

THE BYLAW

ON ACCREDITATION OF HEALTH CARE INSTITUTIONS

(Official Gazette of the Republic of Serbia number 112/2009)

Article 1

This Bylaw determines the manner, procedure and conditions for the accreditation of healthcare institutions.

Article 2

Accreditation is a procedure of assessment of the quality of work of a healthcare institution based on the application of an optimal level of established standards of work in healthcare institutions in certain fields of healthcare, or branches of medicine.

Article 3

The accreditation of healthcare institutions is managed by the Agency for Accreditation of Healthcare Institutions of Serbia (in further text: the Agency).

The accreditation is given to a healthcare institution which the Agency has determined to fulfil the established standards for a specific field of healthcare, or a branch of medicine.

The accreditation is voluntary and is carried out at the request of a healthcare institution.

The cost of the accreditation is paid by the healthcare institution which submitted the request for accreditation.

The healthcare institution submits the request for obtaining the accreditation to the Agency.

Article 4

Together with the application for obtaining accreditation from article 3 of the Bylaw, a healthcare institution submits the following documentation:

- 1) the ruling of the Ministry that governs the affairs of health, or health inspection, on the fulfilment of an inspection for performing healthcare activity;
- 2) proof on registration of healthcare institution;
- 3) the statute
- 4) the legal act on internal organization and systematization of affairs.

Article 5

The Agency submits the information on the amount of total expenses for the accreditation to the healthcare institution that wishes to obtain the accreditation, after receiving the request and the documentation from article 4 of the Bylaw.

Besides the information from article 1 of this article, the Agency submits the contract to the healthcare institution that wants to obtain accreditation. The contract regulates the rights and obligations of the healthcare institution and the Agency.

By signing the contract from paragraph 2 of this article, the process of accreditation begins.

Article 6

After the contract is signed, the Agency is obligated to make the standards for accreditation of healthcare institutions (in further text: the standards) available for the institution.

Article 7

The process of accreditation includes :

- 1) self-assessment (self evaluation);
- 2) external assessment (external evaluation);
- 3) acquiring the accreditation.

Article 8

Self assessment is the evaluation which the health institution carries out to improve the quality of work and the provision of the healthcare services to the clients.

The healthcare institution appoints the coordinator for the accreditation who is responsible for carrying out the accreditation.

The healthcare institution establishes the teams for self assessment of the quality of work of healthcare institution.

The healthcare institution carries out the process of self assessment within the 12 month period starting from the date contract was signed with the Agency.

The healthcare institution submits the report on the results of self assessment to the Agency, after the process of self assessment process is completed.

Article 9

The Agency provides the support for the healthcare institution. The support enables the healthcare institution to carry out the self assessment, and it includes: the provision of the

information on the process of the accreditation and the professional support in the establishment of teams for self assessment, the explanation of standards for accreditation, the provision of educational program regarding the ways of self assessment and its significance for the improvement of quality of work of the institution, and familiarization with the evidence on alignment with the standards (the documents which have to be prepared for the external surveyors).

Article 10

External assessment is evaluation of the quality of work of the healthcare institution in relation to the established standards for certain field of healthcare, or a branch of medicine, and it is carried out by the knowledgeable external surveyors, who are appointed by the Agency (in further text: the Surveyor)

Article 11

The Agency establishes the team for the external evaluation of the quality of work of the healthcare institution.

The Agency informs the healthcare institution, which is in the process of accreditation, how the team is made .

The time of the team's arrival is scheduled ahead and the number of the visiting days is previously defined (in further text: the accreditation visit).

Article 12

The team for the external evaluation of the quality of work of healthcare institution, carries out the assessment of quality of work and the provision of healthcare services in the healthcare institution, in relation to the established standards for certain field of healthcare, or a branch of medicine.

How the team is made depends on the field of healthcare, or a branch of medicine that submits the request for accreditation.

Article 13

The external evaluation is carried out in the healthcare institution and it is done by:

- the examination of the prepared documentation and healthcare documentation;
- discussions with the persons managing the healthcare institution;
- discussions with the employees who participated in the process of self assessment (the teams for self assessment of the quality of work of healthcare institution);
- the visitation of the healthcare institution and reviewing the accommodation capacities;
- the examination of the medical equipment availability in the healthcare institution;

- discussions with the patients and employees;
- the final meeting on which the persons managing the institution and the employees are informed on the finished accreditation visit.

Article 14

The Agency is obligated to submit the results on the self assessment of the healthcare institution to the every team member responsible for the external evaluation of the quality of healthcare institution, at least 21 days before the scheduled accreditation visit.

The Agency develops the plan for evaluation which is submitted to the healthcare institution and the members of the team for external evaluation of the quality of work of the healthcare institution, at least 21 days before the scheduled accreditation visit.

Article 15

During the evaluation, the team for external evaluation of the quality of work of the healthcare institution assesses the work of the healthcare institution according to the criteria which is established by the standards for certain field of healthcare, or a branch of medicine. This is carried out in accordance with the criteria fulfilment assessment scale.

The criteria fulfilment assessment scale is used for showing the level of alignment achieved by the healthcare institution for every criteria of the standard.

The scale includes grades 1-5:

- 1) grade 1 which represents that the criteria is not implemented;
- 2) grade 2 which represents that the criteria is being introduced for implementation;
- 3) grade 3 which represents that the criteria is implemented;
- 4) grade 4 which represents that the criteria is implemented in an improved manner;
- 5) grade 5 which represents the best implementation of the criteria;
- 6) no response – when it is not possible to implement certain criteria in given healthcare institution.

Article 16

After the accreditation visit, the team for external evaluation of the quality of work of healthcare institution submits to the Agency the report on the carried out accreditation visit.

Article 17

The Agency prepares the final report on the accreditation based on the findings by the team for external evaluation of the quality of work of healthcare institution within the 30 days. The report includes all the relevant information regarding the institution, self assessment grades, and the grades and findings of the team for external evaluation of the quality of work of healthcare institution.

The Agency issues a certificate on the accreditation of healthcare institution to the institution for which is established to fulfil all the provided standards for certain field of healthcare, or a branch of medicine.

The certificate on accreditation of healthcare institution is issued for a certain period of time, and the longest for the period of seven years.

Article 18

The healthcare institution obtains the accreditation for the period of one year, if:

- it achieved 40% to 50% of the grades 4 and 5;
- does not have more then 20% of the grades 1 and 2;
- the criteria regarding the safety of patients in the process of treatment is not assessed with the grade lower then 4.

The healthcare institution obtains the accreditation for the period of three years, if:

- it achieved 51% to 70% of the grades 4 and 5;
- does not have more then 15% of the grades 1 and 2;
- the criteria regarding the safety of patients in the process of treatment is not assessed with the grade lower then 4.

The healthcare institution obtains the accreditation for the period of seven years, if:

- it achieved 71% to 100% of the grades 4 and 5;
- does not have more then 10% of the grades 1 and 2;
- the criteria regarding the safety of patients in the process of treatment is not assessed with the grade lower then 4.

Article 19

The Agency submits the final report from article 17, paragraph 1 of the Bylaw to the healthcare institution which submitted the request for accreditation.

Article 20

The healthcare institution submits the plan for improvement of the quality of healthcare to the Agency after receiving the final report from article 17 of the Bylaw. The plan is developed according to the surveyor's recommendations.

Article 21

The Healthcare institution, which obtained the accreditation, is obligated to report any changes regarding the accreditation to the Agency.

Article 22

The Bylaw enters force 8 days upon being published in the Official Gazette of the Republic of Serbia.