



On approval of the rules for interaction on contract fractionation

Unofficial translation

Order of the Minister of Healthcare of the Republic of Kazakhstan No. KR DSM-187/2020 dated November 9, 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on November 10, 2020 under No. 21617.

Unofficial translation

Pursuant to sub-paragraph 54 of Article 7 of the Code of the Republic of Kazakhstan of July 7, 2020 “On Public Health and the Health Care System”, **I HEREBY ORDER:**

1. That the attached rules for interaction on contract fractionation shall be approved.
2. That Order of Minister of Healthcare and Social Development of the Republic of Kazakhstan № 419 dated May 29, 2015 “On Approval of Rules for Interaction on Contract Fractionation” shall be deemed to have lost force (registered with the Register of State Registration of Regulatory Legal Acts under № 11542, published on July 2, 2015 in Adilet, the information and legal system).
3. That in obedience to the procedure established by the legislation of the Republic of Kazakhstan, the Department of Drug Policy of the Ministry of Healthcare of the Republic of Kazakhstan shall:
 - 1) ensure the state registration hereof with the Ministry of Justice of the Republic of Kazakhstan;
 - 2) place this order on the web-site of the Ministry of Healthcare of the Republic of Kazakhstan;
 - 3) within ten working days from the date of state registration hereof with the Ministry of Justice of the Republic of Kazakhstan, submit to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan the information on fulfillment of actions stipulated by sub-paragraphs 1) and 2) of this paragraph.
4. The supervising Vice-Minister of Healthcare of the Republic of Kazakhstan shall be charged with control over execution hereof.
5. This order shall be put into effect ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Annex to order
of the Minister of Healthcare
of the Republic of Kazakhstan
№ KR DSM-187/2020
dated November 9, 2020

Rules of interaction on contract fractionation

Footnote. Rules are in the wording of the order of the Minister of Healthcare of the Republic of Kazakhstan dated 09.11.2023 No. 163 (shall be enforced upon expiry of ten calendar days after the day of its first official publication).

Chapter 1. General provisions

1. These Rules of interaction on contract fractionation (hereinafter - the Rules) have been developed in accordance with subparagraph 54) of Article 7 of the Code of the Republic of Kazakhstan “On Public Health and Healthcare System of the Republic of Kazakhstan” (hereinafter - the Code) and shall determine the procedure for interaction of healthcare organizations on contract fractionation.

2. These Rules shall use the following concepts:

1) a single distributor - a legal entity, carrying out activities within the framework of 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 (hereinafter - the Single distributor);

2) contract fractionation - sending blood components prepared in state healthcare organizations carrying out activities in the field of blood services of the Republic of Kazakhstan abroad for the production of plasma blood products at the factories of a foreign manufacturer in order to provide the population of the Republic of Kazakhstan with blood products;

3) plasma - the liquid part of the blood in which the formed elements are suspended;

4) plasma procurers – state healthcare organizations carrying out activities in the field of blood services;

5) plasma blood products – preparations containing biological substances obtained by processing blood plasma;

6) the main plasma procurer - a republican state healthcare organization carrying out activity in the field of blood service of the Republic of Kazakhstan;

7) fractionator - a manufacturing plant for plasma blood products.

Chapter 2. Procedure for interaction on contract fractionation

3. Interaction on contract fractionation shall be carried out by the following organizations:

1) plasma procurers;

2) fractionator;

3) Single distributor.

4. The procedure for interaction on contract fractionation and the terms of implementation of interaction stages:

1) plasma procurers, before November 1 of the year preceding the year in which the contract for the supply of plasma blood products is concluded within the framework of

contract fractionation (hereinafter - the planning year), shall send information to the main plasma procurer about the planned volumes of plasma procurement;

2) the main plasma procurer, before the first of December of the planning year, shall send information to the Single distributor about the readiness of the plasma procurement for the subsequent production of plasma blood products;

3) plasma procurers shall annually determine the cost of plasma in order to conclude a plasma supply contract with a fractionator;

4) the fractionator shall conclude a plasma supply contract with plasma procurers on the basis of a long-term contract between the Single distributor and the fractionator for the production and supply of plasma blood products within the framework of contract fractionation and organize an assessment of the conditions for the procurement and storage of plasma;

5) an authorized body of the country of the fractionator shall conduct an assessment of plasma procurers in terms of compliance with the principles of procurement and storage of blood components in accordance with the order of the Minister of Healthcare of the Republic of Kazakhstan dated October 20, 2020 No. KR HCM-140/2020 "On approval of the nomenclature, rules of procurement, processing, control quality, storage, sale of blood, its components, as well as rules for blood transfusion, its components" (registered in the Register of state registration of regulatory legal acts under No. 21478);

6) plasma procurers shall ensure the procurement of plasma for the production and supply of plasma preparations for the next year.