



On approval of the rules, terms of post-accreditation monitoring and revocation of the health care accreditation certificate

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan No. KP DSM-227/2020 dated 30 November 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on 2 December 2020 under No. 21708

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Pursuant to sub-paragraph 10 of Article 8 of the Code of the Republic of Kazakhstan of 7 July 2020 “On Public Health and the Healthcare System”, **I HEREBY ORDER:**

1. That the attached rules, terms of post-accreditation monitoring and revocation of health care accreditation certificate shall be approved.

2. That, in the order established by the legislation of the Republic of Kazakhstan, the Committee of Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:

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

2) placement hereof on the official internet resource of the Ministry of Healthcare of the Republic of Kazakhstan;

3) within ten working days after state registration with the Ministry of Justice of the Republic of Kazakhstan, submission to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan of information on execution of measures provided for in sub-paragraphs 1) and 2) of this paragraph.

3. That the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan shall be charged with control over execution hereof.

4. That this order shall be enforced ten calendar days after the date of its first official publication.

*Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Approved by order
of the Minister of Healthcare
of the Republic of Kazakhstan
№ KR DSM-227/2020
dated November 30, 2020

Rules, terms of post-accreditation monitoring and revocation of health care accreditation certificate

Chapter 1: General provisions

1. These rules, terms of post-accreditation monitoring and revocation of accreditation certificate in the field of healthcare (hereinafter - Rules) have been developed in obedience to sub-paragraph 10) of Article 8 of the Code of the Republic of Kazakhstan dated July 7, 2020 “On Public Health and Healthcare System” (hereinafter - Code) and determine the procedure, terms of post-accreditation monitoring and revocation of accreditation certificate in the field of healthcare.

2. The following basic concepts shall be used in these Rules:

1) accreditation - procedure of official recognition of applicant's competence to perform work in a particular field of conformity assessment;

2) post-accreditation monitoring - monitoring of activities of health care entities, organizations and legal entities, accredited in the field of health care for compliance with established requirements;

3) accreditation certificate - official document confirming applicant's accreditation in a particular field of accreditation

4) accredited entity – an entity which passed the accreditation in the field of health care in compliance with the procedure established by sub-paragraph 9) of Article 8 of the Code;

5) expert group - natural persons engaged for external comprehensive evaluation of medical organization for compliance with accreditation standards;

6) external comprehensive evaluation expert - health care organization specialist engaged for external comprehensive evaluation of medical organizations for compliance with accreditation standards as a member of the expert group;

7) external comprehensive evaluation - procedure of evaluation of medical organization activity for compliance with accreditation standards, conducted by the expert group with the exit to the medical organization;

8) focus assessment - assessment of a medical organization based on the analysis of documents and (or) visits to a medical organization, carried out to confirm or clarify the results of previously conducted external comprehensive assessment in cases of doubt on the reliability of the results of external comprehensive assessment, or in a situation that puts the safety of patients, staff and visitors at risk, of which the body accrediting medical organizations became aware.

3. Entities specified in paragraph 7 of Article 25 of the Code, those accredited in the field of health care shall be subject to post-accreditation monitoring.

Post-accreditation monitoring shall be carried out routinely once every three (3) years, but not earlier than six (6) months from the date of receipt of the accreditation certificate. The post-accreditation monitoring plan shall be posted on the website of the relevant accreditation body (organization) performing accreditation in the field of health care (hereinafter the accreditation body).

Unscheduled post-accreditation monitoring shall be conducted in cases, when the accreditation body receives two or more complaints from individuals and (or) legal entities on

the accredited organization's activities within a year from the date of receipt of the accreditation certificate, the review of which has confirmed the facts of violation of rights and freedoms of applicants.

Chapter 2: Procedures for post-accreditation monitoring and revocation of accreditation certificate

5. Within 7 (seven) working days from the date of receipt of the request, the accredited entity shall submit to the accreditation body information and documents required to obtain a certificate of accreditation in compliance with the Rules of accreditation (hereinafter - documents).

6. Post-accreditation monitoring shall be carried out by the accreditation body within 20 (twenty) working days.

In order to conduct post-accreditation monitoring of medical organisations, a commission shall be established by the health care entity that accredits medical organisations, which reviews the results of external comprehensive assessment and makes recommendations on the compliance of activities with the requirements of accreditation standards for medical organisations.

As part of post-accreditation monitoring of medical organisations, if necessary, a focus assessment shall be carried out with the involvement of experts on external comprehensive assessment in the relevant profile in accordance with the Rules for Accreditation.

7. If a full package of documents is submitted, post-accreditation monitoring shall be conducted without visiting the production facilities of the accredited entity.

8. In cases of submission of an incomplete package of documents, unreliable or incomplete information, detection of non-compliance of the accredited entity with one or more requirements of the Accreditation Rules, post-accreditation monitoring shall be conducted with the implementation of on-site visit.

Post-accreditation monitoring with an on-site visit shall be also carried out in case of receiving information from state bodies (organisations) on facts of violations of health legislation by the accredited entity.

Prior to the on-site visit to the accredited entity's production facilities, the accreditation body shall notify in writing 3 (three) working days in advance of the forthcoming visit, indicating the date and time of the visit.

9. If the accredited entity complies with the requirements of the Accreditation Rules based on the results of post-accreditation monitoring, the accreditation body shall issue a positive conclusion in any form.

If non-compliance with the requirements of the Accreditation Rules (hereinafter referred to as non-compliance with requirements) is identified, observations on their elimination shall be issued in an arbitrary form.

The deadline for rectification of non-compliance by an accredited entity shall be no more than 20 (twenty) working days from the date of receipt of the observations. Pursuant to the

application of an accredited entity, the deadline for rectification of non-compliance with requirements shall be extended, but not more than for 20 (twenty) working days.

Upon full elimination of the observations, the accreditation body shall issue a positive conclusion.

10. In cases of incomplete elimination of non-compliance with the requirements specified in the observations, submission of information later than the deadline specified in paragraph 9 of these Rules, the accreditation body shall issue a negative conclusion with revocation of the accreditation certificate.

A certificate of accreditation shall also be withdrawn in cases of:

entry into legal force of a court verdict, court decision or other judicial act and executive document on termination of activities or certain types of activities of an accredited entity;

termination of activity or separate kinds of activity of accredited entity in conformity with civil legislation of the Republic of Kazakhstan.

In case the result of external comprehensive assessment of medical organisations is lower than the threshold value for the category assigned during accreditation, the category shall be changed in obedience to the Rules of Accreditation.

11. The decision of the accreditation body on a positive and/or negative opinion shall be made in the form of an order.

12. In case of withdrawal of accreditation certificate and (or) change of category, within 5 (five) working days, the accreditation body shall inform in writing the accredited entity, in respect of which the post-accreditation monitoring has been conducted, and make appropriate changes on the official website of accreditation body.