

**DECREE**  
**ON THE ANNOUNCEMENT OF THE LAW ON THE SYSTEM OF  
IMPROVEMENT OF QUALITY AND SAFETY, AND ON ACCREDITATION IN  
HEALTHCARE**

The Law on the System of Quality and Safety Improvement, and Accreditation in Healthcare, passed by the Parliament of the Federation of Bosnia and Herzegovina at the session of the House of Representatives held on April 13, 2005, and the session of the House of Peoples held on July 29, 2005, is hereby announced.

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President,  
Niko Lozancic, in person signed

**THE LAW**  
**ON THE SYSTEM OF IMPROVEMENT OF QUALITY AND SAFETY,  
AND ON ACCREDITATION IN HEALTHCARE**

I. GENERAL PROVISIONS

Article 1

This Law shall regulate the system of improvement of quality and safety of health services, as well as the procedure of health institutions' accreditation within the Federation of Bosnia and Herzegovina (hereinafter: The Federation).

This Law shall establish the Healthcare Quality and Accreditation Agency of the Federation of Bosnia and Herzegovina (hereinafter: the Agency) as a competent entity in the field of improvement of quality and safety, and accreditation in healthcare.

The Agency from paragraph 2 of this Article is a legal entity with its rights, duties and responsibilities prescribed by this Law and the Agency Statute, as well as the regulations passed on the basis of this Law and the Agency Statute.

Article 2

Health institutions shall establish the system of improvement of quality and safety of health services with an objective to achieve maximum healthcare quality.

For the purpose of achieving the objective from paragraph 1 of this Article, health institutions may get accredited in the manner, and under the conditions prescribed by this Law, and the regulations passed on the basis of this Law.

### Article 3

The Agency from Article 1, paragraph 2 of this Law shall perform expert activities, and administrative activities related to them, which require specific organization and independence in work in compliance with this Law and regulations passed on the basis of this Law.

Authorized cantonal entities shall undertake appropriate steps with an objective to improve the quality and safety of health services in health institutions in compliance with this Law, regulations passed on the basis of this Law, cantonal Law and other cantonal regulations.

### Article 4

Terms and definitions used in this Law shall be interpreted as follows:

- “Quality Improvement System” is a set of organizational structures, resources, functions and techniques that provide for internal inspection of the quality at the levels of primary and hospital healthcare, and private practice, for the purpose of meeting the expectations of healthcare users;
- “Quality Assurance” is a formal systemic process of determining activities and tasks of a health institution in the field of monitoring the health services quality, perceiving shortcomings and correcting them, allocating the resources to those purposes and developing optimal standards and guidelines for clinical practice;
- “Quality Improvement” is a set of primary principles that present the basis of permanent improvement of the health service provision process, with an objective to meet the needs of patients and other healthcare stakeholders;
- “Safety” is the evaluation of risk acceptability (unfavorable outcome and its seriousness) that relates to a patient’s health condition, clinical education of a health worker, use of technology in a given situation, i.e. in the course of application of a certain medical treatment,
  - a) “safety in health institutions” is an organized system in which educated and trained health workers apply proper working procedures with appropriate resources in safe environment, reducing the number of unfavorable events and outcomes to a minimum
  - b) “safety in health” is a system, and an environment, which enable evasion and prevention of unfavorable events and health outcomes that may arise in the health service provision process
  - c) “safety of health services” is an overall capacity of a health institution for measuring and preventing medical mistakes related to health services provision, irrespective of whether mistakes occurred due to reduced, increased, or erroneous use of health technologies, i.e. due to their abuse
  - d) “safety of patients, i.e. other users of health services” is an absence of unexpected events, i.e. sudden, unexpected diseases, injuries and damages that may arise in the process of health services provision, i.e. in contact with a health institution.

- “Quality of Healthcare” is a degree, to which an increase of expected health outcomes is foreseen in relation to defined healthcare standards;
- “Standard” is a criterion that regulates a set of rules, protocols, requirements or statements of expected standard healthcare quality, which leads to better quality of healthcare in compliance with this Law,
  - a) “minimal standards” are minimal criteria to be met for the purpose of protection and safety of patients,
  - b) “optimal standards” are statements of expectations or requirements, which, once met, ensure provision of a good quality health service;
- “Internal Quality Control” is a process of systemic control of expert activities in relation to prescribed standards;
- “External Quality Control” is a process of external control of health services quality, through which health services provision in a health institution is compared with published standards, and in such manner, possibilities for improvement of health services quality are identified;
- “Clinical Guidelines” are systemically developed, determined guidelines that help health workers, health associates and patients to bring decisions on appropriate health treatment in precisely defined clinical circumstances;
- “Quality Management” is a planned and systemic approach to control of measurement, analysis and improvement of organizational performance with an objective to improve quality of health services and increase probability to meet expected outcomes for patients;
- “Risk Management” is a part of administrative and clinical activities undertaken by a health institution with an aim to identify, evaluate and reduce a risk of injury of patients, other users of health services, and personnel, and a risk of loss inflicted on a health institution itself;
- “Self-evaluation” is a basic prerequisite in accreditation procedure, which implies that all health workers and associates in a health institution self-evaluate the quality of their work with regard to standards prescribed;
- “Incentive” comprises of tangible and intangible incentives to health workers and associates, as active participants in the process of improvement of quality and safety of health services, and accreditation in healthcare (certain expert privileges, payroll incentives, etc);
- “Unfavorable situation” is an unexpected, usually unforeseen or unforeseeable event that was, or could have been, detrimental to patient’s health, health of other users of health services, or health of health workers and associates;
- “Agency” is a competent body in the Federation, which performs expert activities from within the field of improvement of quality and safety of health services, and accreditation in healthcare, as defined by this Law and regulations passed on the basis of this Law;
- “Advisory Council” is an advisory body, which represents interests of the Federation BiH Ministry of Health (hereinafter: Ministry), cantonal health ministries (hereinafter: Cantonal Ministry), chambers, associations of health workers, public health institutes, health institutions and associations of health service users;

- “ALPHA” is an internationally recognized program for primary principles of accreditation in healthcare, i.e. accreditation of accreditors (the Agency), which is applied in the Federation;
- “Accreditation” implies self-evaluation, and is a process of external collegiate examination applied by health institutions, with an aim to precisely check the extent of service provision in comparison with prescribed standards and methods of implementation of continuous health system & services improvement;
- “Accreditation user” is a health institution, a citizen, patient and his family, who may actively participate in evaluating the quality of health services at different levels, and in such manner influence a person who decides on accreditation, with an aim to achieve the top quality in health.

## II. PROCESS OF IMPROVEMENT OF HEALTH SERVICES QUALITY AND SAFETY, AND ITS PARTICIPANTS

### Article 5

Health services quality and safety improvement, and accreditation in healthcare, ensure reaching the following goals:

- determination of the Policy for health services quality and safety, and accreditation in healthcare, and legislation in this field as a basic framework for guidelines, strategic planning, management and overall activities for achieving optimum quality in healthcare, which includes its harmonization at the Federation and cantonal levels;
- establishment of a Federation body responsible for improvement of health services quality and safety, and accreditation in healthcare;
- development of the system of accreditation in healthcare;
- definition of parameters of health services quality;
- coordination, collection, development and passage of optimum organizational and clinical standards;
- definition, evaluation and dissemination of guidelines on the basis of evidence for efficient and effective clinical practice;
- establishment and maintenance of mutual recognition with foreign accreditation-in-health bodies, which apply the same or similar standards.

### Article 6

Participation in the accreditation program is a voluntary process performed upon requests by primary and hospital healthcare institutions, and by private practices (hereinafter: health institutions accreditation).

Accreditation is granted to those health institutions for which there is evidence that they meet standards and criteria prescribed by the Agency, in compliance with this Law and regulations passed on the basis of this Law.

## Article 7

Participants in the health services quality and safety improvement are the following:

1. health institutions
2. health workers and associates
3. health service users
4. public health institutes
5. health insurance funds
6. chambers and associations of health workers
7. health ministries.

Participants from paragraph 1 of this Article shall cooperate and exchange data from within their field of work with the Agency, in compliance with regulations on healthcare and health insurance, if not otherwise prescribed by this Law and regulations passed on the basis of this Law.

### **1. Health Institutions**

## Article 8

Health institutions shall establish, develop and maintain the system of health services quality and safety improvement adjusted to their working conditions.

It is an obligation of a health institution to inform a health service user and the public about the established system from paragraph 1 of this Article.

Authorized health workers and associates in a health institution, health service users, chambers and health workers associations, and the Agency, perform the control of the quality improvement system.

## Article 9

On the basis of the Agency's instructions, a health institution, by its General Act, determines the following: organization of health service optimum quality and safety management; form, method and frequency of performance of internal control of optimum quality and safety of health services in a health institution; types and method of control and information on the quality of work performed by health workers and associates; rights and duties of health workers and associates in the process of health service quality and safety improvement; planning of resources, nomination, composition and competencies of sub-commissions for drugs, medical documentation, infection control, revision of policies and procedures, permanent professional development; safety at work place and provision of a healthy work place, radiation protection, payroll incentive for all employees, who perform activities related to health quality and safety improvement.

The Act from paragraph 1 of this Article is approved by the director of the health institution on the basis of the health institution's expert council proposal.

## Article 10

A health institution shall nominate a Commission for Health Service Quality and Safety Control (hereinafter: the Commission) for the purpose of implementation of certain measures and activities in the health institution.

The Commission from paragraph 1 of this Article performs activities and tasks that relate to the following:

- establishment of the system of health service quality and safety improvement;
- collection of relevant data and information indispensable to internal and external control of quality and safety of health services;
- performance of internal control of health service quality and safety on the basis of the General Act of the health institution;
- definition of health service quality parameters;
- participation in healthcare inspection and pharmaceutical inspection supervision, and expression of position on the findings of healthcare and pharmaceutical inspectors;
- participation in external control of health service quality and safety in the health institution;
- cooperation with the Agency, commissions of other health institutions and other institutions in this field;
- performance of other activities determined by the Agency, i.e. which stem from the provisions of this Law and regulations passed on the basis of this Law.

The Commission members are health workers and associates employed in the health institution, and health service users.

The Commission coordinator runs the Commission.

The Commission's coordinator and its members are nominated by the director of the health institution upon the proposal of the health institution's Expert Council.

The Commission's Rules of Procedure determine more precisely the number of the Commission's members, taking into account the organizational form of the health institution, the Commission's method of work, its voting and decision-making processes, and other issues of interest for its work.

## Article 11

On the basis of the Charter on Patients' Rights, a health institution shall display the following at a visible location:

- Charter on Primary Healthcare Patients' Rights and Duties
- Charter on Hospital Healthcare Patients' Rights and Duties.

The charters from paragraph 1 of this Article guarantee the patients' rights, and provide information to a patient about his/her rights, duties and responsibilities.

The charters from paragraph 1 of this Article are passed by the Ministry, with prior opinion of the participants in the process of quality and safety improvement of the health services, enumerated in Article 7 of this Law.

## Article 12

Health institutions shall regularly inform the Agency on identified incidents and unfavorable circumstances to which patients, other health service users and health workers and associates have been exposed in the course of healthcare provision.

The Agency determines which incidents and unfavorable circumstances in the health institution must be reported.

The report from paragraph 1 of this Article includes as follows: identification, documentary evidence, statistical processing, and analysis of incidents and unfavorable situations, which caused or could have caused damage to persons.

Anonymity and confidential treatment of collected data are guaranteed.

Data from paragraph 2 of this Article may be used exclusively in the process of health service quality and safety improvement in an evaluated health institution, and also for the purpose of education and training of employed health workers and associates with an aim to prevent potential future incidents and unfavorable circumstances in the health institution.

Data from paragraph 2 of this Article may be used, in extraordinary situations, for comparisons and evaluations of health service quality and safety in various self-evaluated health institutions, for the purpose of preparing for the accreditation in healthcare process.

## **2. Health workers and health associates**

### Article 13

Health workers and health associates shall regularly and continuously work on their education and training within their specialization field, in a manner, and under conditions determined by the General Act of the health institution.

Regular and continuous education and training of health workers and associates within their specialization field, planned in the General Act of the health institution from paragraph 1 of this Article, must be in compliance with the program of professional advancement of health workers determined by chambers in healthcare sector.

#### Article 14

Health workers and health associates shall actively participate in a defined program of internal health service quality and safety control in a health institution with regard to standards prescribed.

In the course of internal quality control from paragraph 1 of this Article, health workers and health associates shall observe the Code of Professional Ethics prescribed by the competent chambers from healthcare sector.

### **3. Health Services Users**

#### Article 15

Health services users are entitled, and obliged to participate in the process of health service quality and safety improvement in a health institution.

The users from paragraph 1 of this Article are entitled to elect, and be elected to the Commission and Agency bodies.

### **4. Public Health Institutes**

#### Article 16

The Public Health Institute of the Federation of Bosnia and Herzegovina, and cantonal public health institutes (hereinafter: public health institutes) participate in programming, planning and evaluation of healthcare at the population level.

On the basis of the plan and program performance, and analysis of health condition, the institutes from paragraph 1 of this Article evaluate whether the population's needs and demands for healthcare have been met, and realized. Data that refer to the aforementioned are forwarded to the Agency, for the purpose of preparing developmental concepts of the Health Service Quality and Safety Policy, and improving the process of accreditation in healthcare.

Upon the request by the Agency, public health institutes provide the data on evaluation of the performance of health institutions and sections from their field of work, for the purpose of realization of plan/program tasks of participants in the healthcare planning and programming.

Activities from paragraphs 1, 2, and 3 of this Article are performed on the basis of the healthcare regulations, if not otherwise determined by this Law and regulations passed on the basis of this Law.

## **5. Health Insurance Funds**

### Article 17

Health Insurance and Re-Insurance Fund of the Federation of Bosnia and Herzegovina, and cantonal health insurance funds (hereinafter: health insurance funds) determine methods of incentive financing of accredited health institutions and accredited private practices, provided that they have a status of a health institution under contract, i.e. private practice under contract, in the light of regulations on healthcare and regulations on health insurance.

Health insurance funds base the financing from paragraph 1 of this Article on the criteria of quality and safety of health services in the health institutions.

Criteria from paragraph 2 of this Article are determined by health insurance funds, upon the Ministry's approval and opinions of the Agency and health institutions.

Criteria from paragraph 2 of this Article are more precisely elaborated through the contract between health insurance funds and a health institution, i.e. private practice.

## **6. Chambers and Associations of Health Workers**

### Article 18

Chambers shall determine the procedure for issuing, renewing and revoking the licenses for independent work of health workers, as well as method and conditions for professional advancement of health workers on the basis of healthcare regulations, if not otherwise determined by this Law and regulations passed on the basis of this Law.

In cooperation with the Agency and other health workers associations, the chambers from paragraph 1 of this Article shall also participate in defining, developing, implementing and evaluating the prescribed standards, clinical guidelines and performance indicators, and in implementing and disseminating appropriate methods for improvement of health service quality and safety.

## **7. Health Ministries**

### Article 19

Health ministries shall perform the following activities and tasks in the field of health service quality and safety improvement, and in the field of accreditation in healthcare:

- in cooperation with health insurance funds and the Agency, ministries establish equal and single system of incentive financing of accredited health institutions and private practices;

- ministries adopt priorities for improving the health service quality and safety, proposed by chambers, the Agency, public health institutes and health insurance funds;
- ministries help the development of infrastructure for the health service quality and safety improvement.

#### Article 20

Health ministries cooperate with the Agency, especially in the field of healthcare inspection and pharmaceutical inspection supervision.

Health ministries provide education and additional training of healthcare and pharmaceutical inspectors in the field of health service quality and safety improvement, and accreditation in healthcare, in compliance with this Law, and regulations passed on the basis of this Law.

Education and additional training program for healthcare and pharmaceutical inspectors from paragraph 2 of this Article, is prescribed by the Federation minister of health (hereinafter: the minister) upon the Agency's proposal.

### III. SUPERVISORY BODY FOR HEALTH SERVICE QUALITY AND SAFETY IMPROVEMENT, AND ACCREDITATION IN HEALTHCARE

#### Article 21

The Agency performs expert activities and associating administrative activities that relate to health service quality and safety improvement, and is responsible for the implementation of accreditation in healthcare.

#### Article 22

Within its activities, the Agency, in particular, performs the following:

- coordinates, collects, develops and passes optimal organizational and clinical standards, including clinical guidelines and performance indicators, in compliance with determined priorities of the Agency, and with prior approval by the Ministry;
- develops the system of accreditation in compliance with European and international practices in this field;
- determines the List of competent evaluators of the external quality control;
- performs procedure of accreditation of health institutions in compliance with this Law, and regulations passed on the basis of this Law; in relation to that, it issues, revokes, i.e. renews health institutions' accreditations;
- runs registries and statistics within its field of work;
- determines programs for constant education and training of health workers and associates in this field;

- cooperates with competent bodies and institutions of the Federation and cantons, international institutions and organizations from within the field of improvement of health service quality and safety, and accreditation in healthcare;
- performs other activities based on the policy, laws and by-laws from this field.

## **Organization and Work of the Agency**

### Article 23

For performing the tasks and activities in the Agency, the following bodies shall be established:

- Advisory Council
- Managerial Board
- Competent evaluators of the external quality control
- Director
- Other bodies determined by the Agency Statute.

## **Advisory Council**

### Article 24

The Advisory Council (hereinafter: the Council) is an advisory body from Article 4 of this Law that represents interests of the participants in the health service quality and safety improvement process.

The Council from paragraph 1 of this Article studies health problems, and gives and proposes expert opinions that relate to planning and programming, and other issues referring to the health service quality and safety improvement and accreditation in healthcare.

The Council has 15 members, and it is nominated and dismissed by the Federation minister in compliance with the procedure prescribed by the Regulation on Ministerial, Governmental and Other Nominations of the Federation of Bosnia and Herzegovina.

The Council members nominate the chair of the Council by consensus.

By rule, the chair and members of the Council are appointed to a three-year term, and may be re-appointed for a second consecutive term.

### Article 25

The Council shall perform the following duties:

- provide proposals, suggestions and opinions about strategies, plans, policies and procedures for improvement of the health service quality and safety, and accreditation in healthcare;
- provide opinion about the system of accreditation in healthcare, applied by the Agency;

- provide opinion about the Agency Statute;
- provide opinion about criteria for appointments of competent evaluators of the external quality control, and about the List of Competent Evaluators of the External Quality Control;
- provide opinion about appointment of the Managerial Board;
- provide opinion about appointment of the director and other managerial staff of the Agency;
- perform other activities prescribed by this Law, regulations passed on the basis of this Law, and the Agency Statute.

More precise provisions on the method of appointment and dismissal of the members and the chair of the Council, scope of work, competencies, and other issues of importance to its work are prescribed by the Agency Statute.

## **Managerial Board**

### Article 26

The Managerial Board shall run the Agency.

The Managerial Board shall have seven members, out of whom four external members.

The Managerial Board members shall be appointed and dismissed by the Federation minister, with prior opinion of the Council, and in compliance with the procedure prescribed in the Regulation on Ministerial, Governmental and Other Appointments of the Federation BiH.

The Managerial Board members shall be appointed to a three-year term, and may be re-appointed to a second consecutive term.

### Article 27

The Managerial Board shall perform the following duties:

- pass the Agency's Statute and other acts
- determine plans for work and development of the Agency, annual work plan, and control their execution;
- pass the financial plan and annual budget, and take care of the financial sustainability of the Agency;
- develop and approve the policy and procedures for the Agency's director
- develop, implement and evaluate the system of accreditation in healthcare
- prescribe criteria for appointment of competent evaluators of the external quality control, and determine the List of Competent Evaluators of the External Quality Control;
- make the decision for issuing accreditations, their revocation, i.e. renewal of health institutions' accreditations;

- appoint and dismiss the director, and managerial staff of the Agency, with the Federation minister's approval;
- perform other activities prescribed by this Law, regulations passed on the basis of this Law and the Agency Statute.

More precise provisions on the method of appointment and dismissal of the members of the Managerial Board, scope of work, competencies, and other issues of importance to its work are prescribed by the Agency Statute.

### **Competent Evaluators of the External Quality Control**

#### Article 28

Prominent experts from the healthcare sector, with appropriate working experience within their specialization field, may be appointed as competent external quality control evaluators.

Criteria for appointing competent external quality control evaluators are prescribed by the Managerial Board.

The list of competent external quality control evaluators shall be determined by the Managerial Board every second year.

### **The Agency Director**

#### Article 29

The Agency director shall be appointed and dismissed by the Managerial Board, with prior approval of the Federation minister; he/she shall be appointed to a three-year term, with a possibility of his/her re-appointment to a second consecutive term, in compliance with the procedure prescribed by the Regulation on Ministerial, Governmental and Other Appointments in the Federation of Bosnia and Herzegovina.

#### Article 30

In managing the Agency, the director shall perform the following duties:

- run the Agency
- represent the Agency
- take responsibility for legitimacy of its work, regular and lawful managing of the material/financial activities of the Agency
- perform other activities defined by the Law, regulations passed on the basis of this Law, Statute and other general acts of the Agency.

## Article 31

The members of the Council, and Managerial Board, and the director may be dismissed before expiration of their mandate in the following cases:

- if he/she fails to perform his/her duties in compliance with the Law, Agency Statute, and regulations passed on the basis of the Law and the Agency Statute;
- if there is a binding court ruling that makes him/her inappropriate for fulfilling the assigned duty;
- if he/she makes serious mistakes in his/her work
- if he/she abuses official position and exceeds his/her competencies
- if he/she gains illicit profit and works to the detriment of the Agency
- if he/she personally asks to be relieved of duty
- in other cases prescribed by the Law and Agency Statute.

Early relief of duty, for reasons enumerated under 1, 4 and 5 from paragraph 1 of this Article, may be proposed by each participant in the health service quality and safety improvement process from Article 7 of this Law.

### **The Agency Statute**

## Article 32

The Agency Statute particularly prescribes the following:

- bases for organization, and performance method of the Agency
- the Agency's managerial/administrative bodies
- the Agency's representation, and signing
- staff with specific authorities and responsibilities
- other organizational issues that relate to the Agency's performance.

The Agency Statute is passed by the Managerial Board, with the opinion of the Council. The Agency Statute is subject to approval by the Parliament of the Federation of Bosnia and Herzegovina.

### **The Agency Financing**

## Article 33

Resources indispensable to financing the Agency are obtained from the following:

- Federation BiH and cantonal budgets;
- Contract with health ministries
- Other sources, in a manner, and under conditions prescribed by the Law and Agency Statute.

Sources indispensable to financing the Agency are determined in the Agency's financial plan.

The financial plan from paragraph 2 of this Article is passed by the Managerial Board and is subject to obligatory approval by the Government of the Federation of Bosnia and Herzegovina.

The Agency's financing regulated in such a manner shall be applied in the course of the first three years of its institutionalization. After this period expires, the Agency shall be self-financed.

#### IV. PROCEDURE OF ACCREDITATION IN HEALTHCARE

##### 1. Issuance of Accreditation

###### Article 34

A health institution submits a request for participating in the program of health service quality and safety improvement, and in the procedure of accreditation in healthcare.

The request from paragraph 1 of this Article includes enumerated health institution administrative data, and decision on meeting the requirements that relate to space, equipment and staff for performing the registered business in terms of Article 44 of the Law on Healthcare (Official Gazette of the Federation BiH, no. 29/97).

The Agency shall evaluate the request and enclosed documentation from paragraph 2 of this Article within 30 days from the day of their receipt, and issue an approval for further activities in the procedure of accreditation in healthcare.

The costs of participating in the program of health service quality and safety improvement, and accreditation in healthcare, shall be covered by the health institution.

The costs of accreditation shall be determined by the Managerial Board.

###### Article 35

The Agency shall provide a health institution with necessary information and documents, and explain standards and criteria of the procedure of evaluating the health service quality and safety, and procedure of accreditation in healthcare.

###### Article 36

A health institution shall submit to the Agency all requested data and documentation, which are of interest to a successful completion of the procedure of accreditation in healthcare.

In extraordinary circumstances, the health institution is entitled to withhold from the Agency the confidential data or information that relate to identification of persons, except in the following situations:

- when the data and information submitted do not discover a person's identity
- when a person approves the disclosure of confidential data and information
- when a person's identity has already been disclosed to the public by competent judicial bodies
- when a person's identity disclosure represents a serious risk for health and safety of the patient.

#### Article 37

The Agency recognizes ISO certificates for health institutions' laboratory and radiological departments issued by the Accreditation Institute of Bosnia and Herzegovina, in accordance with accreditation regulations of Bosnia and Herzegovina, if there exists a proof of validity of such a certificate.

#### Article 38

The Agency performs the procedure of health institution accreditation through the team of competent evaluators from the List of Competent External Quality Control Evaluators of the Agency.

The team of competent evaluators from paragraph 1 of this Article performs the external quality control of the health institution, and offers its evaluation of fulfillment of standards in the health institution that is being accredited, in compliance with the provisions of this Law, and regulations passed on the basis of this Law.

In compliance with the external quality control of the health institution from paragraph 2 of this Article, the Agency, as a first-instance body, brings the decision on the health institution accreditation (hereinafter: accreditation), within 60 days from the day of performed external quality control of the health institution.

The compensation for the work of the competent evaluators from paragraph 1 of this Article is determined by the decision of the Agency's director, with prior approval of the Managerial Board.

#### Article 39

The accreditation is issued with the specification of the duration period, which may not exceed three years.

The accreditation includes the following elementary data: name and location of an accredited health institution, scope of surveyed activities of the health institution, designation of the main parameters that are critical in making a positive decision about accreditation; number of the accreditation decision; accreditation duration period;

accreditation evaluation degree; method of use of the accreditation and the Agency's logo, and other data and conditions proposed by the Managerial Board.

In each individual case, the Agency shall send to an accredited health institution / a health institution whose accreditation has been rejected, a report on the external quality control in the health institution, within three months from the day of the aforementioned control at the latest.

The report from paragraph 3 of this Article contains the following data: date of control and names of competent evaluators, type and level of the health institution, executive summary, findings of the control, praises for success in improving the quality and safety of health services, and recommendations for quality and safety improvement in the fields of organization and work in healthcare, where they have been evaluated as insufficient, and deadlines for removing the shortcomings found.

#### Article 40

An appeal to a decision on refusal to issue the accreditation from Article 38, paragraph 3, of this Law, may be filed with the Ministry within 15 days from the day of receipt of the decision, in compliance with the regulations on administrative procedure.

The Decision of the Ministry from paragraph 1 of this Article is final.

#### Article 41

In the course of the accreditation duration, an accredited health institution shall, on regular basis, submit to the Agency the information on maintenance of the standards fulfilled, on activities undertaken to improve the quality and safety of health services in the health institution, and on any significant change that relates to the organization of the health institution and healthcare provision.

The Agency shall be entitled to paying announced annual control visits to accredited health institutions. The Agency shall pay individual, unannounced control visits to accredited health institutions upon the Council's decision.

After the accreditation expires, the accredited health institution shall withdraw from use all written and electronic materials with the Agency's logo.

## **2. Accreditation Revocation**

#### Article 42

In case a health institution fails to maintain the fulfilled standards and criteria prescribed by the regulations, the Agency shall revoke the accreditation.

In the course of the accreditation duration, the accreditation shall also be revoked from the accredited health institution in the following cases:

- for false presentation of quality in the health institution, which has been determined during the control performed;
- for false quality presentation, in which case the quality has been arbitrarily overestimated;
- for quality presentation, which, at the time of control, received a positive opinion, but has aggravated in the meantime, and of whose aggravation the health institution is aware, i.e. there is third parties' evidence;

If accreditation is revoked for a certain period, the use of accreditation and the Agency's logo shall be banned.

Each individual abuse of the accreditation and Agency's logo from paragraph 2 of this Article, shall be determined by the Managerial Board, which, if need be, shall bring a decision on the accreditation revocation from the health institution that committed the abuse.

#### Article 43

An appeal to the decision on the accreditation revocation from Article 42, paragraphs 1 and 3 of this Law, may be filed with the Ministry within 15 days from the day of receipt of the decision, in compliance with the regulations on the administrative procedure.

The Ministry's decision from paragraph 1 of this Article is final.

### **3. Accreditation Renewal**

#### Article 44

Six months prior to the expiry of the accreditation, an accredited health institution may initiate the procedure for the accreditation renewal, upon successfully performed external health service quality control in the health institution, in a manner and according to the procedure prescribed by this Law, and regulations passed on the basis of this Law.

For the renewal of the accreditation, the health institution shall enclose the following documents to its request:

- earlier issued accreditation of the Agency, whose duration is being extended in the renewed procedure;
- analysis of the situation in the field of health service quality and safety improvement, and the self-evaluation of the standards fulfilled and activities undertaken to improve health services quality and safety in the health institution, with a special emphasis on incidents and unfavorable situations that might have occurred, and to which patients, other health service users, health workers and associates might have been exposed, and on the measures undertaken;
- other data requested by the Agency.

#### Article 45

A health institution, whose accreditation has been revoked, may re-submit a request for the accreditation renewal after six-month period expires, calculating from the day of the accreditation revocation.

The health institution shall enclose the following documents to the request from paragraph 1 of this Article:

- earlier issued accreditation and decision on the accreditation revocation; analysis of the situation in the field of health service quality and safety improvement, and the self-evaluation of the standards fulfilled and activities undertaken to improve health service quality and safety in the health institution, with a special emphasis on the measures and activities undertaken to eliminate shortcomings due to which the accreditation has been revoked;
- other data requested by the Agency.

#### Article 46

The decision on the accreditation renewal shall be made by the Agency in a manner and according to the procedure, and terms prescribed by Articles 40 and 45 of this Law.

An appeal to the decision on the accreditation revocation from paragraph 1 of this Article may be filed with the Ministry within 15 days from the day of receipt of the decision, in compliance with the administrative procedure regulations.

The decision of the Ministry from paragraph 2 of this Article is final.

#### Article 47

The Agency shall more precisely determine the method and procedure of the issuance, revocation and renewal of the accreditation by a specific regulation.

#### Article 48

The Agency shall run the register of accredited health institutions and health institutions that participate and have participated in the accreditation program.

The Agency shall submit to all the accredited health institutions the documentation that refers to the accreditation procedure.

The list of accredited health institutions shall be available to the public 15 days upon the decision on the accreditation is made.

#### Article 49

In the course of performing its tasks and activities determined by this Law, the Agency shall work in compliance with the regulations on the personal data protection and regulations on freedom of access to information in the Federation.

### V. CRIMINAL PROVISIONS

#### Article 50

A legal entity using the accreditation in variance with this Law shall be punished with a fine of KM 300 to 6000.

For violations from paragraph 1 of this Article, a responsible individual of a legal entity shall be punished with a fine of KM 500 to 5000.

#### Article 51

A legal entity using the accreditation and Agency's logo in variance with the provisions of this Law in the course of the accreditation duration shall be punished with a fine of KM 300 to 6000 for the following:

- false presentation of quality in the health institution, which has been determined during the control performed;
- false quality presentation, in which case the quality has been arbitrarily overestimated;
- quality presentation, which, at the time of control, received a positive opinion, but has aggravated in the meantime, and of whose aggravation the health institution is aware, i.e. there is third parties' evidence (Article 42, paragraphs 2 and 3 of this Law).

For the violations from paragraph 1 of this Article, a responsible individual of a legal entity shall be punished with a fine of KM 300 to 2000.

### VI. TRANSITIONAL AND FINAL PROVISIONS

#### Article 52

The Agency and its bodies prescribed by this Law shall be formed within the period of six months from the day this Law takes effect.

The Agency Statute shall be passed within the period of six months from the day this Agency begins its work, and its bodies are formed.

Article 53

The participants in the health service quality and safety improvement process shall reconcile their organization and performance with the provisions of this Law within the period of 12 months from the day this Law and regulations passed on the basis of this Law take effect.

Article 54

The regulations for this Law's implementation shall be passed within the period of six months from the day this Law takes effect.

Article 55

This Law represents a foundation act based on which the Agency is registered with the competent court registry.

Article 56

This Law takes effect on the eighth day from the day it is published in the Official Gazette of the Federation of Bosnia and Herzegovina.

Speaker  
House of Peoples  
Parliament of the BiH Federation  
**Slavko Matic**, in person signed

Speaker  
House of Representatives  
Parliament of the BiH Federation  
**Muhamed Ibrahimovic**, in person signed

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