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**Published on the website on April 2025**

**Law No. (38) of 2009 Establishing the National Health Regulatory Authority**

We, Salman bin Hamad Al Khalifa, Acting King of the Kingdom of Bahrain.

Having reviewed the Constitution,

Legislative Decree No. (23) of 1986 regarding Private Hospitals,

Legislative Decree No. (2) of 1987 regarding the Practice of Non-doctors and Pharmacists for the Allied Health Professions,

Legislative Decree No. (7) of 1989 regarding the Practice of the Human Medicine and Dentistry,

Legislative Decree No. (18) of 1997 regarding the Regulation of the Pharmacy Profession and Pharmaceutical Centres,

Legislative Decree No. (39) of 2002 regarding the General Budget,

Criminal Procedures Law promulgated by Legislative Decree No. (46) of 2002 amended by Law No. (41) of 2005;

And the Civil Service Law promulgated by Legislative Decree No. (35) of 2006,

The Shura Council and the Council of Representatives have approved the following Law, which we have ratified and enacted:

Article (1)

The following words and expressions shall have the meanings assigned to them below, unless the context requires otherwise:

Ministry: Ministry of Health.

Minister: Minister of Health.

Authority: National Health Regulatory Authority established under the provisions of this Law.

Board of Directors or Board: The Board of Directors of the Authority.

Chief Executive Officer: The Chief Executive Officer of the Authority.

Deputy Chief Executive Officer: The Deputy Chief Executive Officer of the Authority appointed in accordance with the provisions of Paragraph (b) of Article (10) of this Law.

Health Professions: The professions of human medicine, dentistry, pharmacy, and the allied medical professions specified in the table attached to Legislative Decree No. (2) of 1987 regarding the Practice of Non-doctors and Pharmacists for the Allied Health Professions.

Health Services: Services related to health professions concerning the provision of necessary care for patients, including first aid, medications, aboratory research, radiological examinations, and other related services, as well as the necessary healthcare during visits or treatment at medical centres, public or private hospitals, clinics, physiotherapy centres, or alternative medicine facilities.

Health Institution: Any establishment in which health services are practiced and provided.

Article (2)

An independent public authority, named the "National Health Regulatory Authority," shall be established, endowed with legal personality, financial independence, and administrative autonomy, and subject to ministerial oversight.

Article (3)

The Authority aims to monitor the implementation of health professions and services systems in the Kingdom of Bahrain and to propose their advancement, ensuring optimal efficiency, safety, timeliness, and effectiveness in the delivery of these services across both public and private sectors, in line with the highest scientific principles and health practice standards adopted in the Kingdom of Bahrain under this Law.

Article (4)

a. The Authority shall replace the Ministry in exercising its functions stipulated in:

1- Legislative Decree No. (23) of 1986 regarding Private Hospitals.

2- Legislative Decree No. (2) of 1987 regarding the Practice of Non-doctors and Pharmacists for the Allied Health Professions.

3- Legislative Decree No. (7) of 1989 regarding the Practice of the Human Medicine and Dentistry.

4- Legislative Decree No. (18) of 1997 regarding the Regulation of the Pharmacy Profession and Pharmaceutical Centres.

The Board of Directors shall replace the Minister in exercising the tasks and powers stipulated in the aforementioned Legislative Decrees, provided that this does not conflict with the provisions of this Law.

b. The Authority shall have all the powers necessary to achieve its objectives and exercise its functions, and shall specifically undertake the following:

1- Propose a policy for the development of health services and care systems in the Kingdom, which shall be approved by a decision from the Cabinet.

2- Issue regulations and executive decisions related to the organisation of health professions and services, in accordance with applicable laws.

3- Grant and renew licences for practising Health Professions and operating Health Institutions.

4- Approve the conduct of clinical trials.

5- Establish conditions and quality standards for Health Services that Health Institutions must adhere to.

6- Determine the conditions and rules for the use of information in Health Institutions.

7- Set rules for the registration, pricing, and quality assurance of medicines and pharmaceuticals.

8- Monitor Health Institutions to ensure compliance with licensing conditions and verify the continued availability of health, technical, and and safety standards, and confirm that medical devices and equipment used within these institutions conform to internationally approved standards and specifications.

9- Review patient complaints and follow up on the actions taken regarding them.

10- Hold licensed practitioners accountable for professional errors and violations of the provisions of the Law governing the practice of the profession or the principles, requirements, and ethics of the profession.

Article (5)

The Authority shall have a Board of Directors composed of seven members, including the Chairperson and the Deputy Chairperson, as follows:

1- Three members nominated by the Ministry.

2- One member from the Bahrain Defence Force Hospital.

3- Three members from the private sector.

The Chairperson and members of the Board of Directors must possess integrity, competence, and relevant experience.  
The Board of Directors shall be constituted by a decree upon a proposal by the Prime Minister. Its term shall be three years, renewable for additional similar terms.  
The remuneration of the Chairperson, Deputy Chairperson, and members of the Board of Directors shall be determined by a decree.

Article (6)

a. The Board of Directors shall act as the supreme authority overseeing the affairs of the Authority, endorsing the plans and programmes that govern its operations, and supervising their implementation. To this end, it may take all necessary measures to perform its duties and exercise its powers, including:

1- Proposing a policy for the development of Health Services and Care systems in the Kingdom and submitting its proposals regarding this policy to the Minister for the necessary action to have it approved.

2- Issuing the necessary regulations and decisions to implement the provisions of this Law.

3- Preparing the organisational structure and a regulation to organise the affairs of the Authority’s employees, which includes the procedures and rules for their appointment, promotion, transfer, and determination of their salaries and allowances, without being bound by the provisions related to civil service affairs. The organisational structure and regulation for the organisation of the Authority’s employees shall be approved by a decision from the Cabinet.

4- Forming committees to consider applications for licensing to practice Health Professions and applications for the licensing of Health Institutions, and forming committees responsible for disciplinary accountability of licensed practitioners. These committees shall set the procedures and rules governing their operations. Disciplinary decisions issued by these committees may not be enforced without the Board of Directors’ approval, or if no objection is raised within thirty days of notifying the Board. If the committee determines that the violation constitutes a criminal offence under the law, it must refer the matter to the Board of Directors for submission to the competent judicial authorities.

5- Determining the categories of fees due for granting and renewing licences to practise Health Professions and for the licensing of opening and managing Health Institutions, and determining the methods of collection, after obtaining the approval of the Cabinet.

6- Defining the duties, responsibilities, principles, and ethics of Health Professions, ensuring adherence to Islamic and humanitarian values and the dignity of patients.

7- Issuing an internal regulation to regulate the operations of the Authority.

8- Approving the draft annual budget and final accounts of the Authority.

9- Reviewing the periodic reports submitted by the Chief Executive Officer regarding the operations of the Authority and reporting necessary actions regarding them.

10- Performing other tasks and powers stipulated in this Law.

b. The Board of Directors may delegate one or more committees formed from among its members, the Chairperson, any member of the Board, the Chief Executive Officer, or the Deputy Chief Executive Officer to perform specific tasks.

Article (7)

a. The Board of Directors shall meet at least once every two months, and extraordinary meetings may be convened at the invitation of the Chairperson or upon the request of two members of the Board or the Minister.  
In all cases, members of the Board must be notified of the agenda at least five days prior to the scheduled meeting.

b. The Chief Executive Officer shall attend all meetings of the Board of Directors, except in cases where the Board deems it inappropriate for the Chief Executive Officer to attend.

c. The Board of Directors may invite experts or stakeholders to attend its meetings for consultation and discussion. However, such individuals shall not have voting rights in the Board's decisions.

Article (8)

For a Board of Directors meeting to be valid, a majority of its members must be present, including either the Chairperson or the Deputy Chairperson. Decisions shall be made by a majority vote of those in attendance. In case of a tie, the side with the Chairperson shall prevail. The Chief Executive Officer shall not have voting rights.

Article (9)

The Chairperson shall act as the legal representative of the Authority before the judiciary and in its external relations, while directly supervising the Chief Executive Officer.

Article (10)

a. The Authority shall appoint a Chief Executive Officer by Decree, with the approval of the Cabinet, based on the nomination of the Board of Directors, for a renewable term of three years.

The Board shall decide on the Chief Executive Officer's remuneration, including salaries, allowances, and other financial and in-kind benefits.

b. The Board of Directors may decide to appoint a Deputy Chief Executive Officer, tasked with performing the Chief Executive Officer's duties under conditions and durations defined by the Board's regulations. This decision shall be published in the Official Gazette.  
The Board shall determine the remuneration of the Deputy Chief Executive Officer.

Article (11)

a. The Chief Executive Officer shall oversee the management of the Authority's affairs, including its technical, administrative, and financial operations, and supervise its staff, in accordance with the regulations and decisions issued by the Board.

b. The Chief Executive Officer shall provide quarterly reports to the Board of Directors detailing the Authority's activities, operational progress, and accomplishments as per the established plans and programmes. These reports shall also highlight performance obstacles and propose solutions to overcome them, unless the Board specifies a shorter reporting period.

Article (12)

The Chief Executive Officer or Deputy Chief Executive Officer may resign from their position by submitting a request to the Chair of the Board at least two months prior to the specified resignation date. Acceptance of the Chief Executive Officer's resignation shall be subject to a decision by the Cabinet based on the Board's recommendation. Acceptance of the Deputy Chief Executive Officer's resignation shall be subject to a decision by the Board.

Article (13)

a. If the Chief Executive Officer or Deputy Chief Executive Officer breaches their duties or acts contrary to them, the Board shall appoint a committee from among its members to conduct an investigation into the allegations against either of them. The investigation report, accompanied by a memorandum of opinion, shall be presented to the Board, which shall have the authority to issue a decision imposing the appropriate administrative penalty on the Chief Executive Officer or Deputy Chief Executive Officer in accordance with the penalties regulation issued by the Board.

b. The Chief Executive Officer shall be relieved of their position, following a hearing of their statements, upon the Board's recommendation in the event of a serious breach of their duties or inability to perform them efficiently and effectively. The Board shall nominate a successor to the Chief Executive Officer and take the necessary measures for their appointment.

c. The Deputy Chief Executive Officer shall be relieved of their position, following a hearing of their statements, by a decision of the Board, in the event of a serious breach of their duties or inability to perform them efficiently and effectively.

Article (14)

a. The Authority shall have an independent budget, with the financial year of the Authority commencing at the beginning of the financial year of the State and concluding at its end, except for the Authority's first financial year, which shall commence from the date this Law comes into effect and end at the conclusion of the financial year of the State in force at that time.

The Authority shall be subject to all rules and provisions applicable to the State's general budget in this regard.

b. The Board of Directors shall appoint an external auditor of international stature at the beginning of each financial year to audit the Authority's accounts for a period of three years, which may be renewed for additional periods. The Board shall determine their annual remuneration.

Article (15)

a. The Authority must present periodic reports to the Minister regarding its activities, the progress of its work, and achievements, as well as identify performance obstacles and the solutions adopted to overcome them. The Minister may request the Authority to provide any data, information, decisions, minutes, records, or reports necessary for them to perform oversight of the Authority's operations.

b. Without prejudice to the Authority's independence in carrying out its functions and powers in accordance with the provisions of this law, the Minister shall monitor the Authority's compliance with the provisions of this law and the approved policy for developing Health Services and care systems in the Kingdom as well as assess how efficiently and effectively the Authority carries out its tasks within the available budget allocations.

c. If the Minister determines that any of the Authority's actions are inconsistent with the provisions of the law or the approved policy for developing Health Services and care systems in the Kingdom, or that it is not fulfilling its functions efficiently and effectively, they may object and notify the Board of Directors of their concerns. If the Board insists on its position, the matter shall be referred to the Cabinet to resolve the dispute with a decision issued within thirty days at most from the date the matter is raised.

Article (16)

a. The Chair of the Board may appoint some of the Authority’s experienced employees to inspect the licensed entities to ensure compliance with the provisions of this Law, its regulations, and any decisions made for its implementation. These inspectors are authorized to enter health institutions, review records, and examine the medical devices and equipment used.

b. Employees authorised by the Minister of Justice, in agreement with the Minister and with the approval of the Chair of the Board, shall have the authority of judicial officers regarding crimes that occur in violation of the law within their jurisdiction and are related to their official duties.

The reports prepared regarding these crimes shall be referred to the Public Prosecution by a decision of the Chief Executive Officer.

Article (17)

All records and files related to the licensing of Health Professions and Health Institutions, as well as files concerning appeals against decisions issued regarding these licences, shall be transferred to the Authority.

Article (18)

The decisions in force at the time of the promulgation of this Law regarding the regulation of Health Professions and Health Services shall remain applicable, provided they do not conflict with the provisions of this Law, until the Authority issues the necessary decisions to implement its provisions within one year.

Article (19)

Any provision that conflicts with the provisions of this Law shall be repealed.

Article (20)

The Prime Minister and the Ministers—each within their jurisdiction—shall implement the provisions of this Law, and it shall come into force from the day following the date of its publication in the Official Gazette.

Acting King of the Kingdom of Bahrain

Salman bin Hamad Al Khalifa

Issued at Riffa Palace

On:

16 Rajab 1430 AH

Corresponding to:

9 July 2009