



**On approval of the rules for development and approval of documents of the state sanitary-epidemiological regulation system**

*Unofficial translation*

Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. ҚР DSM-297/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on December 22, 2020 No. 21854

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In accordance with paragraph 3 of Article 94 of the Code of the Republic of Kazakhstan dated July 7, 2020 On Public Health and Health Care System **I hereby ORDER:**

1. Approve the attached rules for development and approval of documents of the state sanitary-epidemiological regulation system.
2. Invalidate Order No. 197 of the Acting Minister of National Economy of the Republic of Kazakhstan as of December 31, 2014 "On approval of the Rules for development and approval of documents of the state system of sanitary-epidemiological regulation" (registered in the Register of State Registration of Regulatory Legal Acts under No. 10248, published 22 April 2016 in the "Adilet" Legal Information System).
3. The Committee for Sanitary-Epidemiological Control of the Ministry of Healthcare of the Republic of Kazakhstan, in the manner prescribed by the legislation of the Republic of Kazakhstan, shall:
  - 1) provide the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;
  - 2) post this order on the Internet resource of the Ministry of Healthcare of the Republic of Kazakhstan after its official publication;
  - 3) provide the official publication of this order in the Reference Control Bank of Regulatory Legal Acts of the Republic of Kazakhstan as an electronic document from the moment they are entered into the Register of State Registration of Regulatory Legal Acts.
4. Control over the execution of this order shall be assigned to the supervising Vice Minister of Healthcare of the Republic of Kazakhstan.
5. This order shall take effect upon expiry of ten calendar days after the date of its first official publication.

*Minister of Healthcare  
of the Republic of Kazakhstan*

*A. Tsoi*

Approved  
by order No. KR DSM-297/2020  
of the Minister of Healthcare  
of the Republic of Kazakhstan  
as of December 21, 2020

# **Rules for development and approval of documents of the state sanitary-epidemiological regulation system**

## **Chapter 1. General Provisions**

1. The rules for development and approval of documents of the state sanitary-epidemiological regulation system (hereinafter -the Rules) have been developed in accordance with paragraph 3 of Article 94 of the Code of the Republic of Kazakhstan as of July 7, 2020 On Public Health and Health Care System (hereinafter- the Code) and define the procedure of development, adoption of documents of the state sanitary-epidemiological regulation system (hereinafter - documents).

2. State sanitary-epidemiological regulation shall be exercised by the sanitary-epidemiological service and include:

1) development of uniform requirements for validation of documents and oversight of their development;

2) development (processing), examination, approval and publication of documents;

3) study, generalization of application practice, oversight of the application of documents;

4) formation and maintenance of a unified data bank of documents;

5) harmonization of documents with generally accepted international requirements.

3. The documents shall include sanitary rules, hygienic standards, technical regulations, uniform sanitary-epidemiological and hygienic requirements for commodities of the Eurasian Economic Union, instructions, guidelines, recommended practices, strategies, orders, rules and standards.

4. Regulatory legal acts in the field of sanitary-epidemiological welfare of the population shall include sanitary rules, hygienic standards, rules, technical regulations and uniform sanitary-epidemiological and hygienic requirements for commodities of the Eurasian Economic Union.

5. In the development and adoption of regulatory legal acts on sanitary-epidemiological welfare of the population, the state bodies shall coordinate them with the state body in the field of sanitary-epidemiological welfare of the population.

6. The developer body shall direct to the expert councils and the National Chamber of Entrepreneurs of the Republic of Kazakhstan a notification of the placement of the respective draft regulatory legal act involving the business entities' interests, on the Internet portal of open regulatory legal acts to obtain expert opinions, including with each subsequent approval of this draft with involved state bodies.

7. Documents shall be developed and approved in accordance with the Constitution of the Republic of Kazakhstan, the Code and other regulatory legal acts of the Republic of Kazakhstan.

8. Development and adoption of the documents shall be carried out by the state body in the field of sanitary-epidemiological welfare of the population in accordance with article 94 of the Code.

9. The state body in the field of sanitary-epidemiological welfare of the population, within the framework of harmonization of documents with generally accepted international requirements, shall develop and approve:

1) technical regulations of the Eurasian Economic Union in accordance with the Procedure for development, adoption, amendment and cancellation of technical regulation of the Customs Union , approved by the Decision of the Council of the Eurasian Economic Commission of June 20, 2012 No. 48 in accordance with Article 52 of the Treaty on the Eurasian Economic Union of May 29 2014, ratified by the Law of the Republic of Kazakhstan dated October 14, 2014 No. 240 "On Ratification of the Treaty on the Eurasian Economic Union" (hereinafter - the Treaty).

2) uniform sanitary-epidemiological and hygienic requirements of the Eurasian Economic Union in accordance with the Procedure for development, adoption, amendment and application of unified sanitary- epidemiological and hygienic requirements and procedures approved by the Decision of the Council of the Eurasian Economic Commission of October 18, 2016 No. 109 in accordance with paragraph 3, article 57 of the Treaty.

## **Chapter 2. Procedure for documents development and approval**

10. Development of documents shall be comprised of the following stages:

- 1) planning of the document development;
- 2) drafting of a document;
- 3) approval of a document.

11. Planning with the approval of the plan for documents development shall conform to the acts, resolutions, orders of higher authorities, proposals of state bodies and organizations.

12. The plan shall indicate the names of the documents under development, persons responsible for the development and time allotment for their development.

13. In the event that the persons authorized to develop the document initiate development of a draft that is not included in the plan, an official memo or letter shall be presented to the head of the authorized body, setting out:

- 1) the essence of the problem requiring legal regulation;
- 2) the objectives of the proposed legal regulation;
- 3) specific measures aimed to solve the problem, which are intended to underlie the document;
- 4) the list of current documents on the problematic issue and analysis of the shortcomings of the current legal regulation;

5) predictive analysis of socio-economic consequences in case of adoption of the document.

14. For the development and approval of documents, the state body in the field of sanitary-epidemiological welfare of the population shall establish a task force.

15. The task force shall be comprised of at least five members.

The task force shall involve representatives of relevant state bodies, public, scientific and other organizations.

16. Development and approval of the draft document shall be assigned to the department of the state body in the field of sanitary-epidemiological welfare of the population.

17. In the course of document provisions drafting, the executive officer of the department shall collect and study:

- 1) the legislation of the Republic of Kazakhstan;
- 2) international agreements;
- 3) practice of applying the relevant effective documents;
- 4) foreign sanitary-epidemiological legislation;
- 5) scientific literature and publications from periodicals;
- 6) data from sociological and other research, including scientific research, if any;
- 7) information sources.

18. The draft document shall meet the following criteria:

- 1) logical elaboration of the legal regulation theme;
- 2) logical and consistent presentation (from general to specific, most important to less important);
- 3) logical and grammatical coherence of the text;
- 4) precision and clarity of the text;
- 5) consistency of the new provisions with the concurrently existing provisions, linkage with the provisions that need to be canceled, changed or supplemented;
- 6) exclusion of possible ambiguity of understanding and interpretation of the text.

19. The state body in the field of sanitary-epidemiological welfare of the population shall ensure compliance of documents with legal technicalities established by the Rules for the execution, adoption, state registration of regulatory legal acts and their cancellation, approved by Resolution No. 568 of the Government of the Republic of Kazakhstan dated October 6, 2016.

20. Along with development of a document containing new regulatory requirements, proposals shall be attached to these documents on amending, supplementing or invalidating the corresponding previously issued documents or parts thereof, if necessary.

21. Introduction of amendments, additions and invalidation of documents shall be executed in the manner prescribed by the current legislation of the Republic of Kazakhstan.

22. Documents shall be developed and submitted for approval in Kazakh and Russian languages.

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