His Majesty
King Hamad Bin Isa Al Khalifa

The King of the Kingdom of Bahrain
His Royal Highness Prince Salman bin Hamad Al Khalifa, the Crown Prince and Prime Minister
Since the establishment of its strategy (2016-2020), the Authority has strived for the past five years to accomplish the initiatives set out in that strategy. With the support of the Supreme Council of Health, the Authority was able to complete more than 90% of these initiatives, which focused on establishing the infrastructure of regulations and decisions governing its work, as well as contributing to the updating of the resolutions and laws governing the health sector in the Kingdom of Bahrain.

During the last four years of the strategy, the Supreme Council of Health has issued 21 regulatory decisions in the field of regulating professionals, health facilities and medicines. The most important of these decisions are the issuance of national standards for the classification and licensing of health professionals and updating the technical and engineering requirements that should be met in health facilities, and decisions related to the evaluation and accreditation of the facilities.

By the third quarter of the year 2019, the Authority has updated its website, which has become a comprehensive portal for all procedures, regulations and information related to the organization of the health sector in the Kingdom of Bahrain. Among the most prominent features of the site is the allocation of a special section of the site under the name of the Health Investment Center, which contains all the guiding information for the investors wishing to invest in the health field in the Kingdom.

By the end of 2019, the Authority moved to the new building which allowed it to provide a better service to its customers and easy accessibility. A dedicated investors’ office has been opened to provide support to investors by advising on investment opportunities in the health sector, laws, rules and regulations related to the type of investments and requirements of the Authority, and to provide support to investors in taking investment decisions. The office also follows up investment applications and coordinates with the relevant bodies and ministries, as well as other departments of the authority and supports investors in the establishment of the health facilities in an effective manner.

Through the Supreme Council of Health, the Authority has been able to implement the electronic system for the release of imported medicines for the Kingdom, in addition to applying the licensing system for health professionals in cooperation with the Information & e-government Authority.
Introduction

In the field of improving the quality of health services, the Authority has completed the accreditation of 36 healthcare facility, over the past four years. This has contributed to improving the quality of performance in the accredited facilities. And in order to achieve international recognition, the Authority aspires in the coming years to obtain international accreditation for the national accreditation program to be accredited as a national body that provides local accreditation to health care facilities.

In 2018, the Authority received the Government Excellence Award for Best Government Practices in the field of Health facilities Assessment and Accreditation. In 2019, it received the Best Government Practices Award, from MENPAR institute for administration research in the middle east and north Africa region.

With the issuance of Health Insurance Law No. (23) of 2018, new tasks have been added to the authority, including monitoring and auditing of insurance coverage providers to ensure the availability of insurance benefits in accordance with the health packages approved by the Supreme Council of Health and the extent of health service providers to ensure their commitment to providing the health services agreed upon within the health packages, and monitoring the price list of the insurance services provided.

The biggest challenge facing the Authority is to complete the electronic system for its full services, which will facilitate the licensing of professionals and health facilities, licensing, registering and importing pharmaceuticals and medical devices. We will work in the next phase to automate all the authority procedures.

Beginning of the year 2020, the authority took the initiative to update its strategy in order to plan for the next five years, and accordingly, the new strategy was issued after Supreme Council of Health approval. The new strategy continues to preserve the vision and strategic goals with the introduction of amendments to procedures and monitoring indicators that reflect the reality of organizing health services, and the new strategy also reflects future directions for organizing the health sector in the Kingdom in line with local and international developments in this regard.
Our Mission

Regulate the provision of healthcare in Bahrain to ensure high efficiency, safety and effectiveness in delivering health services; both in the governmental and private sector based on the best scientific principles and health practice standards accredited in the Kingdom.
Responsibilities

Issuing regulations and executive decisions related to regulating health professions and services.

Granting and renewing licenses for healthcare facilities and health professionals.

Establishing rules for registering, pricing and quality assurance of medicines and pharmaceutical products.

Licensing and registering medical devices and supplies.

Inspecting health facilities to ensure compliance with the terms of licensing.

Monitoring and auditing the insurance coverage providers, their prices, and the health services provided through them.

Approving clinical Trials.

Accreditation of health facilities.

Determining the conditions and rules for the use of information in health facilities.

Studying patients’ complaints, investigating medical errors & taking disciplinary action against professionals and facilities conducting medical errors or breaking medical ethics and conduct.
OUR GOALS
We aim to achieve our vision through three strategic goals:

• **Regulated and accountable healthcare sector:** By ensuring that all healthcare facilities professionals, medicines and medical devices registered in the Kingdom of Bahrain meet the required licensing standards.

• **Safe and trusted health services:** Through continuous assessment of the quality of health services provided to ensure compliance with accreditation standards and ensure the safety of medicine and medical devices used in the health sector and safety of clinical research conducted in the Kingdom.

• **Protected health rights:** by Preserving patients’ rights and safety, we will act to protect the rights and the safety of all people using the health care facilities.
Our Goals

1. Regulated and Accountable Healthcare sector
2. Safe and Trusted Health Services
3. Protected Health Rights
Goal 1: Regulated and Accountable Healthcare Sector
Goal 1: Regulated and Accountable Healthcare Sector

**Strategies**

1. Licensing & Monitoring of healthcare and pharmaceutical facilities to ensure their compliance with the technical, safety and engineering requirements.

2. Monitoring and correcting the violations detected in healthcare and pharmaceutical facilities.

**Procedures**

1. Review professionals license applications to ensure that their qualifications and experience are in accordance with the professionals qualification requirements of Bahrain.

2. Ensure the medical fitness of professionals & attainment of the required continuous professional development hours before renewing their licenses.

3. Review Submitted CPD programs to ensure compliance with required standards.

4. Review all medicines and pharmaceutical products applications for registration /importation to ensure they meet the requirements before importation.

5. Review all medical devices & supplies applications for registration /importation to ensure they meet the requirements before importation.
Goal 1: Regulated and accountable healthcare sector

Strategy 1
Ensure the compliance of healthcare and pharmaceutical facilities with technical, safety and engineering requirements

Procedures
1. Licensing & Monitoring of healthcare and pharmaceutical facilities to ensure their compliance with the technical, safety and engineering requirements
2. Monitoring and correcting the violations observed in healthcare and pharmaceutical facilities.

KPIs
1. Percentage of licensed health and pharmaceutical facilities that comply with more than 70% of the requirements. (Scale 100%)
2. Percentage of health and pharmaceutical facilities that corrected the violations during the specified period (scale 90%)
Goal 1: Regulated and accountable healthcare sector

Strategy 2
Ensure the competence of health professionals.

Procedures
1. Review professionals license applications to ensure that their qualifications and experience are in accordance with the professionals qualifications requirements of Bahrain.
2. Ensure the medical fitness of professionals & attainment of the required continuous professional development hours before renewing their licenses

KPIs
1. Percentage of professionals granted license to practice according to PQR from total submitted annually (scale 100%)
2. Percentage of licenses renewed annually according to the requirements from the total submitted for renewal (scale more than 95%)
Goal 1: Regulated and accountable healthcare sector

Goal 1

Strategy 3
Ensure the quality of Continuous professionals development Programs CPD.

Procedures
Review Submitted CPD programs to ensure compliance with required standards

KPIs
Percentage of approved CPD programs from the total submitted (Scale is more than 70%)

1
Goal 1: Regulated and accountable healthcare sector

Strategy 4
Ensure the quality of medicines and pharmaceutical products

Procedures
Review all medicines and pharmaceutical products applications for registration/importation to ensure they meet the requirements before importation.

KPIs
1. Percentage of drugs and pharmaceutical products registered annually from the total imported medicines to the Kingdom of Bahrain (the scale is more than 70%)
2. Percentage of drugs & pharmaceutical products imported with temporary registration from the totally submitted (the scale is less than 30%)
Goal 1: Regulated and accountable healthcare sector

Strategy 5
Ensure the quality of medical devices & supplies

Procedure
Review all medical devices & supplies applications for registration /importation to ensure they meet the requirements before importation.

KPIs
1. Percentage of registered devices of the total applied devices annually (scale 50% annually)
2. Percentage of devices approved to be released according to standards from the total imported (scale more than 100%)
Goal 2: Safe and Trusted HealthCare Services
Goal 2: Safe and Trusted HealthCare Services

**Strategies**

1. Implement the national accreditation program to hospitals, health centres & laboratories

2. Ensure the safety of medicines & pharmaceutical products
   - Follow up medicines & pharmaceutical products’ warnings and take necessary measures towards them
   - Develop pharmacovigilance program for Reporting medicines post-marketing side effects

3. Ensure the safety of medical devices
   - Follow up medical devices & supplies’ warnings and take the necessary measures towards them
   - Monitor health facilities to ensure that the medical devices used meet the requirements and standards

4. Ensure safe application of clinical trials
   - Review submitted clinical trials to ensure they meet the standards required prior to authorization

**Procedures**

- Ensure the quality of health services
- Ensure the safety of medical devices
- Ensure the safety of medicines & pharmaceutical products
Goal 2: Safe and Trusted HealthCare Services

**Strategy 1**
Ensure the quality of health services.

**Procedure**
- Implement the national accreditation program to hospitals and health centres & laboratories

**KPIs**
1. Percentage of health facilities accredited among the planned annually (scale more than 80%)
2. Percentage of the fully compliant quality standards out of the total standards assessed in health facilities. (The scale is more than 80%)
3. Percentage of facilities that implemented more than 80% of improvement recommendations during the accreditation period. (The scale is more than 80%)
Goal 2: Safe and Trusted HealthCare Services

Strategy 2
Ensure the safety of medicines and pharmaceutical products

Procedure
1. Follow up medicines & pharmaceutical products’ warnings and take necessary measures towards them
2. Develop pharmacovigilance program for Reporting medicines’ post-marketing side effects

KPIs
1. Percentage of medicines & pharmaceutical products withdrawn from the market annually from the total reported recalls (scale 100%)
2. Pharmacovigilance program fully established by end of 2023
Goal 2: Safe and Trusted Healthcare Services

Strategy 3
Ensure the safety of medical devices & supplies

Procedure
1. Follow up medical devices & supplies' warnings and take the necessary measures.
2. Monitor health facilities to ensure that the medical devices used meet the requirements and standards

KPIs
1. Percentage of medical devices & supplies withdrawn from the market annually from the total reported warnings (scale 100%)
Goal 2: Safe and Trusted HealthCare Services

Goal 2

Strategy 4
Ensure safe application of clinical research

Procedure
Review submitted clinical trials to ensure they meet the standards required prior to authorization

KPIs
1
Percentage of the approved clinical trials that meet requirements from the total submitted annually. (Scale 100%)
Goal 3: Protected Health Rights
Goal 3: Protected Health Rights

### Strategies

1. Application of medical liability insurance
   - Issue regulations for medical liability insurance and determine the professional categories to be insured

2. Medical errors & sentinel events monitoring
   - Monitor medical error and sentinel events reported by health facilities & ensure that they implement corrective measures

3. Professionals and facilities accountability
   - 1. Investigate claims of medical/ethical/professional errors and determine medical liability.
   - 2. Investigate claims of facilities' violations and determine liability.
   - 3. Take disciplinary measures against health professionals and facilities responsible for medical/ethical/professional error/institutional violations.

4. Monitoring health insurance coverage
   - 1. Monitoring and auditing providers of health insurance to ensure the availability of insurance benefits in accordance with health packages approved by the Supreme Council of Health.
   - 2. Monitoring and auditing health service providers to ensure their commitment to providing health services agreed upon within health packages.
   - 3. Monitoring the price list of insurance services provided and notified to NHRA.
Goal 3: Protected Health Rights

Strategy 1
Application of medical liability insurance.

Procedure
Issue regulations for medical liability insurance and determine the professional categories to be insured.

KPIs
1. Implementation of insurance regulations for medical liability by 2023. (Scale 100%)
2. Percentage of professionals insured against medical liabilities from the total. (Scale 100%)
Goal 3: Protected Health Rights

**Goal 3**
Monitor medical errors and sentinel events reported by health facilities & ensure that they implement corrective measures.

**Strategy 2**
Monitor medical errors & sentinel events.

**KPIs**
1. Develop an online reporting & monitoring system for medical errors and sentinel events by end of 2022.
Goal 3: Protected Health Rights

**Strategy 3**

**Professionals and facilities accountability**

**Procedure**

1. Investigate claims of medical/professional/ethical errors and determine medical liability.
2. Investigate claims of facilities’ violations and determine liability.
3. Take disciplinary measures against health professionals and facilities responsible for medical/professional/ethical error/institutional violation.

**KPIs**

1. Percentage of professionals who committed medical/ethical/professional errors against whom measures (attention letter, disciplinary, amendments procedures, acceptance of procedure taken by the facility) have been taken by NHRA from the total. (Scale 100%)

2. The Percentage of individuals practicing without a license whom were referred to the Public Prosecution out of the total incidents detected by NHRA (scale 100%)

3. Percentage of facilities in which violations have been detected and for which measures have been taken (warning letter, disciplinary action, modification of procedures, approval of procedures by the establishment only, referral to the prosecution, referral to the prosecution, closure) of all violating facilities. (Scale is 100%)
Goal 3: Protected Health Rights

Strategy 2
Monitoring health insurance coverage

Procedures
1. Monitoring and auditing providers of health insurance to ensure the availability of insurance benefits in accordance with health packages approved by the Supreme Council of Health.
2. Monitoring and auditing health service providers to ensure their commitment to providing health services agreed upon within health packages.
3. Monitoring the price list of insurance services provided and notified to NHRA.

KPIs

1. Percentage of insurance service providers audited from the total providers (scale of 100%)
2. Percentage of health facilities held accountable due to violation of provision of health services in accordance with agreed package, from the total violations detected. (scale of 100%)
3. Percentage of insurance service providers held accountable due to violation of the declared prices of insurance services out of total violations detected (scale of 100%)
Proposed projects to ensure the achievement of strategic objectives
The Authority shall review and update resolutions and laws governing its work and regulating the private sector.
Develop updated accreditation standards based on gap analysis

Train surveyors on the new standards

Conduct mock surveys prior to implementation of new standards

Implement new standards in the first quarter of 2024

Obtain international accreditation for the Authority

Obtain recognition of the International Quality Association as a recognized accreditation body for the evaluation and accreditation of healthcare facilities in the Kingdom of Bahrain

Review current standards with stakeholders

Contract with an expert consultant to conduct standards gap analyses
The Authority will automatize all its services through the implementation of several online services for all its procedures.
In order to ensure that health facilities and health professionals comply with the requirements and standards, NHRA will organize several training workshops, conferences and seminars to raise the level of quality in the provision of health services.
The Way Forward

We are dedicated to improving our services to achieve our vision.

Monitor
We will continue to monitor the performance of health sector to ensure high quality care.

Improve
We are dedicated to improving our services to achieve our vision.