On approval of the rules for the provision of medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance, as well as the rules and methods for generating the need for medicines and medical devices within the guaranteed volume of free medical care 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

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) the rules for the provision of medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in accordance with Appendix 1 to this order;

2) the rules and methodology for forming the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance in accordance with Appendix 2 to this order.

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
No. RK HM-89

Rules for the provision of medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance

Chapter 1. General Provisions

1. These rules for the provision of medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance are developed in accordance with subparagraph 49) of Article 7 of the Code of the Republic of Kazakhstan "On the health of the people and the healthcare system" (hereinafter - Code) and determine the procedure for providing medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance (hereinafter referred to as the Rules).

2. The following concepts are used in these Rules:

1) guaranteed volume of free medical care (hereinafter referred to as GVFMC) - the volume of medical care provided at the expense of budgetary funds;

2) compulsory social health insurance (hereinafter - CSHI) - 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;

3) 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 the services of healthcare entities providing medical care in the volume and on the terms provided for in the contract for the purchase of medical services, and other functions determined by the laws of the Republic of Kazakhstan ;

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

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

6) medicinal formulary on the organization of health care - 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 the healthcare organization in the manner determined by the authorized body;

7) medical devices - medical devices and medical equipment;

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

9) 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;

10) 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 the Code;

11) 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) - a 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 on an outpatient basis, including the names and characteristics of medicines, medical devices and specialized medical products in the context certain categories of citizens of the Republic of Kazakhstan with certain diseases (conditions) (hereinafter - the List);

12) 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);

13) objects in the field of circulation of medicines and medical devices - a pharmacy, including those selling via the Internet, a pharmacy in healthcare organizations, a mobile pharmacy for remote rural areas, organized from a pharmacy, a pharmacy (distribution) warehouse, a warehouse for temporary storage of medicines funds, medical devices, an optics store, a medical device store, a warehouse for medical devices, organizations for the production of medicines and medical devices;

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

15) 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;

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

17) pharmaceutical service - 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.

Chapter 2. The procedure for providing medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance

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

1) determination of the need in accordance with the rules and methodology for the formation of the need for medicines and medical devices within the framework of the guaranteed volume of medical care and (or) in the compulsory health insurance system, approved by the authorized body in accordance with subparagraph 92) of Article 7 of the Code;

2) organization and conduct of the procurement of medicines, medical devices and specialized medical products within the framework of the State Compulsory Health Insurance and (or) in the compulsory medical insurance system, pharmaceutical services, in accordance with the Rules for organizing and conducting the procurement of medicines, medical devices and specialized medical products within the guaranteed volume free medical care and (or) in the system of compulsory social health insurance, pharmaceutical services, approved by the Decree of the Government of the Republic of Kazakhstan dated June 4, 2021 No. 375 “On approval of the Rules for organizing and conducting the procurement of medicines, medical devices and specialized medical products within the guaranteed volume free medical care and (or) in the system of compulsory social health insurance, pharmaceutical services and invalidation of some decisions of the Government of the Republic of Kazakhstan”;

3) organization and conduct of the procurement of services for the storage and transportation of medicines and medical devices, services for the accounting and sale of medicines and medical devices by a single distributor within the framework of the state volume of free medical care and (or) in the compulsory health insurance system in accordance with the Rules for the procurement of services for the storage and transportation of medicines funds and medical devices , services for the accounting and sale of medicines and medical devices by a single distributor within the guaranteed volume of free medical care and (or) in

the system of compulsory social health insurance, approved by the Decree of the Government of the Republic of Kazakhstan dated February 9, 2021 No. 47 "On approval of the Rules for the procurement of services for the storage and transportation of medicines and medical devices, services for the accounting and sale of medicines and medical devices by a single distributor within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance and invalidation of some decisions of the Government of the Republic of Kazakhstan";

4) provision by medical organizations of timely and high-quality medical care, availability of safe, high-quality and effective medicines, and medical devices;

5) provision by local public health authorities of the availability of the provision of medicines and medical devices, including 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 No. RK HM-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 No. 22513) and with the Rules for assessing the rational use of medicines, approved by order of the Minister of Health of the Republic of Kazakhstan dated November 3, 2020 No. RK HM-179/2020 "On approval of the rules for assessing the rational use of medicines" (registered in the Register of State Registration of Regulatory Legal acts under No. 21586);

7) storage, accounting of medicines and medical devices in the provision of medical care within the framework of the guaranteed volume of medical care and (or) in the compulsory medical insurance system in accordance with the Rules for the storage and transportation of medicines and medical devices, approved by order of the Minister of Health of the Republic of Kazakhstan dated February 16, 2021 No. RK HM-19 "On approval of the rules for the storage and transportation of medicines and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under No. 22230);

8) payment of the cost of medicines and medical devices, pharmaceutical services within the framework of the guaranteed volume of medical care and (or) in the compulsory medical insurance system in accordance with the Rules for the payment of 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 for subjects in the field of circulation of medicines and medical devices, approved by the order of the Minister of Health of the Republic of Kazakhstan dated November 27, 2020 No. RK HM-210/2020 "On approval of the Rules for payment of the cost of pharmaceutical services within the guaranteed volume of free medical care and (or) medical care in the system compulsory social health insurance for subjects in the field of circulation of medicines and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under No. 21715);

9) compliance with the conditions of ethics for the promotion of medicines and medical devices in accordance with the Rules of ethics for the promotion of medicines and medical devices, approved by order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. RK HM-294/2020 "On approval of the rules of ethics for the promotion of medicines and medical devices" (registered in the Register of State Registration of Regulatory Legal Acts under No. 21870).

4. In medical organizations that provide medical care at all levels within the framework of the guaranteed volume of free medical care and (or) in the compulsory medical insurance system, a stock of medicines and medical devices is created: for at least one month, with the exception of medical care for HIV infection, where a stock of medicines and medical products is created for at least three months.

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 No. RK HM-75 (registered in the Register of State Registration of Regulatory Legal Acts under No. 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 No. 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 No. 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 No. RK HM-61 "On approval of the rules for co-payment" (registered in the Register of State Registration of Regulatory Legal Acts under No. 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. The provision of medicines and medical devices on an outpatient basis is reflected in the relevant information system of the authorized body in terms of:

1) planned medicines and medical products;

2) purchased medicines and medical devices;

3) prescribed medicines and medical devices;

4) provision or refusal to provide medicines and medical devices due to their absence, or refusal to receive them by the patient.

In case of incorrect prescription or dispensing of a medicinal product or medical device, the prescription correction is entered into the information system of the authorized body within a period of not more than 5 working days from the date of issuance.

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.

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. Provision of medicines to newly identified patients begins with a generic drug (generic) or a biosimilar drug (biosimilar, biosimilar drug, biosimilar), except in the absence of registered generic drugs (generic) or biosimilar drugs (biosimilar, biosimilar drug, biosimilar) or individual intolerance to the drug. Providing drugs to patients with hemophilia, diabetes mellitus, condition after organ and tissue transplantation, epilepsy, who previously received original drugs, continues with drugs from one manufacturer. The transfer of patients from the original drug to a generic drug (generic) or a biosimilar drug (biosimilar, biosimilar drug, biosimilar), or from one generic drug (generic) to another, is carried out according to the doctor's prescription in accordance with clinical protocols and a formulary guide .

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. Decision on the provision of medicines, medical devices and specialized medical products not included in the list 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), is accepted by local representative bodies on the proposal of local government health authorities of regions, cities of republican significance and the capital in accordance with clinical protocols, regardless from the presence of state registration in the Republic of Kazakhstan and the approved marginal price for the trade name of a medicinal product or medical device, for the international non-proprietary name of a medicinal product or a technical characteristic of a medical device within the framework of the GVFMC and (or) in the CSHI system.

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 No. 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 No. 21913).

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 No. 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 No. 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 No. KR HM-175/2020 "On approval of the forms of accounting documentation in the field of healthcare" (hereinafter - Order No. KR HM-175/ 2020) (registered in the Register of State Registration of Regulatory Legal Acts under No. 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-replacing conditions within the framework of the guaranteed volume of free medical care and (or) in the OSMI system are marked upon

admission with a stamp of a medical organization indicating the name of the medical organization, its address and a mark "Is free".

28. Medicines and medical devices in the provision of emergency medical care , medical care in inpatient, hospital-replacing conditions within the framework of the guaranteed volume of free medical care and (or) in the compulsory health insurance system are subject to accounting in sum and quantitative terms in medical documentation and (or) automated accounting programs (medical information systems) use of medicines and medical devices.

For the purpose of rational use (prescribing) of medicines and medical devices, analysis of data on provision of citizens, local public health authorities of regions, cities of republican significance and the capital monitor the work of medical information systems in subordinate medical organizations, including those on drug provision, and ensure timeliness of data entry and their reliability.

29. Medicines and medical devices purchased for the provision of medical care within the framework of the guaranteed volume of medical care and (or) in the system of compulsory health insurance and paid services are subject to separate storage and accounting.

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

Rules and methodology for forming the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance

Chapter 1. General Provisions

1. These rules and the methodology for forming the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance (hereinafter referred to as the Rules) are developed in accordance with subparagraph 92) of Article 7 of the Code of the Republic of Kazakhstan " On health of the people and the health care system" (hereinafter referred to as the Code) and

determine the procedure and methodology for the formation of the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance.

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 (Defined Daily Dose - DDD) is a value corresponding to the average daily dose of the medicinal product when used according to the main indications, established 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.

Chapter 2. The procedure for the formation of the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance

3. The need for medicines and medical devices within the framework of the guaranteed volume of free medical care (hereinafter referred to as the GVFMC) and (or) in the system of compulsory social health insurance (hereinafter referred to as the CSHI) is formed by medical organizations:

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

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

4. The need for medicines and medical devices within the framework of the guaranteed volume of medical care and (or) in the compulsory medical insurance system is formed for a three-year period.

5. Calculation of the need for medicines and medical devices within the framework of the guaranteed volume of medical care and (or) in the compulsory medical insurance system is carried out in accordance with the Methodology for the formation of the need for medicines and medical devices within the framework of the guaranteed compulsory medical care and (or) in the compulsory medical insurance system specified in Chapter 3 of these Rules based on the following information:

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

2) statistical data from the information systems "Electronic Register of Dispensary Patients" (hereinafter - ERDP), "Electronic Register of Inpatients" (hereinafter - ERI), " Electronic Register of Cancer Patients" (hereinafter - ERCP) to determine the predicted number of patients and (or) bed days;

3) the values of the established daily dose (Defined Daily Dose) (hereinafter - DDD) and the duration of administration (number of days) for medicines according to the data of the World Health Organization Collaborating Center for Drug Statistics Methodology (www.whocc.no) (hereinafter - WHO);

In the absence of DDD values calculated by WHO, the calculation of DDD is made 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 medicinal product;

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 medicine (for patients with chronic diseases requiring constant use of medicines and medical devices is equal to the number of days in a year);

5) the marginal price for the international non-proprietary name of the medicinal product or the technical characteristics of the medical device and (or) for the trade name of the medicinal product or medical device within the framework of the guaranteed volume of medical care and (or) in the CSMI system, approved by the authorized body.

Paragraph 1. The procedure for the formation of the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance when providing medical care in inpatient and inpatient-replacing conditions

6. Before April 1 of the current financial year, the medical organization forms the need for :

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

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

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 devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance when providing medical care on an outpatient basis

8. The medical organization, before March 15 of the current financial year, forms the need for:

1) in medicines and medical devices included in the list medicines and medical devices purchased from the Single Distributor for a three-year period;

2) in medicines and medical devices included in the list of medicines and medical devices not purchased from the Single Distributor for a three-year period.

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 forming the need for medicines and medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance

19. Calculation of the need for medicines and medical devices within the framework of the guaranteed volume of medical care and (or) in the compulsory medical insurance system is carried out in two ways:

1) based on the established daily dose for medicines

2) based on actual consumption data for the previous financial year for medical devices.

20. The following formulas are used to calculate the predicted need for medicines for the provision of medical care in an outpatient setting:

PMP=DDD x ACDA x NPC x NPP (1), where

PMP - predicted need for a medicinal product (in purchase units) per year on an outpatient basis;

DDD is the established daily dose;

ACDA - average course duration of application (days);

NPC- the number of predicted courses per year;

NPP - the number of predicted patients per year.

The following formula is used to calculate the predicted need for medical devices for the provision of medical care in an outpatient setting:

FNMD=ACMD x ACDA x NPC x NPP (2), where

FNMD - forecasted need for a medical device (in units of purchase) per year on an outpatient basis;

ACMD - average actual consumption of medical devices per patient for the previous financial year;

ACDA - average course duration of application (days);

NPC - the number of predicted courses per year;

NPP - the number of predicted patients per year;

MP - marginal price in accordance with the approved regulatory legal act in terms of DDD for the least expensive dosage form and dosage.

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

NPO= PNOB - PDB (3), where

NPO - the need for the purchase of a medicinal product (in units of purchase) per year on an outpatient basis;

PNOB - predicted need for a drug per year on an outpatient basis;

PDB - projected drug balance as of January 1 of the next year (as of April 1 of the next year for antiretrovirals).

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

21. To calculate the predicted need for medicines for the provision of medical care in inpatient and hospital-replacing conditions, the following formulas are used:

FNMPIRC= DDD x ACSHC x PCSHC x NPP / DUI(4), where

FNMPIRC - forecasted need for a medicinal product (in purchase units) per year in inpatient and inpatient-replacing conditions;

DD is the established daily dose;

ACSHC - the average course duration of use (days) in stationary and hospital-replacing conditions;

PCSHC - the number of predicted courses in stationary and hospital-replacing conditions per year;

NPP - the number of predicted patients in inpatient and hospital-replacing conditions per year;

DUI - dosage unit of measurement.

The following formula is used to calculate the predicted need for medical devices for the provision of medical care in inpatient and inpatient-replacing conditions:

FNMD=ACMD x ACSHC x NPC x NPP (5), where

FNMD - forecasted need for a medical device (in units of purchase) per year in hospital and hospital-replacing conditions;

ACMD - the average actual consumption of medical devices in inpatient and inpatient settings per patient for the previous financial year;

ACSHC - the average course duration of use (days) in stationary and hospital-replacing conditions;

NPC - the number of predicted courses in stationary and hospital-replacing conditions per year;

NPP - the number of predicted patients in inpatient and hospital-replacing conditions per year.

To calculate the need for the purchase of medicines and medical devices used in inpatient and hospital-replacing conditions, the following formula is used:

NPMP = PNMPSHC - PBM (6), where

NPMP - the need to purchase a medicinal product per year in inpatient and inpatient-replacing conditions;

PNMPSHC - predicted need for a medicinal product per year in stationary and hospital-replacing conditions;

PBM - the predicted balance of medicines on January 1 of the 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 procurement units is multiplied by the marginal price in accordance with the approved regulatory legal act .

Appendix 3
to the order of the
Minister of Health
of the Republic of Kazakhstan
dated August 20, 2021
No. 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 No. 766 “On Approval of the Rules for Providing Medicines to Citizens” (registered in the Register of State Registration of Regulatory Legal Acts under No. 12199).

2. Order of the Minister of Health of the Republic of Kazakhstan dated May 14, 2019 No. 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 No. 766 “On Approval of the Rules for Providing Medicines to Citizens” (registered in Register of state registration of normative legal acts under No. 18677).

3. Order of the Minister of Health of the Republic of Kazakhstan dated May 19, 2020 No. 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 No. 766 “On approval of the rules for providing medicines to citizens” (registered in the Register of State Registration of Normative Legal Acts under No. 20672).

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