application for medicines and medical devices is sent for approval to the local government health authority of regions, cities of republican significance and the capital.

The local public health authority of regions, cities of republican significance and the capital considers the application for the validity of the volumes of medicines and medical devices based on the dynamics of the incidence and (or) the epidemiological situation in the region and the reliability of statistical data and the predicted number of patients.

13. The term for consideration of an application for medicines and medical devices in the local health authority of regions, cities of republican significance and the capital does not exceed five working days from the date of receipt.

14. Within one working day from the date of approval by the local public health authority of regions, cities of republican significance and the capital, the medical organization sends an application for medicines and medical devices to the branch of the Fund in the corresponding region, city of republican significance and the capital.

15. The branch of the Fund considers the application within 7 working days from the date of receipt of the application for medicines and medical devices for compliance with the List and the correctness of calculations according to the established formulas provided for in paragraph 19 of these Rules for each name of the medicine or medical device.

16. After approval of the application for medicines and medical devices of a medical organization, the branch of the Fund includes in a single application for medicines and medical devices for a three-year period for the region, city of republican significance and the capital and sends it to the Fund.

17. The Fund considers a single application for medicines and medical devices for a three-year period for the region, the city of republican significance and the capital for the availability (or sufficiency) and provision of financial resources within the allocated funds in the context of the budgets of the State Compulsory Commissariat of Communal Health and CSHI.

18. Based on the unified applications of the regions, the Fund forms a consolidated application for medicines and medical devices for a three-year period across the country by regions, indicating nosologies, names, dosages and volumes for each dosage form of medicines and characteristics of medical devices, the number of patients and sends to the authorized body no later than April 15 of the current financial year.

Chapter 3. Methodology for the formation of the need for medicines and medical products within the guaranteed volume of free medical care, additional 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 compulsory social health insurance

Footnote. The title of Chapter 3 is in the wording of the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of standards for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are introduced in effective from 01.01.2023).

19. The calculation of the need for medicines and medical devices within the framework of the GVFMC, the additional volume of medical care for persons held in pre-trial detention facilities and institutions of the penal (penitentiary) system, at the expense of budgetary funds and (or) in the CSHI system is carried out:

- 1) taking into account the established daily dose for medicines;
- 2) based on data on the actual consumption of medicines and medical devices for the previous financial year.

Footnote. Paragraph 19 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

20. To calculate the projected need for medicines for outpatient medical care, the following formulas are used:

$PLSPA = USD \times UPC \times CPC \times KPP / DEI$ (1), where

PLSPA is the projected need for a drug (in purchase units) per year on an outpatient basis;

USD is the established daily dose;

UPC – the average course duration of application (days);

CPC – the number of projected courses per year;

KPP is the number of predicted patients per year.

To calculate the projected need for medical devices for outpatient medical care, the following formula is used:

$PMIPA = FPMI \times UPC \times CPC \times CHECKPOINT$ (2), where

PMIPA is the projected need for a medical device (in purchase units) per year on an outpatient basis;

FPMI is the average actual consumption of medical devices per patient for the previous fiscal year;

UPC – the average course duration of application (days);

CPC – the number of projected courses per year;

KPP – the number of predicted patients per year;

PC is the maximum price in accordance with the approved regulatory legal act in terms of USD for the least expensive dosage form and dosage.

To calculate the need for the purchase of medicines and medical devices used on an outpatient basis, the following formula is used:

$PZA = PLC(MI)PA - PO$ (3), where

PLSA – the need to purchase a medicinal product (in purchase units) per year on an outpatient basis;

PLSPA – the projected need for a drug per year in an outpatient setting;

PO is the projected balance of medicines as of January 1 next year (as of April 1 next year for antiretroviral drugs).

To calculate the financial security necessary to cover the needs determined in accordance with formulas (1-3) of these Rules, the value of the need in purchase units is multiplied by the marginal price in accordance with the approved regulatory legal act.

Footnote. Paragraph 20 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing

medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

21. To calculate the projected need for medicines for medical care in inpatient and hospital-substituting conditions, the following formulas are used:

$PLSPS = USD \times UPC \times CPC \times KPP / DEI$ (4), where

PLSPS is the projected need for a drug (in purchase units) per year in inpatient and inpatient–substituting conditions;

USD is the established daily dose;

UPC is the average course duration of application (days) in stationary and inpatient–substituting conditions;

CPC – the number of predicted courses in stationary and inpatient-substituting conditions per year;

KPP – the number of predicted patients in inpatient and inpatient replacement conditions per year;

DEI is the dosage of the unit of measurement.

To calculate the projected need for medical devices for the provision of medical care in inpatient and hospital-substituting conditions, the following formula is used:

$PMIPS = FPMI \times UPC \times CPC \times KPP$ (5), where

PMIPS is the projected need for a medical device (in purchase units) per year in stationary and hospital–substituting conditions;

FPMI is the average actual consumption of medical devices in inpatient and inpatient replacement conditions per patient for the previous financial year;

UPC is the average course duration of application (days) in stationary and inpatient–substituting conditions;

CPC – the number of predicted courses in stationary and inpatient-substituting conditions per year;

KPP is the number of predicted patients in inpatient and inpatient replacement conditions per year.

The following formula is used to calculate the need for the purchase of medicines and medical devices used in inpatient and inpatient replacement conditions:

$PLSPS = PLSPA - BY$ (6), where

PLSZ – the need to purchase a medicinal product per year in inpatient and inpatient-substituting conditions;

PLSPS – the projected need for a drug per year in inpatient and inpatient-substituting conditions;

PO is the projected balance of medicines as of January 1 next year.

To calculate the financial security necessary to cover the needs determined in accordance with formulas (4-6) of these Rules, the value of the need in purchase units is multiplied by the marginal price in accordance with the approved regulatory legal act.

Footnote. Paragraph 21 - as amended by the Order of the Minister of Health of the Republic of Kazakhstan dated 05.08.2022 № KR DSM-75 (effective ten calendar days after the date of its first official publication, with the exception of the norms for persons providing medical care to persons held in pre-trial detention facilities of the penal (penitentiary) system, which are put into effect from 01.01.2023).

Appendix 3
to the order of the
Minister of Health
of the Republic of Kazakhstan
dated August 20, 2021
№ RK HM-89

List of invalidated some orders of the Ministry of Health of the Republic of Kazakhstan

1. Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated September 30, 2015 № 766 “On Approval of the Rules for Providing Medicines to Citizens” (registered in the Register of State Registration of Regulatory Legal Acts under № 12199).

2. Order of the Minister of Health of the Republic of Kazakhstan dated May 14, 2019 № RK HM-75 “On Amendments to the Order of the Minister of Health and Social Development of the Republic of Kazakhstan” dated September 30, 2015 № 766 “On Approval of the Rules for Providing Medicines to Citizens” (registered in Register of state registration of normative legal acts under № 18677).

3. Order of the Minister of Health of the Republic of Kazakhstan dated May 19, 2020 № RK HM-51/2020 “On Amendments to the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated September 30, 2015 № 766 “On approval of the rules for providing medicines to citizens” (registered in the Register of State Registration of Normative Legal Acts under № 20672).