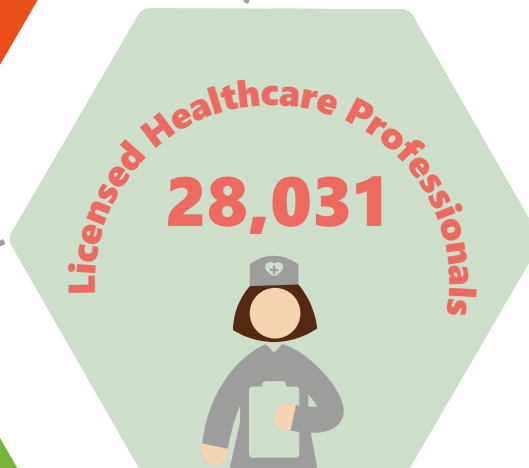




# NHRA Annual Report 2017





**His Royal Highness Prince  
Khalifa Bin Salman Al Khalifa**  
The Prime Minister of the  
Kingdom of Bahrain



**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 &  
Deputy Supreme Commander & First  
Deputy Prime Minister of the  
Kingdom of Bahrain



الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY

## **From the CEO**

The National Health Regulatory Authority (NHRA) saw many new developments in the year 2017. It was a year in which our greatest accomplishment was to achieve 84% of our planned initiatives outlined in our strategic plan. This achievement would not have been possible without the support of the Supreme Council of Health and the efforts of all our dedicated staff at NHRA.

The NHRA has issued 16 policies and guidelines, highlighting our procedures and regulations, in relation to licensing facilities, professionals, medicines, advertisement, continuous professional development, accreditation, patient's complaints, reporting incidents and inspection. These policies and guidelines primary aims are to support our clients in a way that promotes collaboration and open communication.

In 2017, the total number of licensed healthcare facilities was 671, that includes 194 medical centres, 21 hospitals and 171 clinics, of which 58% are located in the Capital Governorate.

In this past year, we also saw an increase in the investment of new medical centres and pharmacies. Initial approval was granted to 110 facilities, that included 20 dental centres, 15 general medical centres and 13 alternative medicine centres. The number of new pharmacies licensed in the last year was 51 bringing the total number of pharmacies registered with the Authority to 213 pharmacies.

The number of registered professionals in the Authority for 2017 reached 28,031 that included 6,131 doctors, 14,395 nurses, 4,520 allied health 1,887 pharmacists and 1,098 dentists.

In pursuant of the decision of the Supreme Council of Health to link continuous professional education with the renewal of licenses for healthcare professionals, the authority approved 3,022 continuing professional development training programs. These programs included conferences, workshops, scientific forums and lectures. In the area of clinical trials, the Authority has reviewed and made judgement on 12 clinical trials in the private and public sectors.

The total number of registered pharmaceuticals with the Authority are 3,760 Medicines, 729 Health Products and 311 Alternative Medicine Products. Additionally, the authority reviewed 8,178 medical devices of which 6,861 were approved with a value of approximately 25 million Bahraini dinars.

By far the greatest achievement for us in 2017 was the implementation of the first National Accreditation Program in the Kingdom of Bahrain. Select Healthcare facilities underwent a comprehensive assessment of all services provided by them, ranging from governance and medical care to patient and building safety, infection control, quality and other criteria that impact patient safety and quality. The accreditation team successfully completed surveying 8 private hospitals and 6 affiliated medical centres.

Four hospitals were awarded the diamond level of accreditation, achieving more than 95% of the required standards. Three hospitals were awarded the platinum level of accreditation, achieving between 90% and 94% of the standards. One hospital was awarded the gold level of accreditation achieving between 85% and 89% of the required standards.

As for complaints and medical errors, the Authority received 237 cases last year, of which 136 were direct complaints from patients and 47 were incidents reported from healthcare facilities. Fifty-two cases were referred by the prosecution and the courts, 56% against the private sector and 42% against the government sector.

The Authority completed the investigation on 118 cases of which medical error was proved in only 44 of them.

In total, the authority implemented 66 disciplinary actions on professionals, 47 against doctors and 15 against nurses. The disciplinary proceedings included 34 suspensions, 21 warnings, and 10 license cancellations. A monetary fine was issued for one facility.

In spite of some of the great strides we made in 2017, we also faced our fair share of challenges, one of the biggest being the lack of a comprehensive information system for all our procedures. This IT development encountered numerous technical issues that have contributed to the delay of its implementation. For 2018, we have once again reaffirmed our commitment to improve the IT system and enable our customers to apply for their licensing online and in turn allow us to finalize our approvals in an efficient and effective manner.

To overcome some of our challenges we faced in 2017, the government has approved to increase our budget and human resource capacity as requested in our budgetary report for 2018. This increase in funds will help to enhance and improve our services that we offer to the Kingdom of Bahrain.

This report will highlight NHRA activities and statistics for the year 2017 and will shed some light on the most important achievements.

**Dr. Mariam Al Jalahma**



## **NHRA vision and goals**

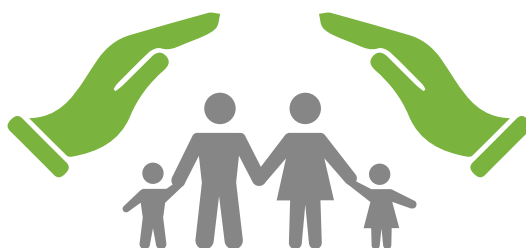
The National Health Regulatory Authorities' (NHRA) vision is to promote safe and high-quality care in the Kingdom of Bahrain. In 2016 the Supreme Council for Health approved the five-year strategy plan for NHRA which aims to achieve the vision through 3 strategic goals.



**Regulated & Accountable Facilities**



**Safe & Trusted Health Services**



**Preserved Health Rights**

Of the thirty initiatives that were included in the strategy, NHRA was successful in implementing 84% of the initiatives by the end of 2017.

## Overview of NHRA Strategy

The National Health Regulatory Authorities vision is to promote safe and high quality in the delivery of health care in the Kingdom of Bahrain. In 2016, the Supreme Council for Health had approved the five-year strategy plan for NHRA which aimed to achieve the vision through 3 strategic goals. In total 30 initiatives were included in the strategy, by the end of 2017 NHRA had implemented 84% of the initiatives.

The achievements are summarised below:

### Department

### 2017 Implemented Initiatives

#### Professionals

- Establishing a licensing categorisation that unifies criteria of professional licensing
- Establishing professionals code of ethics
- Developing regulations to link renewal of licensing with Continuous Professional Development

#### Facilities

- Implementing the National Health Accreditation Program
- Developing facility classification
- Developing regulations for licensing of health care facilities

#### Pharmaceuticals

- Developing regulatory standards for registration of medicines and pharmaceutical products.
- Developing categorization standards for pharmaceuticals and health products
- Establishing rules for the destruction or re-export of medicines not complying with the specifications and standards
- Subjecting all drugs for laboratory testing to ensure its compliance with the technical standards

#### Medical Devices

- Developing regulatory standards for registration of medical supplies and devices

#### Complaints

- Establish Accountability Committee for health care facilities
- Develop Disciplinary Committees for different professions

#### HR & Finance

- Develop internal NHRA policies & procedures
- Develop a risk assessment plan
- Develop training plan for all NHRA staff based on performance evaluation
- Develop the financial policy for NHRA



## **Strategic Plan in Detail**

This Strategic Plan is the result of an inclusive authority wide planning process.

The plan highlights key directions for success and accompanying goals, which support our mission and vision for the organization.

The Plan, in all its parts, articulates a transformational approach to the services we provide to the people of the Kingdom and, in essence, reaffirms our commitment to work in collaboration with the clients we serve. It is our way of endorsing the authorities strongly held belief that the people of Bahrain deserve high quality, accessible and timely service from the NHRA.

# Strategic Plan in Detail

## Professionals Regulation Section

Strategy	Strategy KPI	Procedures	Initiative KPIs	Status
Ensure the competence of health service providers	1 Existence of unified criteria for professional categorization	Establishing unified criteria of professional licensing categorization	Produce the final document by June 2017 Produce the final document of Code of ethics by end of September 2017	Completed
	2 Existence of professional code of ethics	Developing professional code of ethics	Produce the final document of Code of ethics by end of September 2017	Completed
	3 Percentage of renewed licensed linked to CPD hours of total licenses	Developing regulations to link renewal of licensing with CPD	Issue a resolution for professional licensing conditions by end of 2016  Develop CPD regulations by march 2017	Completed  Completed
Implement a malpractice insurance system	Percentage of health care workers who are covered with malpractice insurance	Setting conditions and regulations for insurance malpractice insurance	Develop a proposal for categories of hospitals and professionals to have a mandatory malpractice insurance by mid of 2018	Under Process

# Health Care Facility Section

Strategy	Strategy KPI	Procedures	Initiative KPIs	Status
<p>Ensure efficient health care facilities</p>	<p>Existence of regulations for the technical requirements for health facilities</p>	<p>Developing regulations for licensing of health care facilities</p>	<p>Issue a resolution for regulations for licensing of health care facilities by mid of 2017</p>	<p>Completed</p>
	<p>Existence of regulations for the establishment of pharmaceutical facilities, drug warehouses and the establishment of pharmaceutical factories</p>	<p>Establish regulations for licensing pharmaceutical facilities</p> <p>Developing regulations for the licensing of drug warehouses</p> <p>Developing regulations for licensing pharmaceutical factories</p>	<p>Issue a resolution for regulating pharmaceutical facilities, factories and warehouses by the end of 2017</p>	<p>Under Process</p>
	<p>Establishment regulations for the licensing of specialized health facilities</p>	<p>Developing regulations for specialized health facilities</p>	<p>Develop CAM regulations by the end of 2016</p> <p>Develop Addiction management regulations by end of 2017</p> <p>Develop IVF regulations by mid of 2018</p>	<p>Completed</p> <p>In progress</p> <p>In progress</p>

Strategy	Strategy KPI	Procedures	Initiative KPIs	Status
<p>Ensure the quality of health services</p>	<p>1 Adopting accreditation standards for health facilities</p> <p>2 Adopting facility classification</p>	<p>3 Implementing the national accreditation program</p> <p>4 Developing facility classification</p>	<ul style="list-style-type: none"> <li>• Issue a resolution regulating accreditation by end of 2016</li> <li>• Issue accreditation policy by January 2017</li> <li>• Implement accreditation by May 2017</li> </ul>	<p>Completed</p> <p>Completed</p> <p>Completed</p>

# Pharmaceutical Products Regulation Section

Strategy	Strategy KPI	Procedures	Initiative KPIs	Status
<p>Ensure the quality of medicines</p>	<p>Existence of regulatory standards for registration of medicines and pharmaceutical products</p> <p>Percentage of categorized pharmaceuticals and health products</p>	<p>Developing regulatory standards for registration of medicines and pharmaceutical products.</p> <p>Developing categorization standards for pharmaceuticals and health products</p>	<p>Issue regulations by January 2017</p> <p>Update the old version by June 2017</p>	<p>Completed</p> <p>Completed</p>
<p>Ensure the availability of safe drugs</p>	<p>Presence of pharmacovigilance system</p> <p>Percentage of destroyed drugs annually from total registered</p> <p>Percentage of drugs tested annually from registered</p>	<p>Developing pharmacovigilance system</p> <p>Establishing rules for the destruction or re-export of medicines not complying with the specifications and standards</p> <p>Subjecting all drugs for laboratory testing to ensure its compliance with the technical standards</p>	<p>Develop a proposal for initiating a pharmacovigilance system by mid of 2018 Implements the system by end of 2018</p>	<p>Under Process</p>

# Complaint Section

Strategy	KPI	Procedures	Responsibility
Professional accountability	Percentage of health facilities who received a disciplinary action	Initiate a Committee for Medical accountability for health care facilities	Completed
	Percentage of professionals who received a disciplinary action	Develop Disciplinary committees for different professions	Completed
Surveillance of medical errors	Presence of an effective Surveillance system for medical errors reporting	Develop a Surveillance system for reporting medical errors	Under Process
Safe clinical trials	Presence of guidelines regulating clinical trials	Establishing clinical trials regulations	Completed
		Establishing ethical research committees	Completed
Ensure the competence of health service providers	Existence of regulation for accrediting continues professional education programs.	Develop a national guideline for CPD programs accreditation	Completed

## Strategy

Ensure the quality of medical supplies and devices

---

Ensure the safety of medical supplies and devices

## KPI

Existence of regulatory standards for registration of medical supplies and devices

Percentage of registered medical devices

---

Percentage of medical devices recall or adverse event

## Procedures

Developing regulatory standards for registration of medical supplies and devices by 2017

Establish a comprehensive medical device national data base by end of 2018

---

Develop a Surveillance system for reporting medical devices recall, alert and adverse events by end of 2019

## Responsibility

Completed

In progress

---

Under Process

# Human Resources & Finance Section

Strategy	KPI	Procedures	Responsibility
Develop the human resources of NHRA	1 Internal policies developed & Publish.	1 Develop internal NHRA policies & procedures	In process
	2 The new organizational structure finalized and approved by CSB.	2 Update NHRA organization structure	In process
	3 Risk assessment plan is in place	3 Develop a risk assessment plan	Done
	4 NHRA IT system is developed and functional	4 Update the IT system of NHRA	In process
	5 All NHRA jobs are occupied	5 Complete the employment procedures	Done
	6 All NHRA staff are evaluated annually	6 Complete performance assessment procedures.	Done
	7 Existence of an annual training plan for all NHRA staff	7 Develop training plan for all NHRA staff based on performance evaluation	Done



Strategy	KPI	Procedures	Responsibility
Develop Financial resources of NHRA	<p>1 The financial plan is adopted and published</p> <p>2 Adopted regulations for committees' payment are published</p> <p>3 Visitng consultants' payment scheme is adopted are published</p>	<p>Develop the financial policy for NHRA</p> <p>Develop regulations for committees' financial payment</p> <p>Develop Regulations for consultant's payment</p>	<p>Done</p> <p>Done</p> <p>Done</p>



**Published  
Resolutions,  
Guidelines, Policies  
and Contracts**

## Supreme Council of Health Resolutions

The Supreme Council of Health issued four important resolutions in 2017 regarding drug registration and regulation, facilities licensing, and professional licensing:

### Published Resolutions

1. Resolution No (8) Amendments of some articles in resolution No (12) for drug registration policy.
2. Resolution No. (15) For 2017 Regarding Technical & Engineering Conditions Required in Health Care Facilities.
3. Resolution NO. (3) For 2017 Regarding Healthcare Professionals licensing requirements and standards.
4. Resolution No. (41) For 2017 regarding Issuing a Track and Trace System for the Supply Chain of Medicine within the Kingdom of Bahrain.

### Partnership & Contracts

In an effort to ease workflow processes at NHRA and effectively collaborate with our clients NHRA signed four important agreements with international companies in relation to professional licensing, drug and medical devices registration.

Agreements were signed with:

- **The Data Flow Group** for verification of professional qualifications, work experience, licensing
- **Prometric** for providing technology-enabled testing and assessments for licensure exams
- **Extedo** for providing EURS (EXTEDO Universal Review System) that serves as a complete eCTD validation and reviewing solution that evaluates whether any eCTD submission conforms to the mandated standards
- **Dahlman Middle East** to examine and ensure the safety and quality of medical and surgical equipment used in the Kingdom of Bahrain

NHRA Publications 2017

# Published NHRA Guidelines and Policies Overview of the Year



## Key

PPR – Pharmaceutical Products Registration  
HPR -Health Professionals Regulation  
HCF – Health Care Facilities  
MC – Medical Complaints

CT & CPD – Clinical Trials & Continuing Professional Education  
ACC – Accreditation  
MD – Medical Device



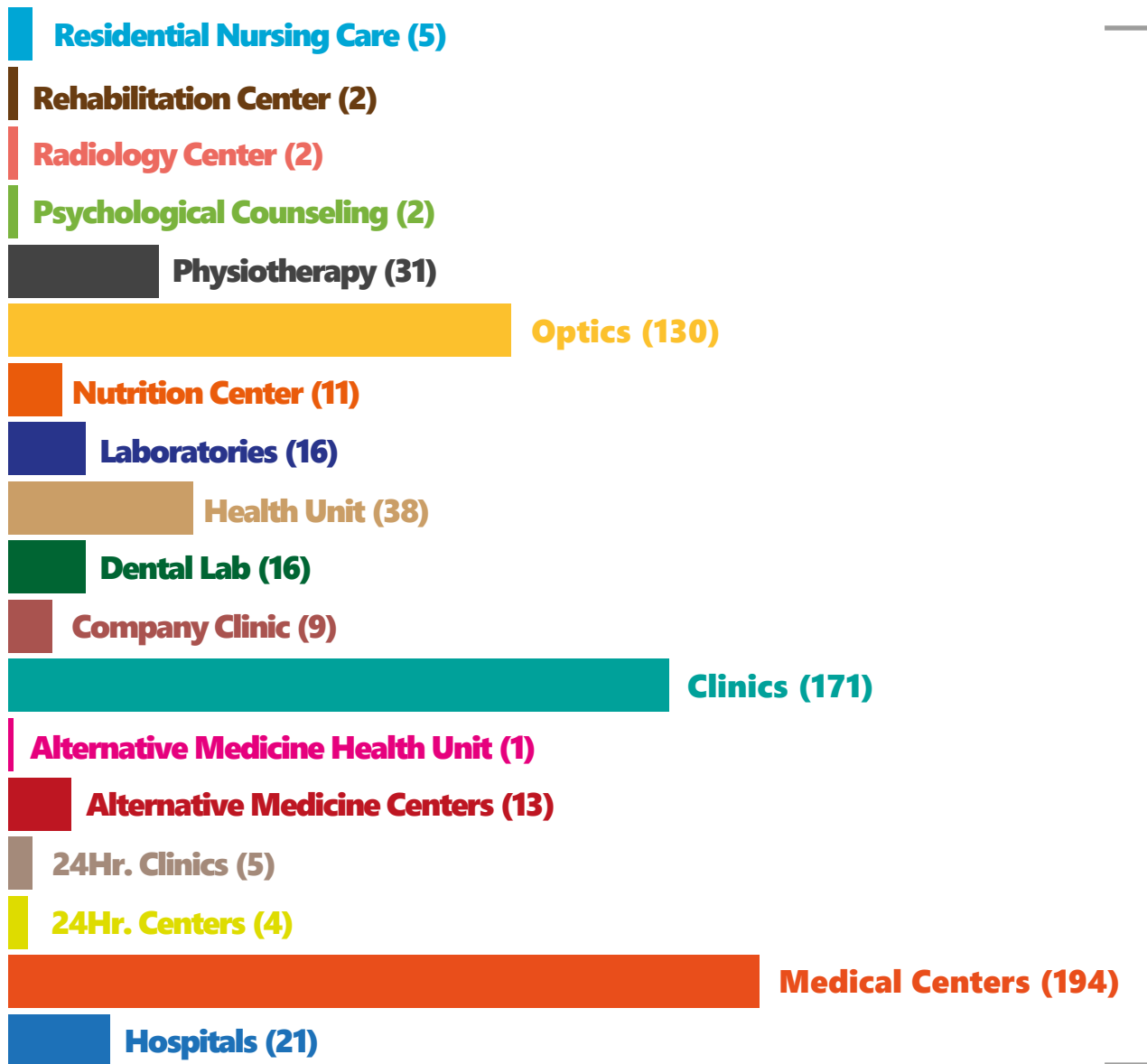
## **Health Care Facility Regulations**

In 2017, the total number of registered healthcare facilities in the Kingdom of Bahrain reached 761. The NHRA has seen a significant increase in the applications for new medical centers in Bahrain due to an open market strategy by the Kingdom. The majority of these applications have been for general medical centers, dental centers, complementary medicine centers, and dermatology centers. At present there are 194 medical centers in Bahrain.

The greatest concentration of healthcare facilities and services in Bahrain has been within the Capital Governorate. The Capital Governorate has 76% of all hospitals, 78% of all private hospital beds, 55% of all medical centers and 68% of all clinics within Bahrain.

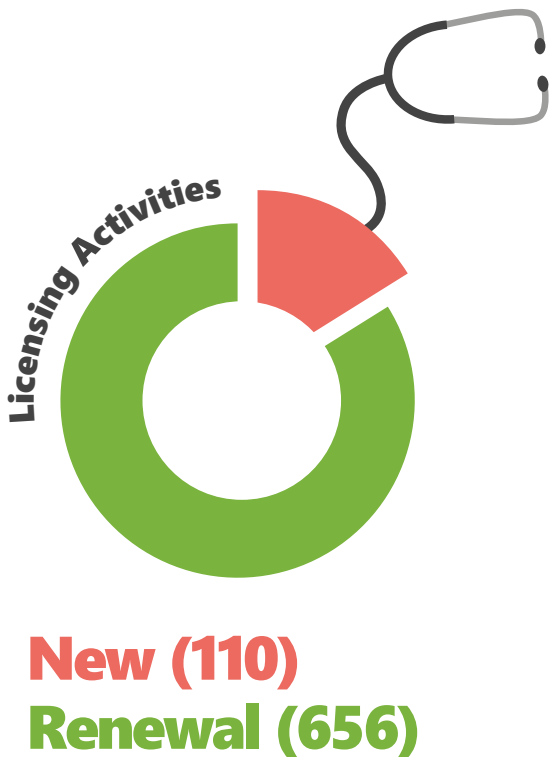
The following infographics demonstrate facility statistics in 2017.

# Healthcare Facilities Licensing



671 Licensed Facilities

## Licensing Activities:



## Licensing Applications for New Healthcare Facilities in the Kingdom of Bahrain

Number of New Applications Submitted in 2017

**234**

Number of Preliminary Approvals Issued 2017

**103**

### Classification of Facilities with Preliminary Approval

- |   |  |
|---|--|
| <b>Audiology - 4</b>                        | <b>Psychological counseling Center - 2</b> |
| <b>Dental Lab - 5</b>                       | <b>Company Clinic - 1</b>                  |
| <b>Laboratories - 2</b>                     | <b>Part Time Clinic - 1</b>                |
| <b>Optics - 8</b>                           | <b>Full Time Clinic - 5</b>                |
| <b>Residential Nursing Care Service - 4</b> | <b>Dental Clinic - 2</b>                   |
| <b>Nutrition Center - 2</b>                 | <b>Dental Center - 20</b>                  |
| <b>Physiotherapy - 5</b>                    | <b>Specialized Center - 3</b>              |
| <b>Alternative Medicine Center - 14</b>     | <b>General Medical Center - 15</b>         |
| <b>Rehabilitation Center - 2</b>            | <b>Hospital - 7</b>                        |
| <b>Rehabilitation Hospitals - 1</b>         |  |

# Healthcare Facilities Overview

## Hospitals:

Total Number of Licensed Private Hospitals: **21**

### Geographic Distribution of Private Hospitals

Capital - 16  
 Muharraq - 1  
 Northern - 1  
 Southern - 3



### Number of Beds in the Private Sector

Capital - 518  
 Muharraq - 50  
 Northern - 35  
 Southern - 62



## Centers

Registered Medical Centers  
**194**

**70**

General Medical Centers

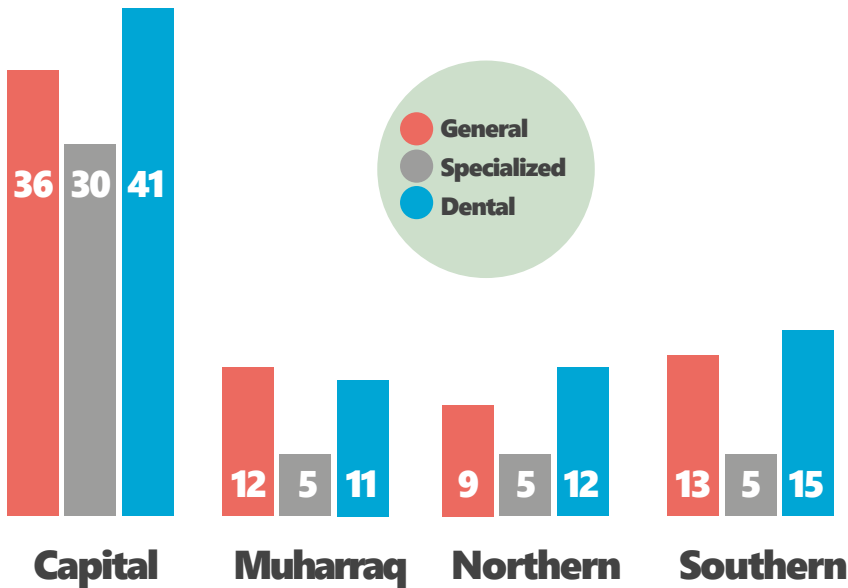
**79**

Dental Centers

**45**

Specialized Centers

## Distribution of Medical Centers

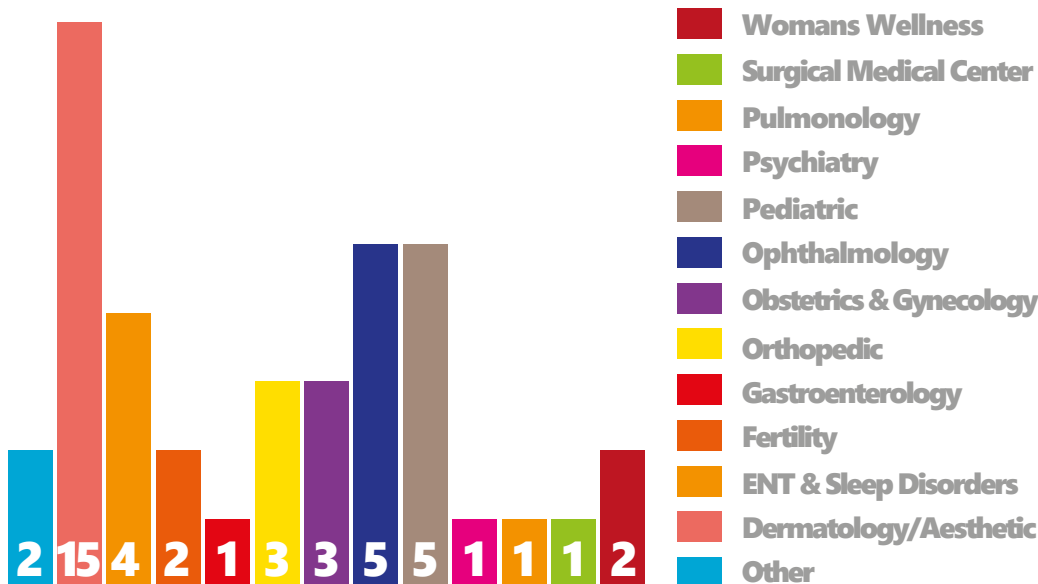


### 126 Dental Healthcare Facilities:



Dental Hospital - 2  
 Dental Center - 79  
 Dental Clinic - 28  
 24 hr Dental Clinic - 1  
 Dental Lab - 16

## Distribution of Specialized Medical Centers



## Clinics:

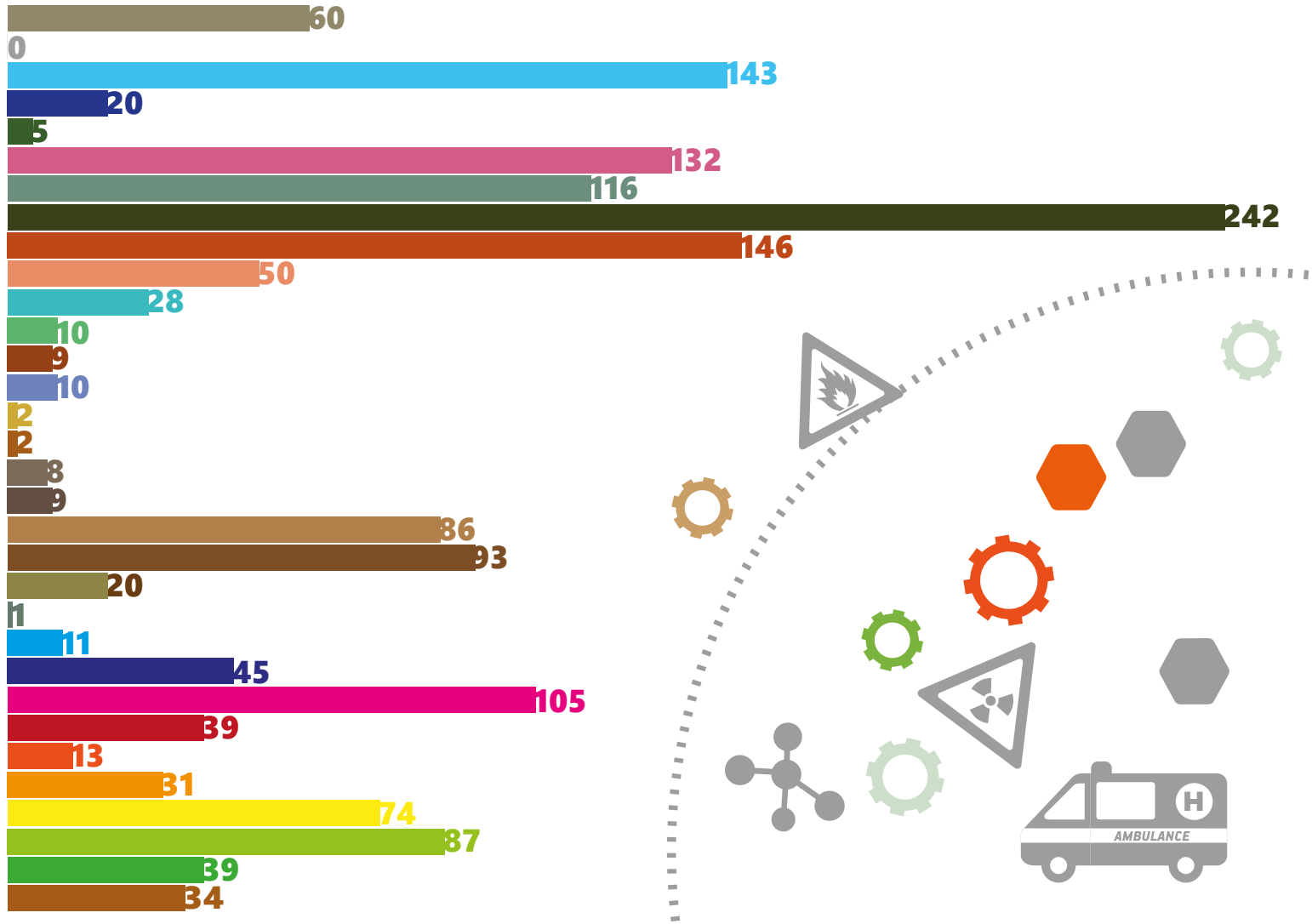
**171**

Registered Private Clinics

99 Medical Clinics  
 46 Part Time Clinics  
 26 Dental Clinics



# Types of Violations Identified During Inspection Visits



- |                         |  |  |
|-------------------------|--|--|
| No violations           | Unlicensed allied                              | Patient/Human safety                                 |
| Contract                | Unlicensed nurses                              | Laundry  |
| Sterilization           | Previously stamped transcripts                 | Facility License Expiry                              |
| Medicine Expiry         | Previously stamped periscription               | Patient Privacy                                      |
| Unregistered Medicine   | Operation theatre Design                       | Environmentally friendly for disabled                |
| Medicine storage        | Housing connected to facility                  | Sign Boards  |
| Waste Storage           | Fire Safety                                    | Supreme Council of Environment on X-ray leakage test |
| Infection Control       | Building Maintanance                           | Ensuring security of doctor stamp                    |
| Device Maintenance      | Ambulance/contract                             |  |
| Patient Records Storage | Narcotic discrepancies                         |  |
| Patient Records Notes   | Practise license & advertisement discrepancies |  |
| Unlicensed Medics       | Storage of Tools                               |  |





**Pharmacy  
Regulations**

## **Pharmacy Licensing**

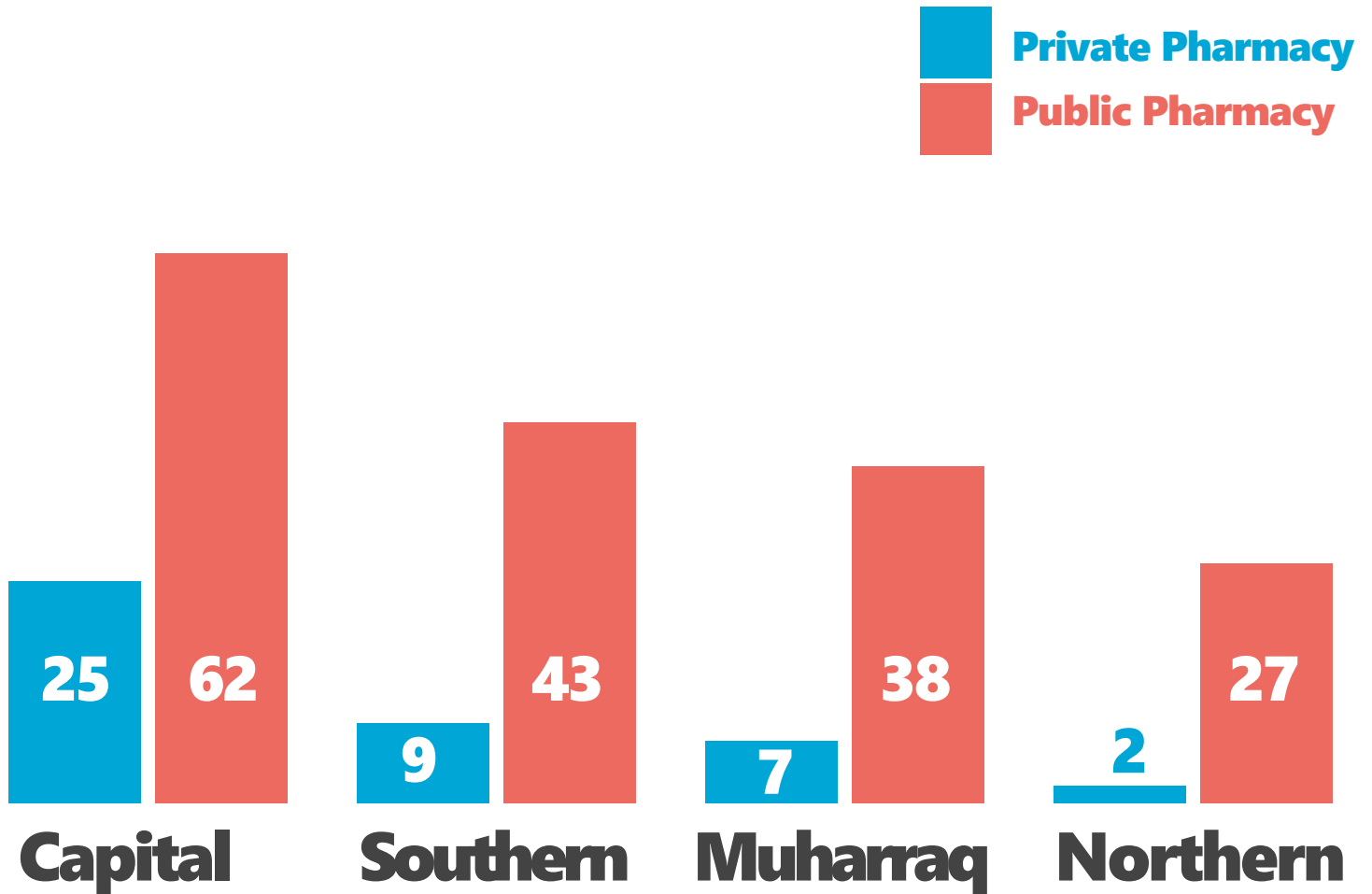
The number of licensed pharmacies has increased from 188 in 2016 to 213 pharmacies in 2017; this increase could be attributed to amendments in the pharmacy law which has permitted the pharmacies to open up to 5 branches and for non-pharmacists to be able to invest in opening pharmacies.

The following infographics demonstrate pharmacy statistics in 2017.

# Pharmacy Licensing and Inspection Activities

**213** Total Number of Licensed Pharmacies:

**43 Private Pharmacies** **170 Public Pharmacies**



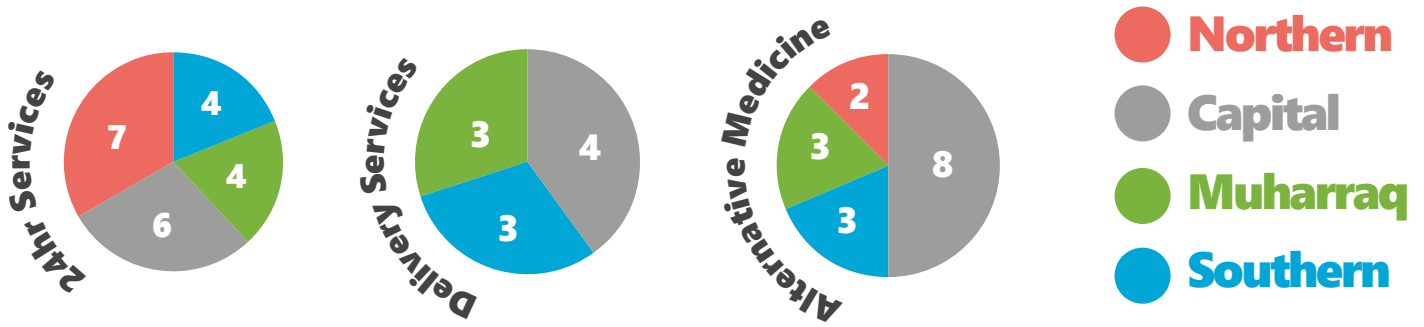
Approvals Issued to facilities for:

**4** Preparation rooms

**4** Change in activities from retail to import pharmacy

**1** Change in activity from import to retail pharmacy

# Geographic Distribution of Public Pharmacies



Inspection visits carried out in 2017

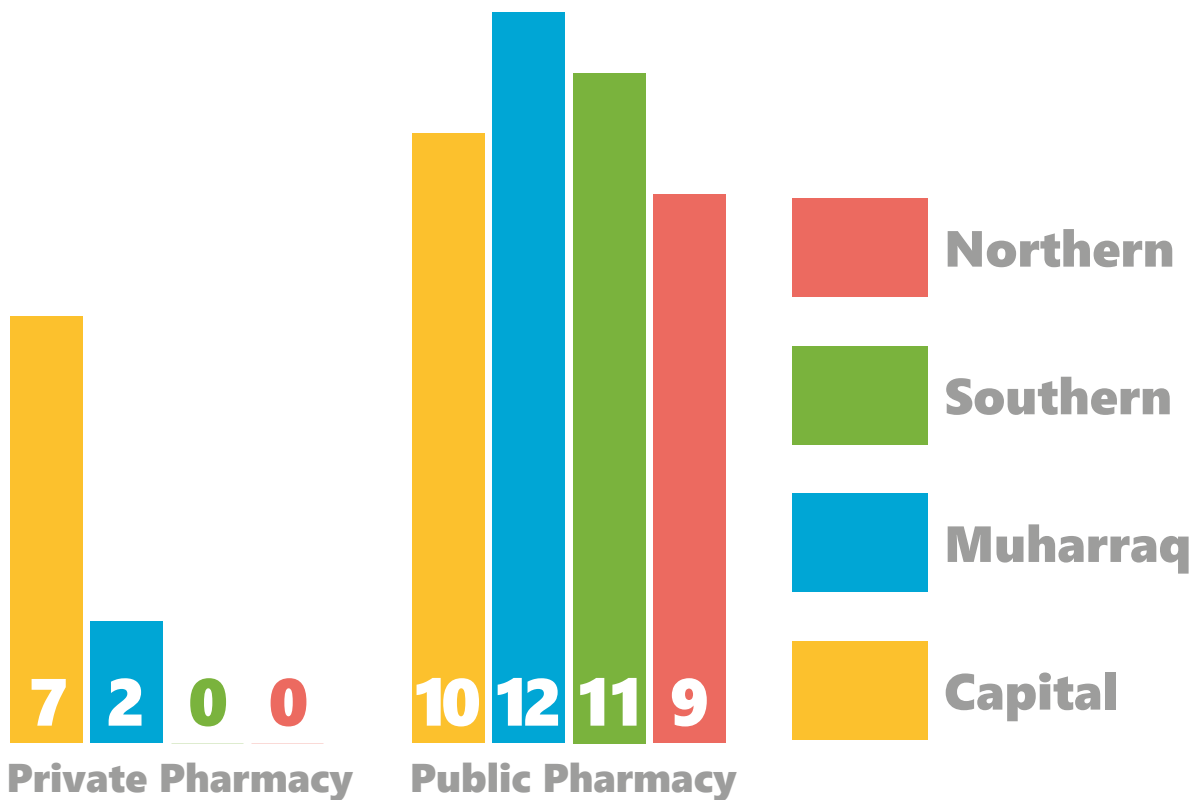
# 791

Types of **Violations** Identified - **118**

- 24 Medicine Violation
- 34 Licensing Violation
- 15 Pharmacy Set-Up Violation
- 38 Temperature/Humidity / Fridge Violation
- 7 Price Violation

## Licensing Activities

Licenses issued to **51** new pharmacies



## Department Activities:

Quality control assessment for 34 Laboratories in the Kingdom of Bahrain.

Medical Waste Management in Private Healthcare- Regulation, Transformation and Process.



**Health Care  
Professional  
Regulations**

## **Professional Regulations**

In 2017, the NHRA saw the number of registered healthcare professionals increase to 28,466 from 23,987 in the previous year. These professionals consisted of 6,131 doctors, 1,098 dentists, 14,395 nurses, 1,887 pharmacists and 4,550 allied healthcare professionals.

Pursuant to the decision of the Supreme Council of Health to link the renewal of licenses of healthcare professionals to continuing professional development (CPD), the authority approved 3,022 training programs, including conferences, workshops, scientific forums and lectures. In addition, the NHRA has approved 12 new clinical trials in the private and public sectors.

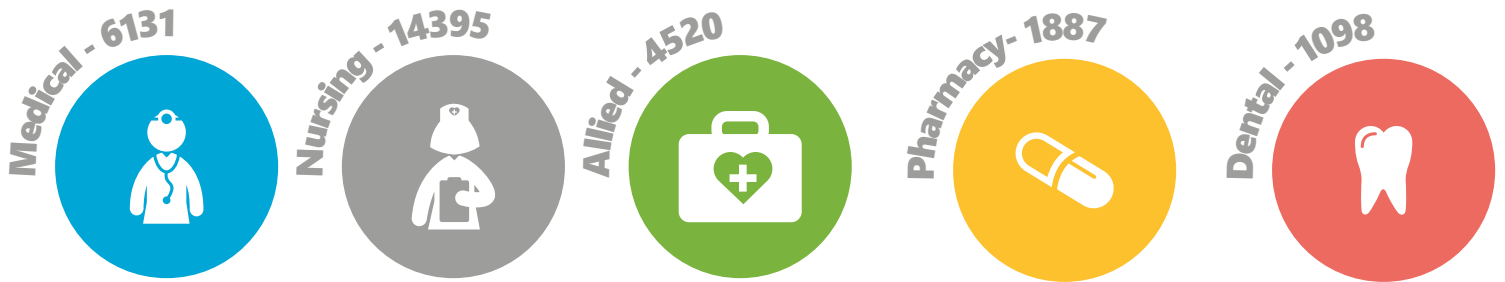
The following infographics demonstrate Professionals statistics in 2017.

# Healthcare Professionals Regulation

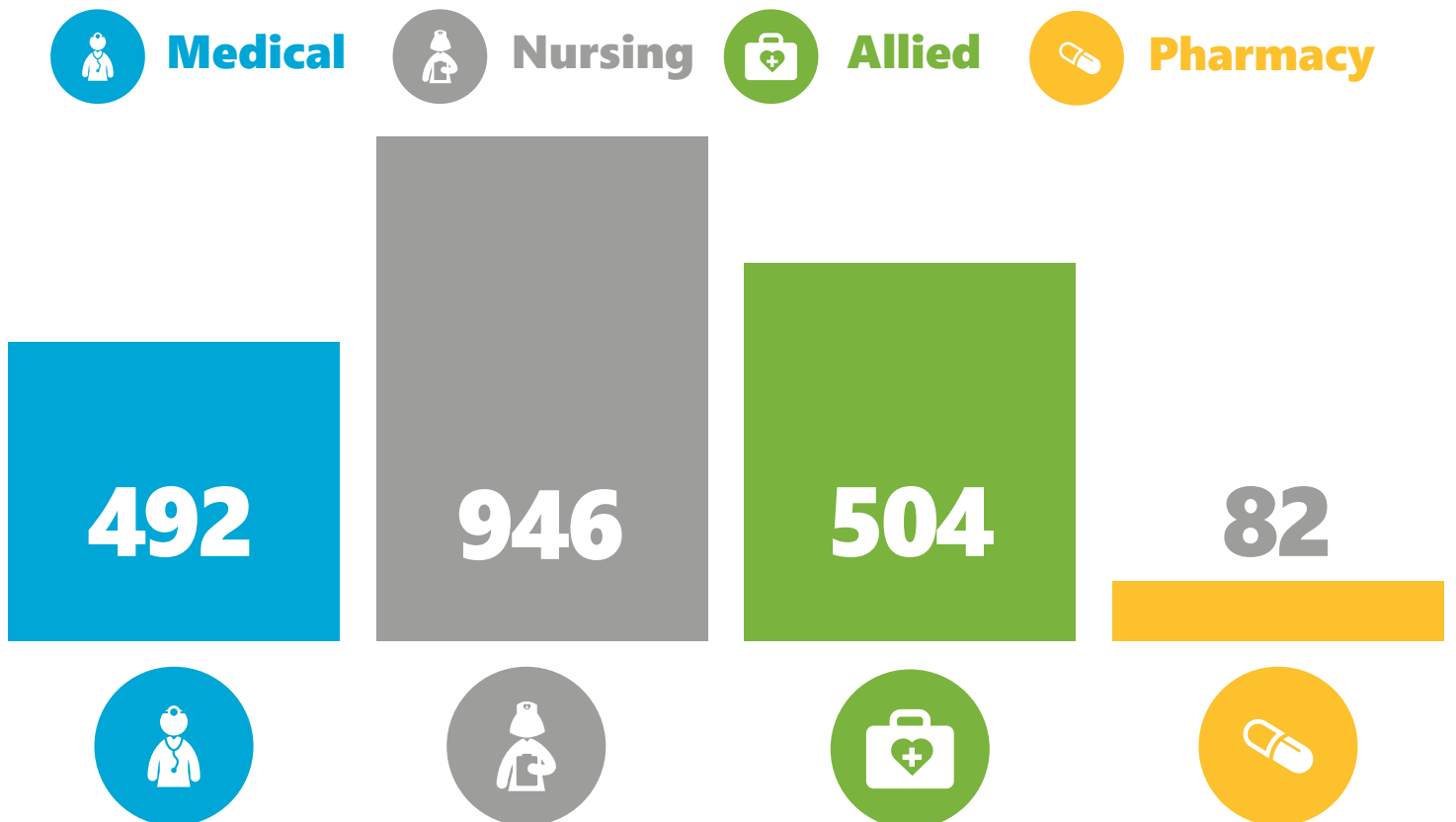
Total number of Healthcare Professionals Registered in the Kingdom of Bahrain:

# 28,031

## Distribution of Registered Professionals in the Kingdom of Bahrain



## New License Applications Processed





## NHRA Registered Physicians by Professional Category

Consultant

1125

Specialist

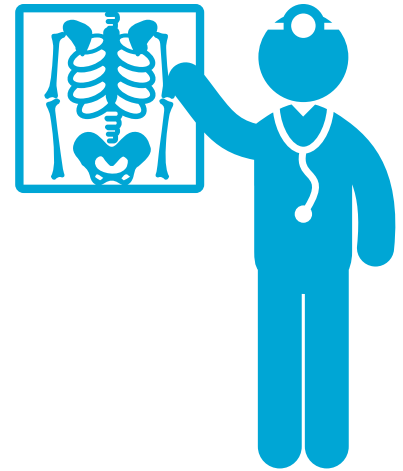
694

General

4282

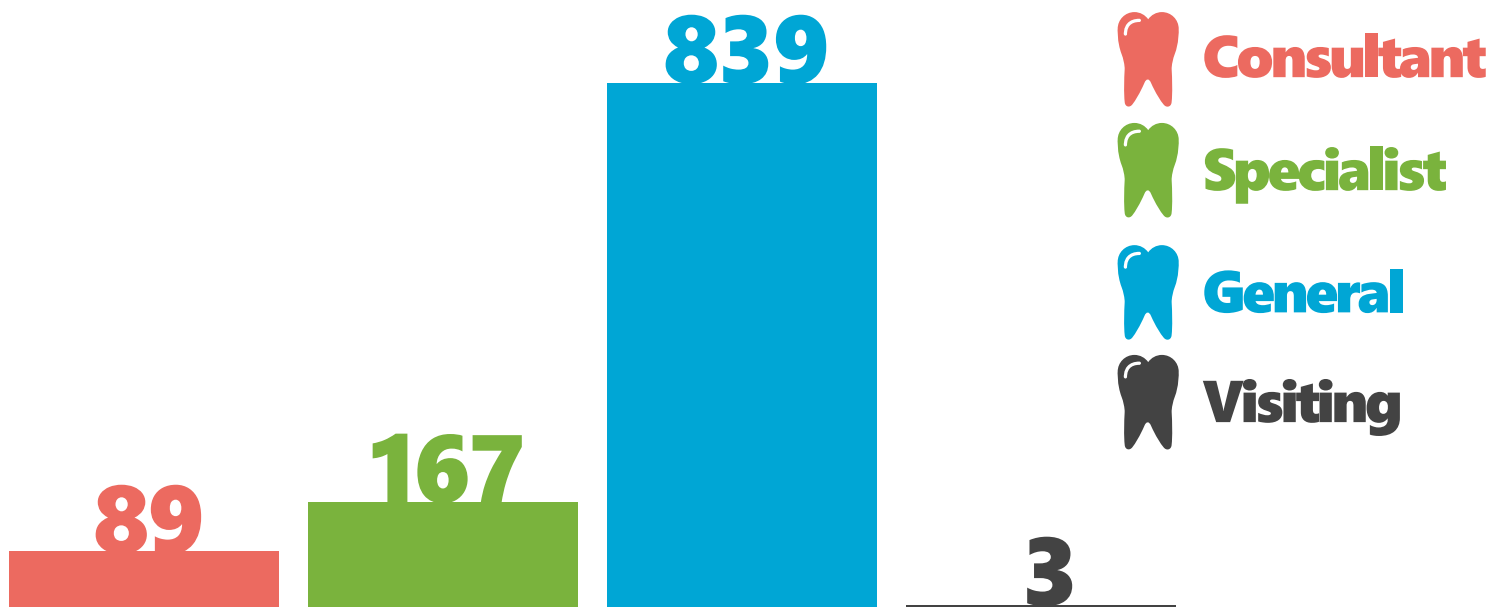
Visiting

30



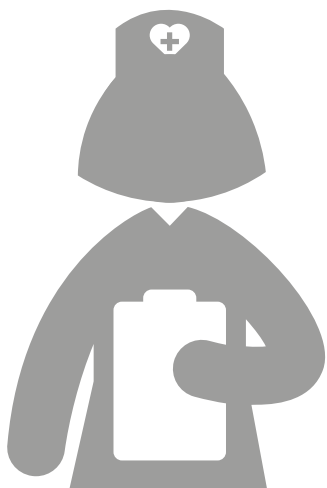
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## NHRA Registered Dentists by Professional Category



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## NHRA Registered Nurses by Professional Category



Practical

205

Midwife

322

Specialist

262

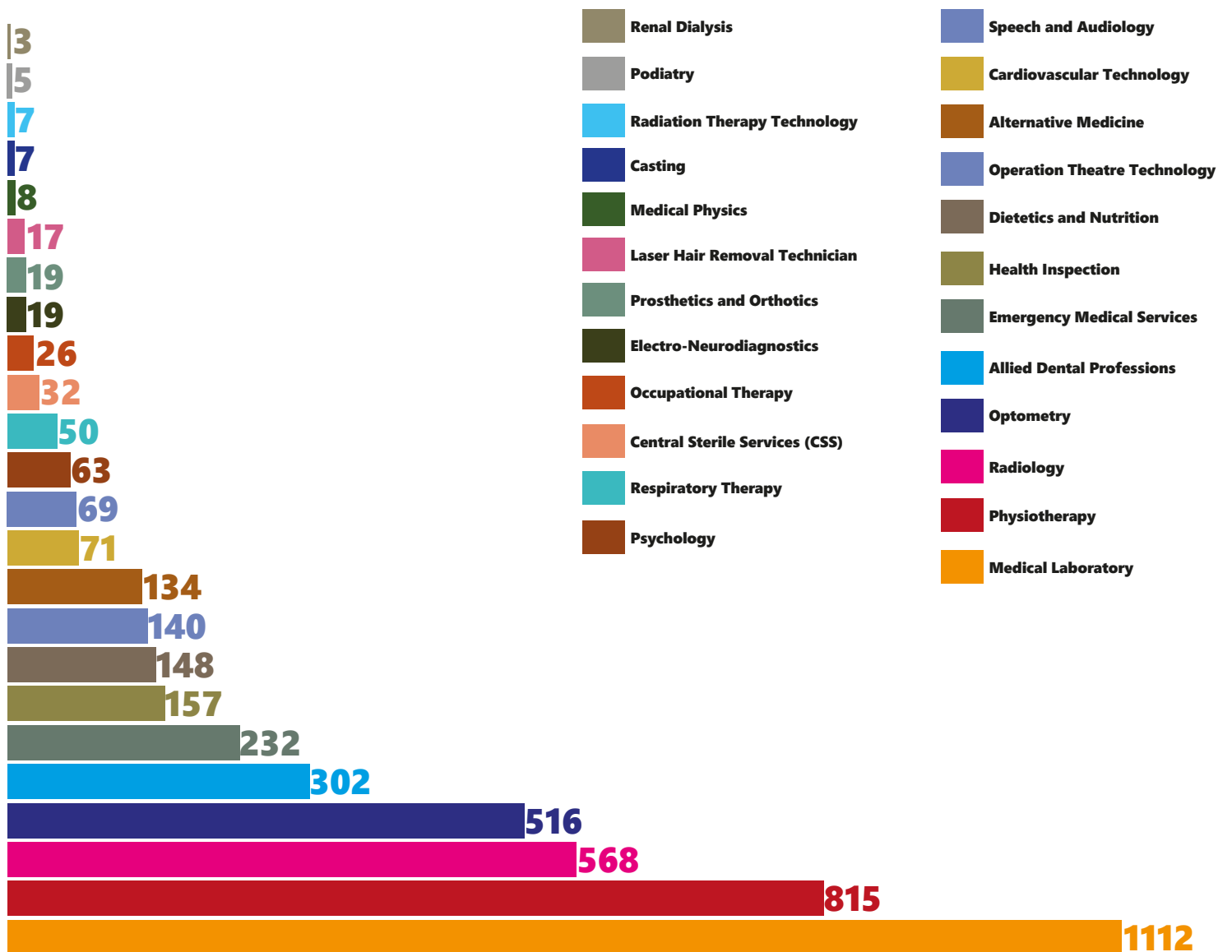
General

13605

# NHRA Registered Pharmacists by Professional Category



## NHRA Registered Allied Health Professionals



## Healthcare Professional Regulations Department Achievements in 2017

- 3 Medical Licensure Examinations (361 candidates)**
- 3 Dental Licensure Examinations (130 candidates)**
- 3 Nursing Licensure Examination (374 candidates)**
- 2 Pharmacy Licensure examinations (49 candidates)**
- 3 Optometry Licensure Examination (16 candidates)**





**Pharmaceutical  
Regulations**

## **Pharmaceutical Products Regulations**

The total number of drugs registered at NHRA has reached 3760 drugs, 311 CAM products and 729 health products.

In 2017, the Supreme Council of Health issued Resolution 41 for the implementation of a track and trace system for supply chain of medicines in the Kingdom of Bahrain. This resolution states that it is mandatory by December 2019, for all the medications entering Bahrain to have the Two-Dimensional Barcode printed on the packaging of the product in accordance with the standards set by Global Standards One (GS1).

The barcode shall contain the following:

1. The Global Trade Item Number (GTIN) of the Medicine.
2. The expiry date of the Medicine.
3. The batch number.

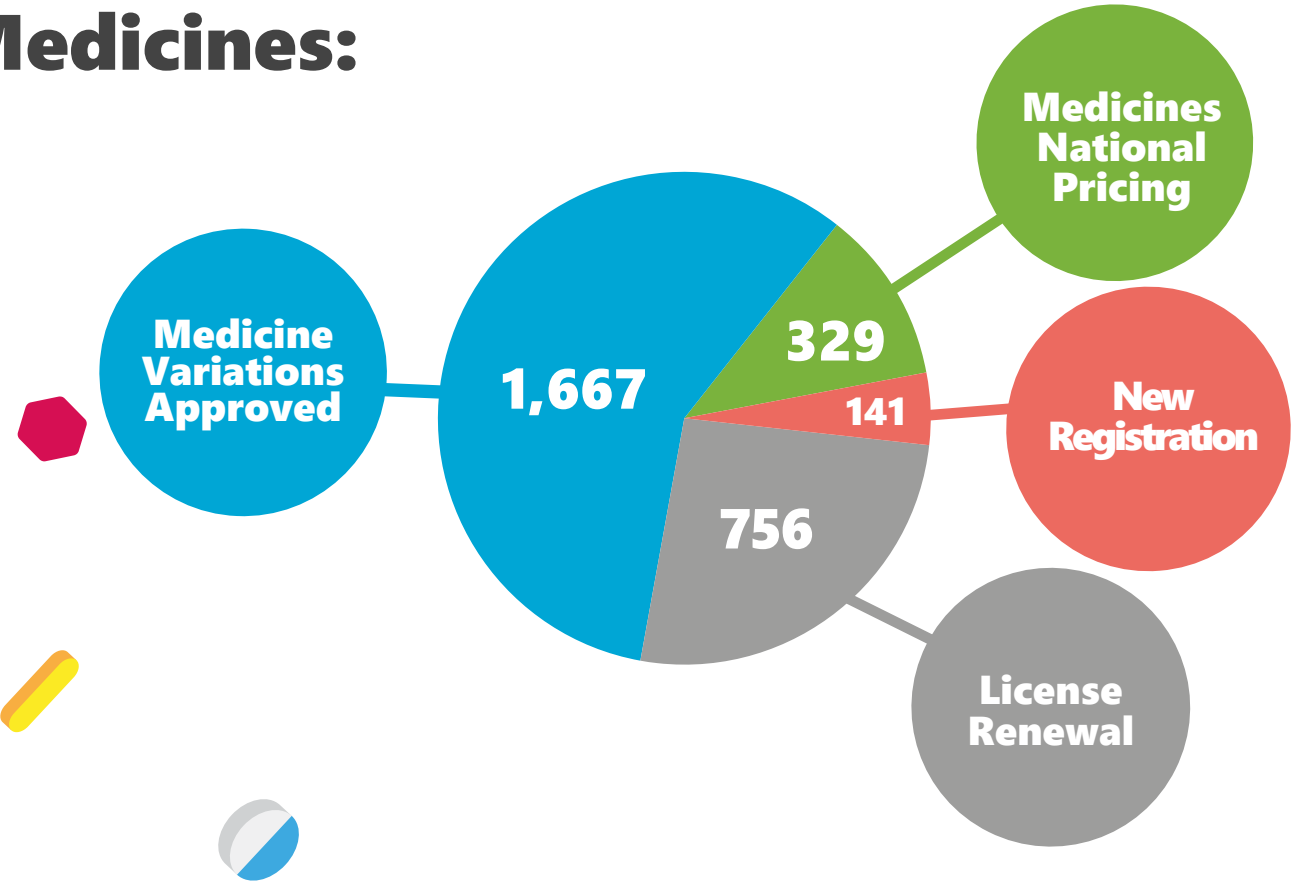
The following infographics demonstrate pharmaceutical statistics in 2017.

# Pharmaceutical Products Registration

# 3760

Total Number of Medicines Registered in the Kingdom of Bahrain.

## Medicines:



Pre-Approval Applications Processed

# 4498

Invoices (approximately) Processed:

# 14,200

Temporary Importation of Non Registered Products

# 2,120

Pharmaceutical Products Classification

# 351

International Manufacturing Sites Registration

# 88

# Alternative/Complementary Medicines



**Total Number of Alternative Medicines Approved in the Kingdom of Bahrain: 311**

**New Alternative Medicines Applications Processed: 77**

---

## Health Products:

**New Registration**

**111**

**Licenses Renewal**

**50**

**729**

Total Number of Health Products Registered in the Kingdom of Bahrain

A circular graphic featuring a ring of colorful capsules (yellow, red, blue, green) around the perimeter. The number '729' is prominently displayed in the center in a large, bold, blue font. The text 'Total Number of Health Products Registered in the Kingdom of Bahrain' is written along the inner curve of the capsule ring.

# Electronic Common Technical Document (eCTD)

- Interface for the Pharmaceutical Industry to Agency Transfer of Regulatory Information

Baseline Importation Status of applications

# 98%



**Staff Educated and Continuously Developed Through the Following Activities:**

- 1 eCTD Implementation Training**
- 2 Health Products and Supplements Workshop**
- 3 Biosimilars Workshop**
- 4 Alternative Medicines Workshop**
- 5 Pharmacoeconomics**
- 6 Detecting Counterfeit Medical Products**
- 7 Homeopathic Conference**





**Medical  
Device  
Regulations**



## **Medical Devices Regulations**

The NHRA received 8178 applications for medical devices licenses, of which 6861 were approved. The remaining applications were rejected due to various violations such as counterfeit certificates or device.

The total cost of the approved devices was 24,841,633.13 BD.

The following infographics demonstrate medical device statistics in 2017.

# Medical Devices Licensing

# 8178

total number of new medical device applications assessed

**6861** Total Approved

**1317**

**Medical Device**  
(Ofog - Online Application)

**Combined Medical Device**  
(Manual Application)

6648

X  
1247

213

X  
70

## Types of Medical Device Violations Identified

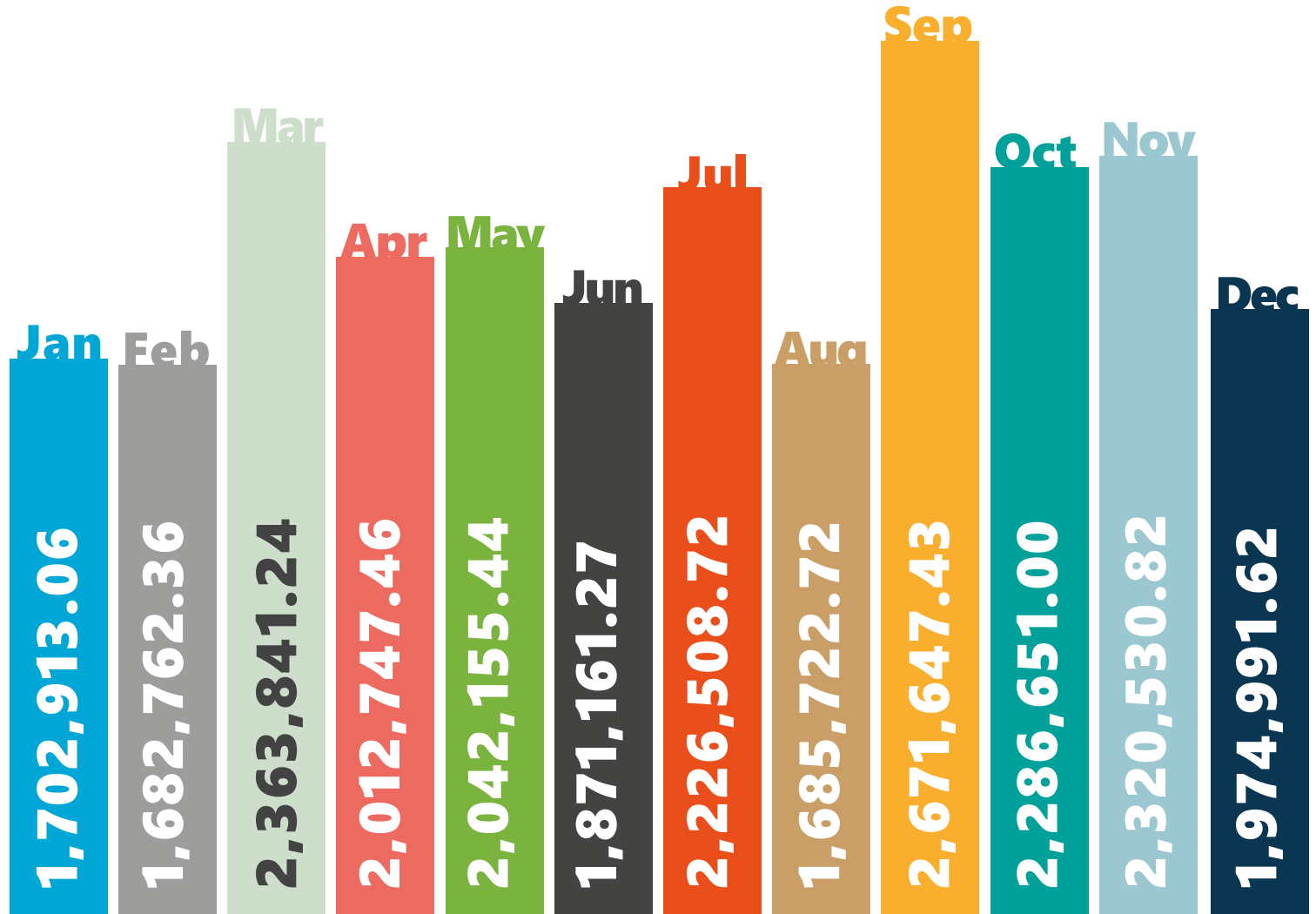
**24**

- 20 Counterfeit Certificate
- 2 Counterfeit Device
- 2 Counterfeit Instrument

## Total Value of Medical Devices Imported:

# 24,841,633.13 Bhd

## Total Value (Bhd) of Shipments by Month



**VALUE Bhd**

## Department Achievements:

1. Membership in the ISO international committee (ISO/TC 106, ISO/TC 150, ISO/TC 170, ISO/TC 194, ISO/TC 198, ISO/TC 198/WG8, ISO/TC 198/WG13, ISO/TC 198/WG14, ISO/TC 210).
2. Membership in the GCC central registration
3. Hosted TC11 GSO meeting
4. Proposed classification criteria of medical devices to GCC



## **Regulating Alternative and Complementary Medicine (CAM)**

The regulation of Alternative and Complementary Medicine (CAM) practices by resolution 33 for 2016 had lead to the registration of 13 CAM centers in Bahrain. These centers offer various CAM services such as Ayurveda, Cupping, Chiropractic, Homeopathy, Naturopathy and Chinese Medicine.

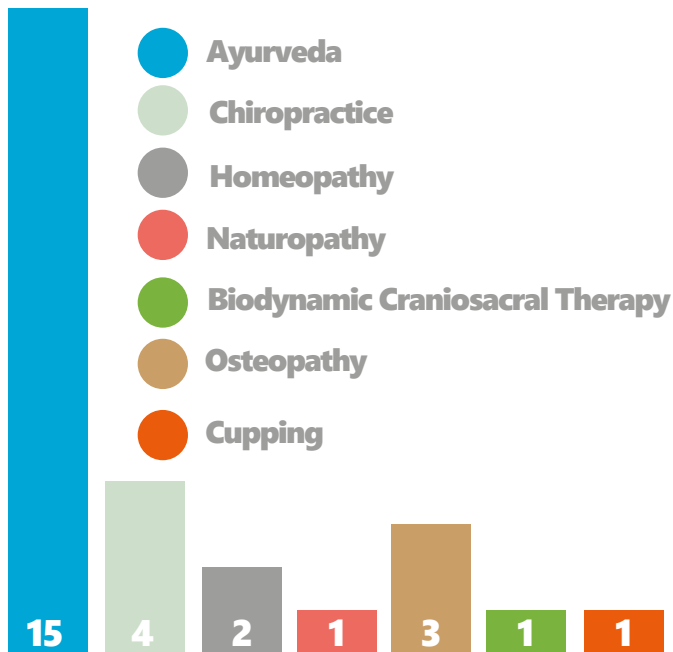
The following infographics demonstrate CAM statistics in 2017.

# Alternative Medicine

## Applications Referred From Healthcare Professionals Department:



### Licensed Alternative Medicine Practitioners by Specialty



### Licensed Alternative Medicine Technicians by Services Provided



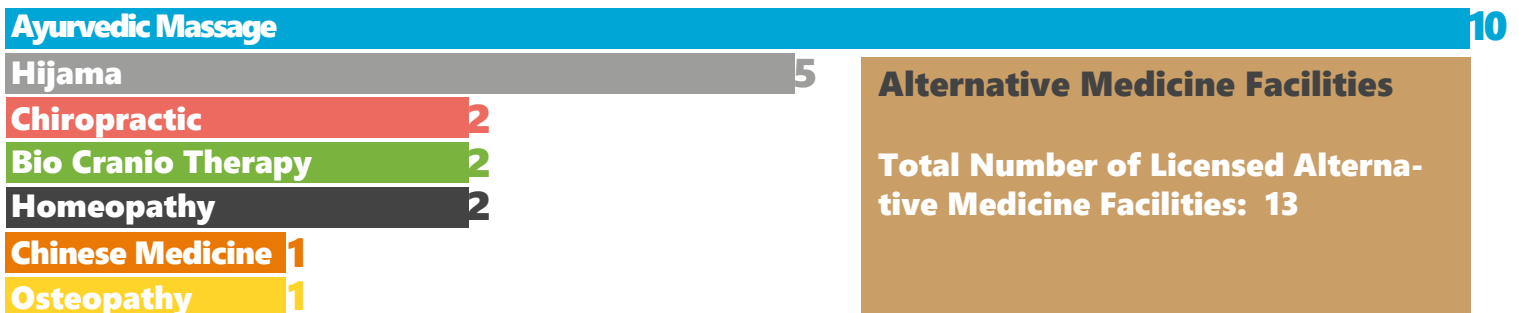
### New Applications for Alternative Medicine Professionals

**Total Number for Alternative Medicine Physicians License: 1**

**Total Number for Alternative Medicine Practitioners License: 19**

**Total Number for Alternative Medicine Technicians License: 33**

## Types of Alternative Medicine Services Available in the Kingdom of Bahrain



### Alternative Medicine Facilities

**Total Number of Licensed Alternative Medicine Facilities: 13**

**New Applications for Alternative Medicine Facilities: 11**

**Total Number of Alternative Medicine Products Approved: 311**



**Continuous  
Professional  
Development  
& Clinical Trial  
Regulations**

## **Continuous Professional Development and Clinical Trials**

In pursuant of the decision of the Supreme Council of Health to link continuous professional education with the renewal of licenses for healthcare professionals, the Authority approved 3,022 continuing professional development training programs. These programs included conferences, workshops, scientific forums and lectures. In the area of clinical trials, the Authority has reviewed and made judgement on 12 clinical trials in the private and public sectors.



# Approving Continuing Professional Development Programs

# 3022

Approved CPD Activities in 2017

Distribution of Approved CPD

**52%**  
Government

**48%**  
Private

## Types of Approved CPD Activities



# Distribution of Approved CPD Activities According to Speciality

**121** Dentistry

**82** Nursing

**63** Internal Medicine

**54** Cardiology

**53** Pharmacology

**52** Pediatric

**51** Infection Control & Prevention

**46** Orthopedic

**37** BLS, ACLS & PALS

**34** Health Care Quality

**34** Emergency Medicine

**32** Health Care Accreditation

**31** Physiotherapy

**31** Obs & Gyn

**31** Endocrinology & Diabetology

**30** Urology

**30** G. Medicine

**29** Pulmonology

**28** Neurology

**28** General Surgery

**27** Primary Health Care

**27** Patient Safety & Management

**25** Ophthalmology

**24** Radiology

**21** Health Care Management

**18** Forensic Medicine

**16** Oncology

**16** E.N.T

**14** Laboratories & Pathology

**13** Dermatology

**12** Rheumatology

**12** Hematology

**9** Psychiatry

**9** Inspection for Health facilities

**7** Nutrition

**6** Plastic Surgery

**6** Health Research

**6** Genetic

**3** Medical Ethics

**3** Anesthesiology

**2** Sport Medicine

**2** Medical Education

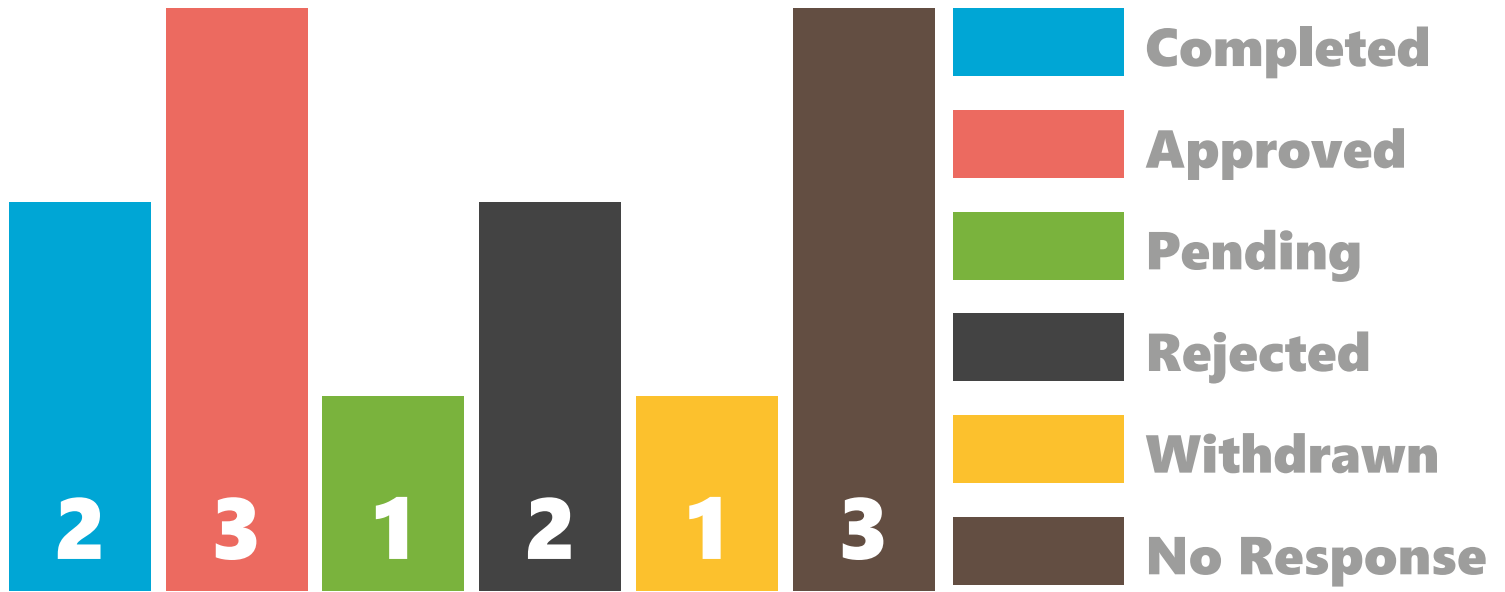
**1** Occupational Medicine



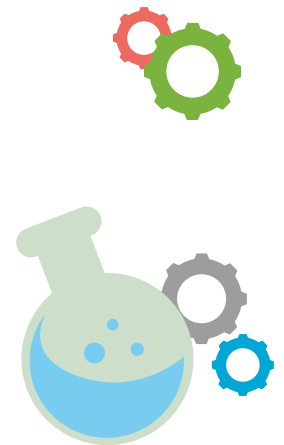
Internal Activities

**1846**

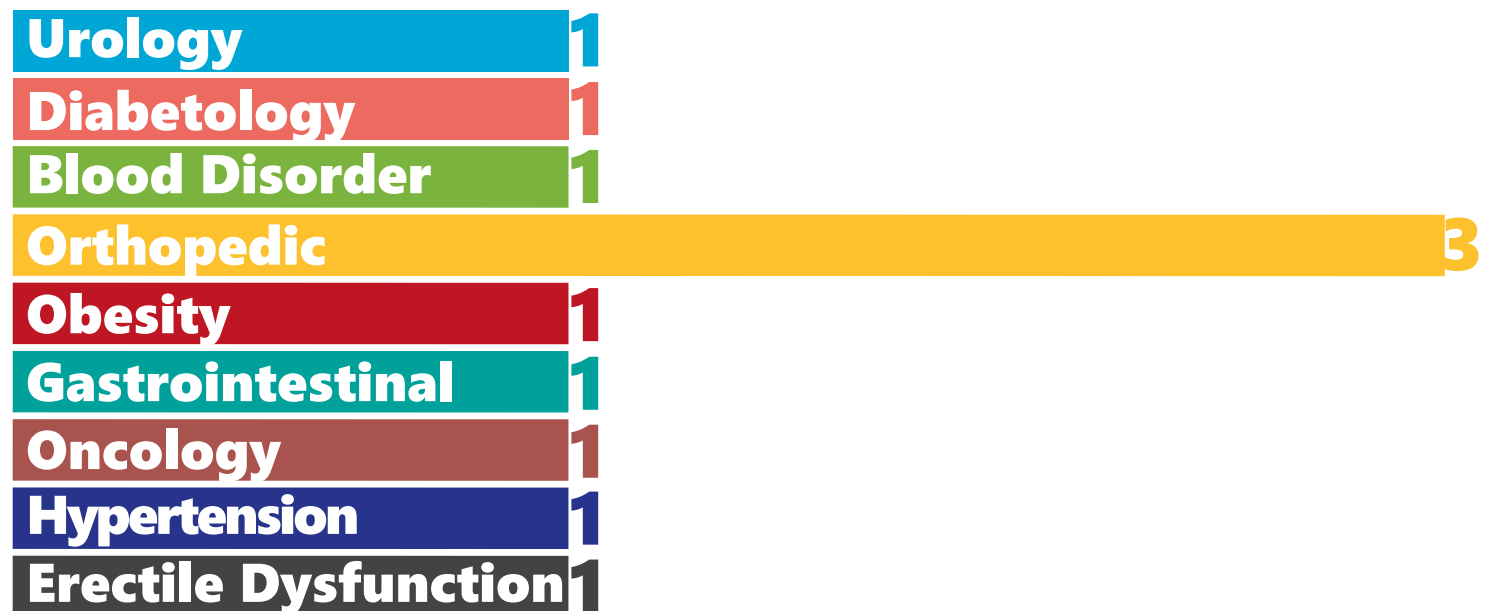
# Outcomes of 12 Clinical Trial Applications Submitted to NHRA



## Clinical Trials Submissions by Sector



## Distribution of Clinical Trials Applications by Speciality





**Medical  
Complaints**

## **Medical Complaints**

The NHRA received 237 complaints in 2017, of which 136 were direct complaints from patients and 47 were incidents reported by health facilities. There were also 52 cases which were referred by the prosecution and the courts. The breakdown of the complaints were 57% against the private sector and 42% against the government sector. In addition, 66% of the complaints were against doctors and 14% against healthcare facilities.

The NHRA completed the investigation of 118 cases of which medical error was proved in only 44 of them.

The following infographics demonstrate complaint, incidents and lawsuit cases statistics in 2017.

# Medical Complaints 2017

# 237

cases received by NHRA

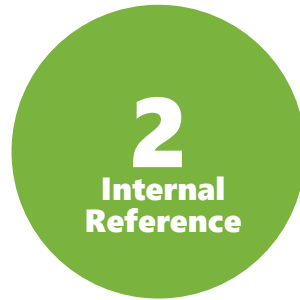
Reported from the Public



Reported by Health Care Facilities



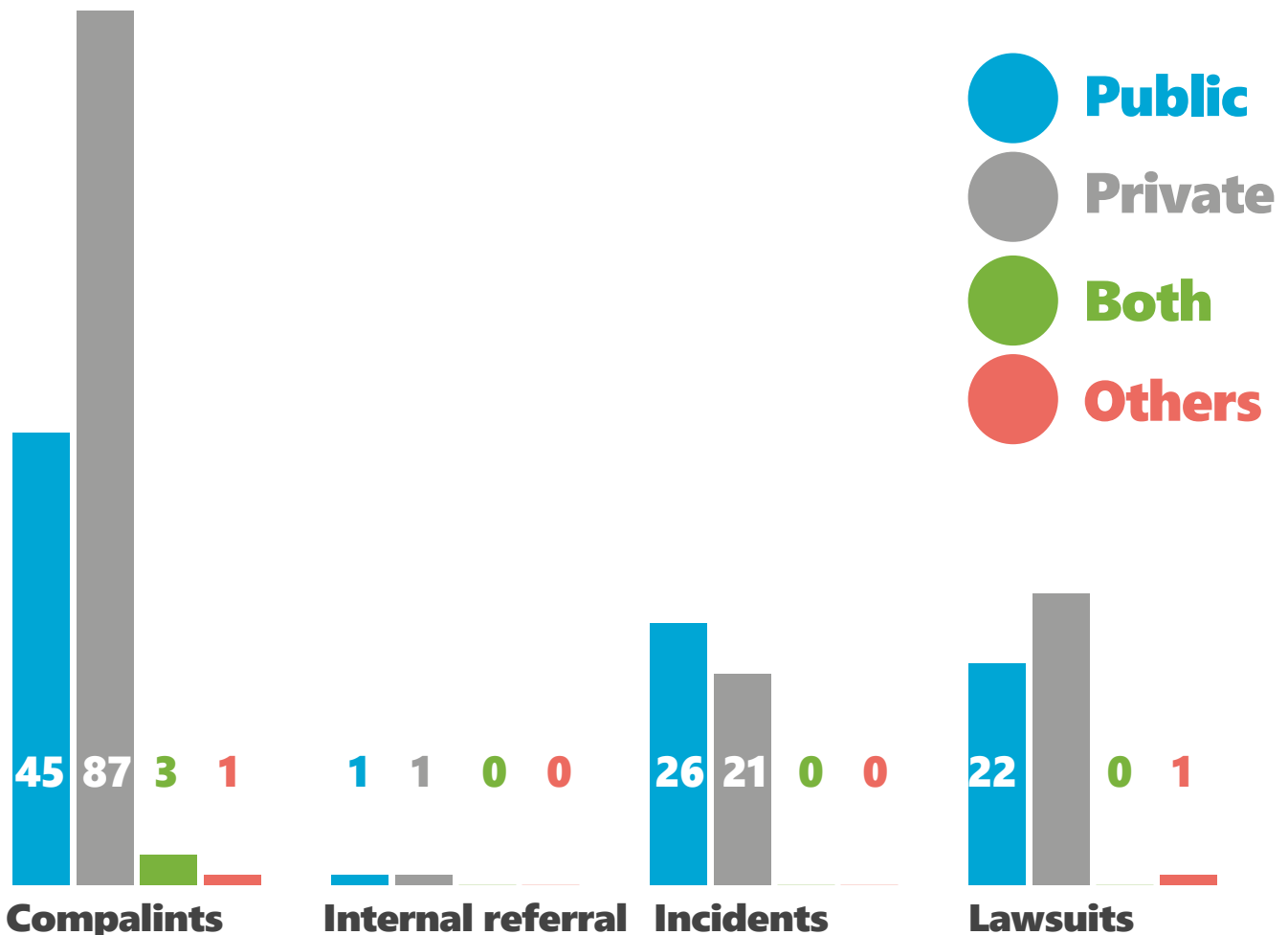
NHRA



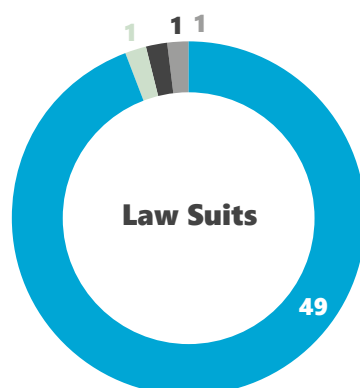
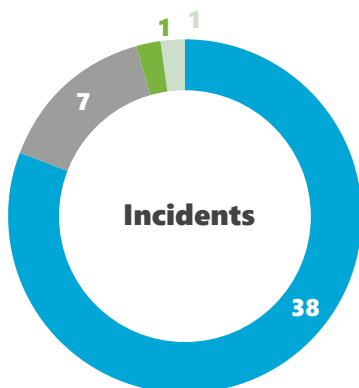
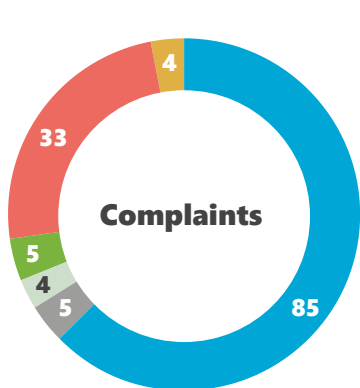
Referred by Judicial Authorities



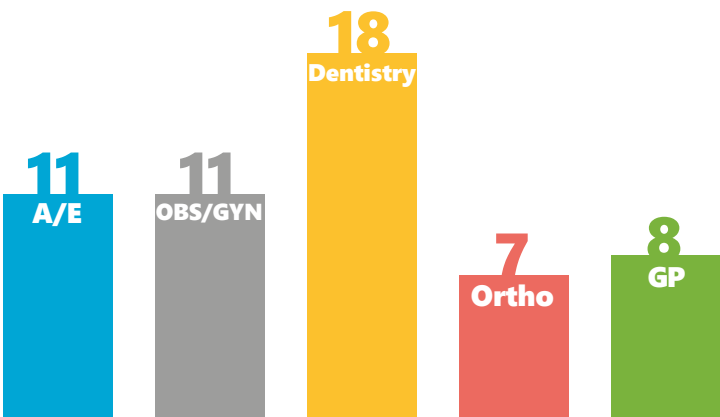
## Distribution of Complaints, Incidents and Lawsuits by Health Sector



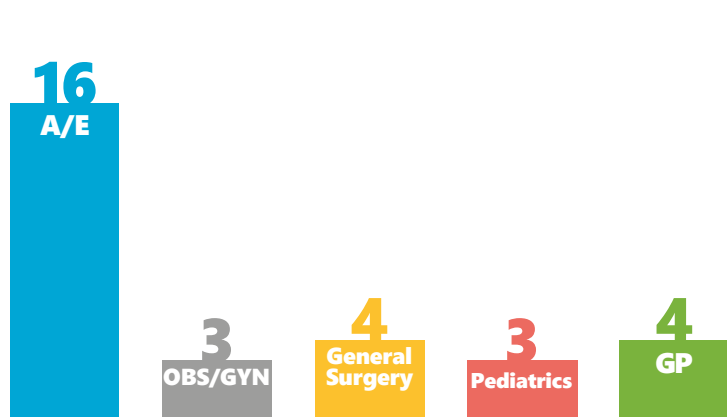
# Distribution of Complaints, Incidents and Lawsuits according to health profession



## Distribution of Complaints According to the Most Frequent Specialty



## Distribution of Incidents According to the Most Frequent Specialty



## Distribution of Lawsuits According to the Most Frequent Specialty



# Cases investigated:

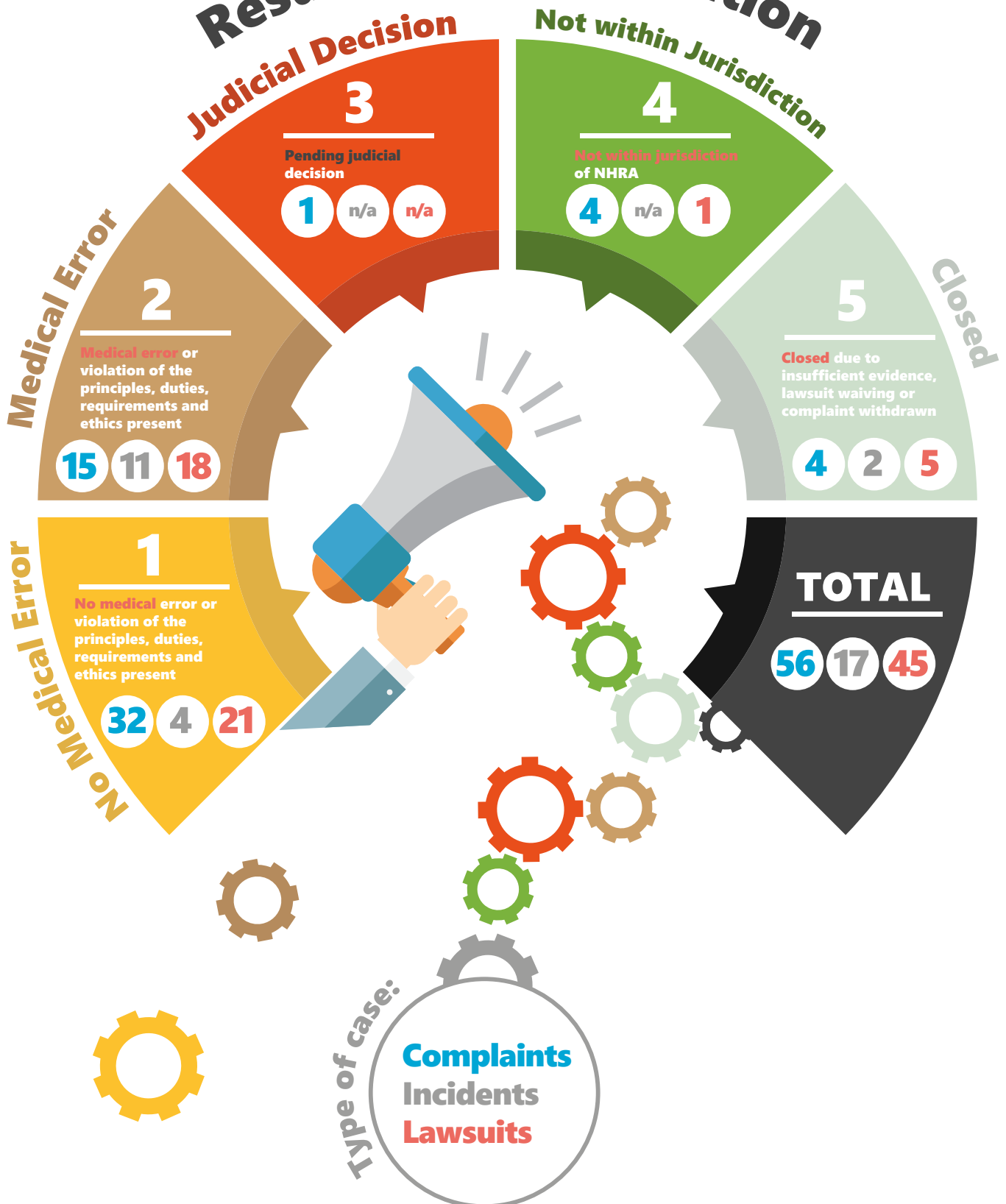
**56**  
COMPLAINTS

**17**  
INCIDENTS

**45**  
LAWSUITS

have been  
completed in  
2017

## Results of Investigation





**In 2017 a total of 66 disciplinary decisions were issued by disciplinary committees at NHRA.**

Of the **66**

disciplinary actions taken

**47** Against doctors

**15** Against nurses

**1** Against allied health professionals

**2** Against pharmacists

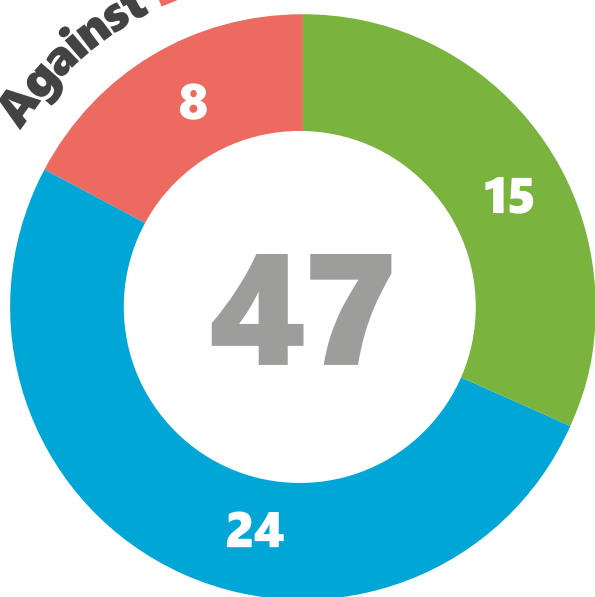
**1** Against a health facility

## Types of Disciplinary Actions taken in 2017

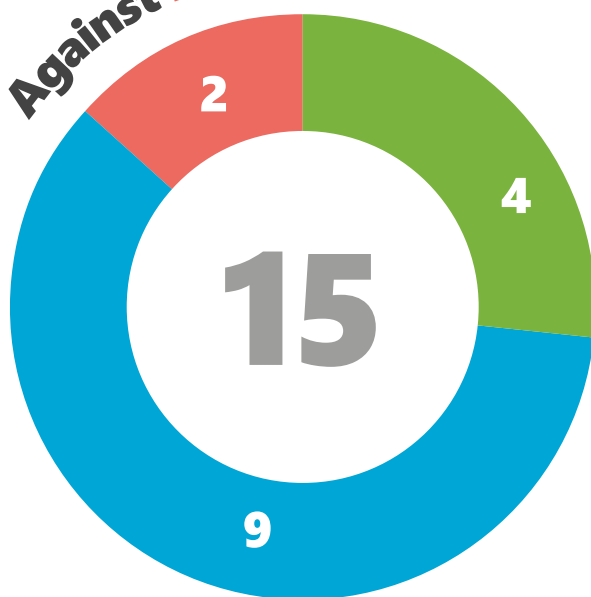
**66 Disciplinary Actions Issued:**

- **34 Suspensions**
- **21 Written Warnings Issued**
- **10 Licenses Canceled**
- **1 Financial Penalty Issued**

**Against Doctors**



**Against Nurses**



against **pharmacists**: **2** written warning  
against **allied health**: **1** suspension  
against health **facility**: **1** financial penalty

 Suspension

 Written Warning

 License Cancellation

 Financial Penalty



## Implementation of the National Accreditation Program

The journey of implementing the National Accreditation program began in November 2016 with the preparation of the legal infrastructure and detailed review of the accreditation standards. Thereafter, a rigorous training program was conducted over a span of a couple of months and our first hospital visit for accreditation was in May 2017. Since then we have successfully accredited 14 healthcare facilities.

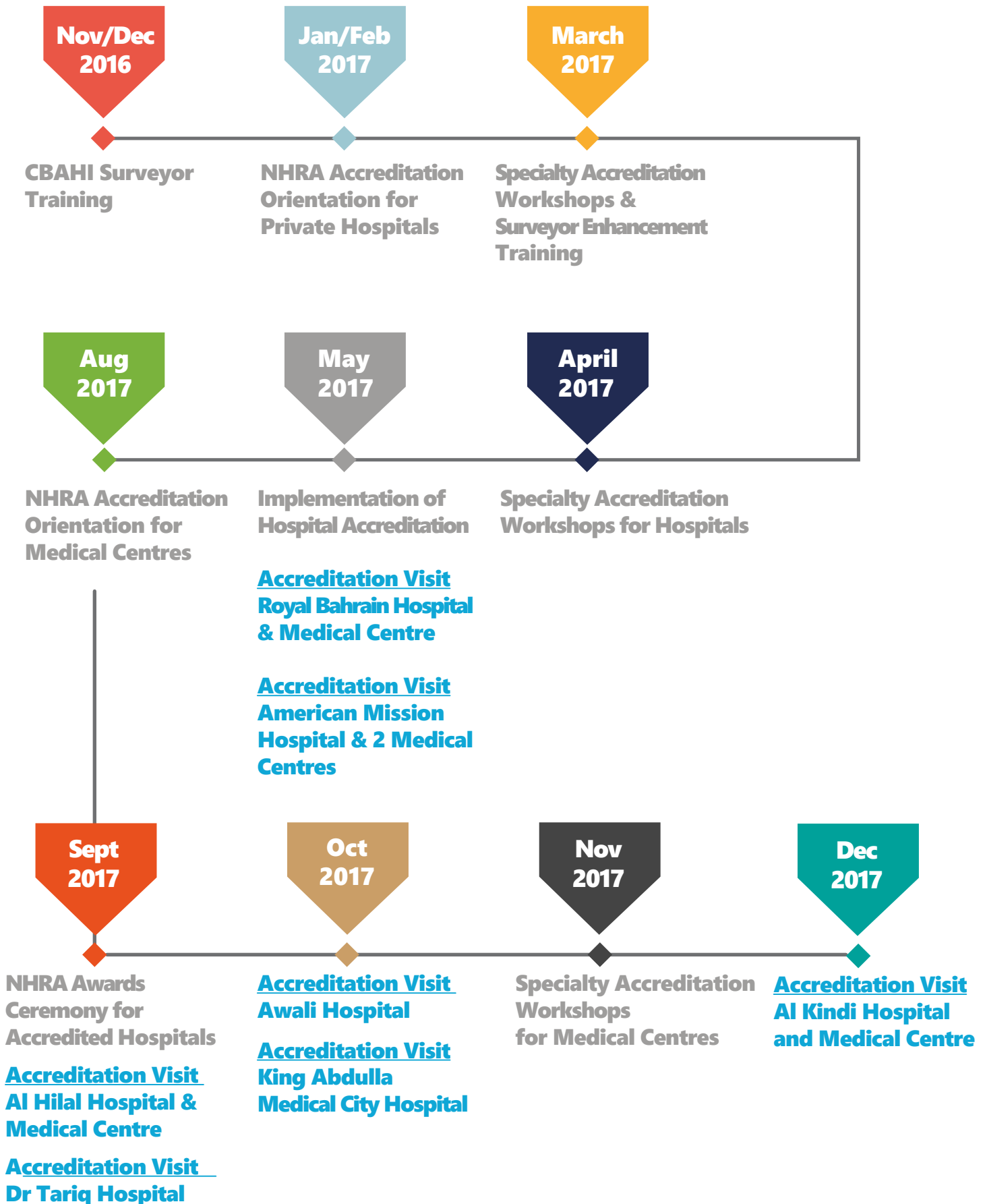
NHRA is committed to ensure the high quality of health services provided, and that these services are rigorously evaluated and continuously monitored so as to establish and maintain public confidence of the healthcare system in the Kingdom. Furthermore, we have made accreditation mandatory for all licensed healthcare facilities.

NHRA's fundamental principles for accreditation include the following:

- To support and encourage **just-culture values, attitudes** and **practices** between NHRA and healthcare facilities
- To establish a strong, effective, constructive, mutually beneficial and **on-going partnership** with all healthcare facilities
- To adopt the **peer review approach**, that entails an in-depth discussion between peers rather than a "tick-box" method of auditing/inspecting
- To encompass key areas for quality improvement by **recommending** internationally accepted **evidence-based practices**
- To ensure that the **recommendations** made will be of **added-value**, that are **contextual**, appropriate, patient-centered, feasible and cost-effective for the facility

We now should take pride in the fact that Bahrain has a successful accreditation program, one of the first in the Gulf, which is based on international standards and guidelines, yet culturally relevant to the practice of medicine in the hospitals and medical centers in the Kingdom of Bahrain.

# NHRA Accreditation Implementation Timeline



# Accreditation Activities

14

Healthcare  
Facilities  
Surveyed

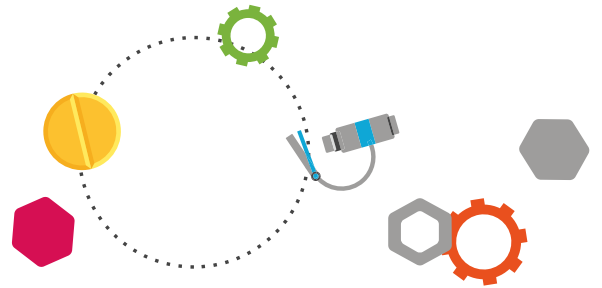
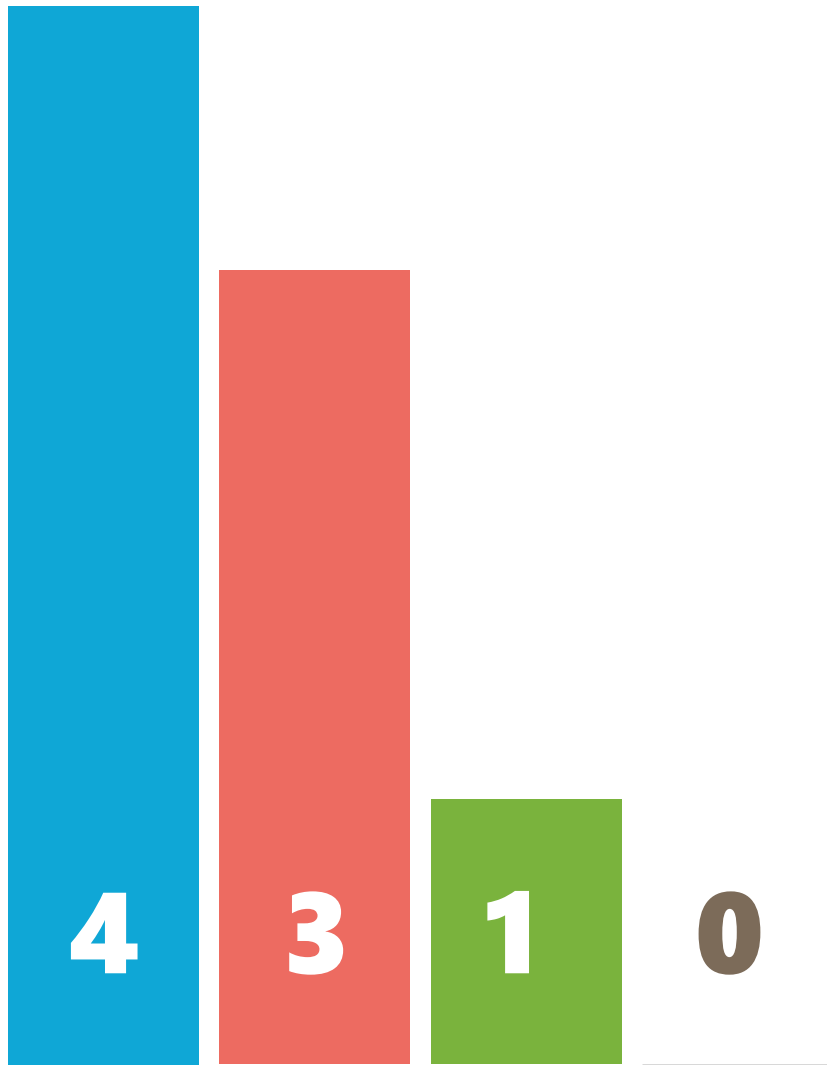
17

Accreditation  
Committee  
Meetings  
Convened

22

Accreditation  
Workshops  
Conducted  
by NHRA

## Distribution of Hospital Awards



## Distribution of Medical Center Awards

3

**Diamond**

3

**Platinum**

0

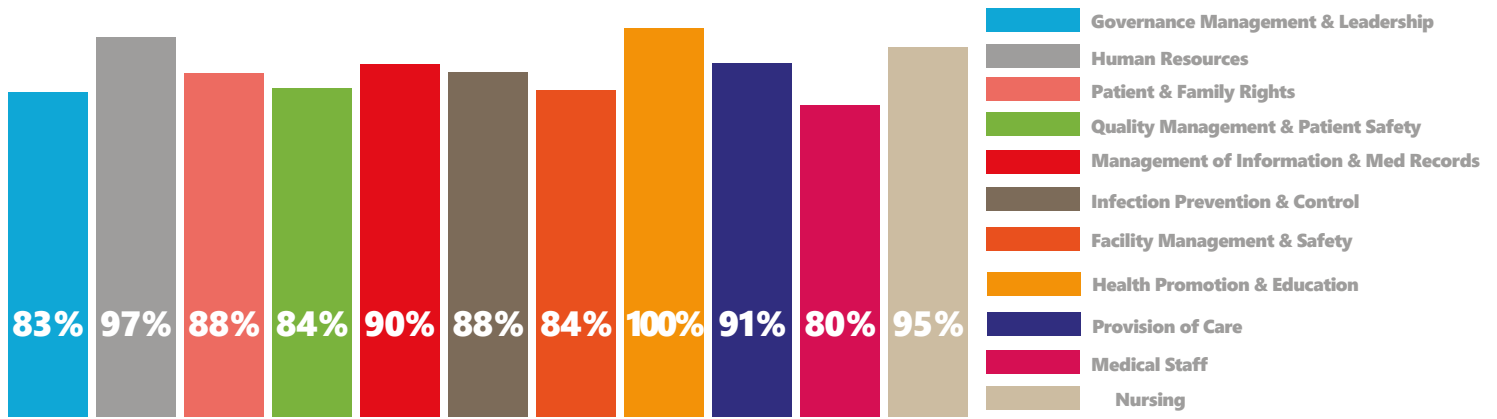
**Gold**

0

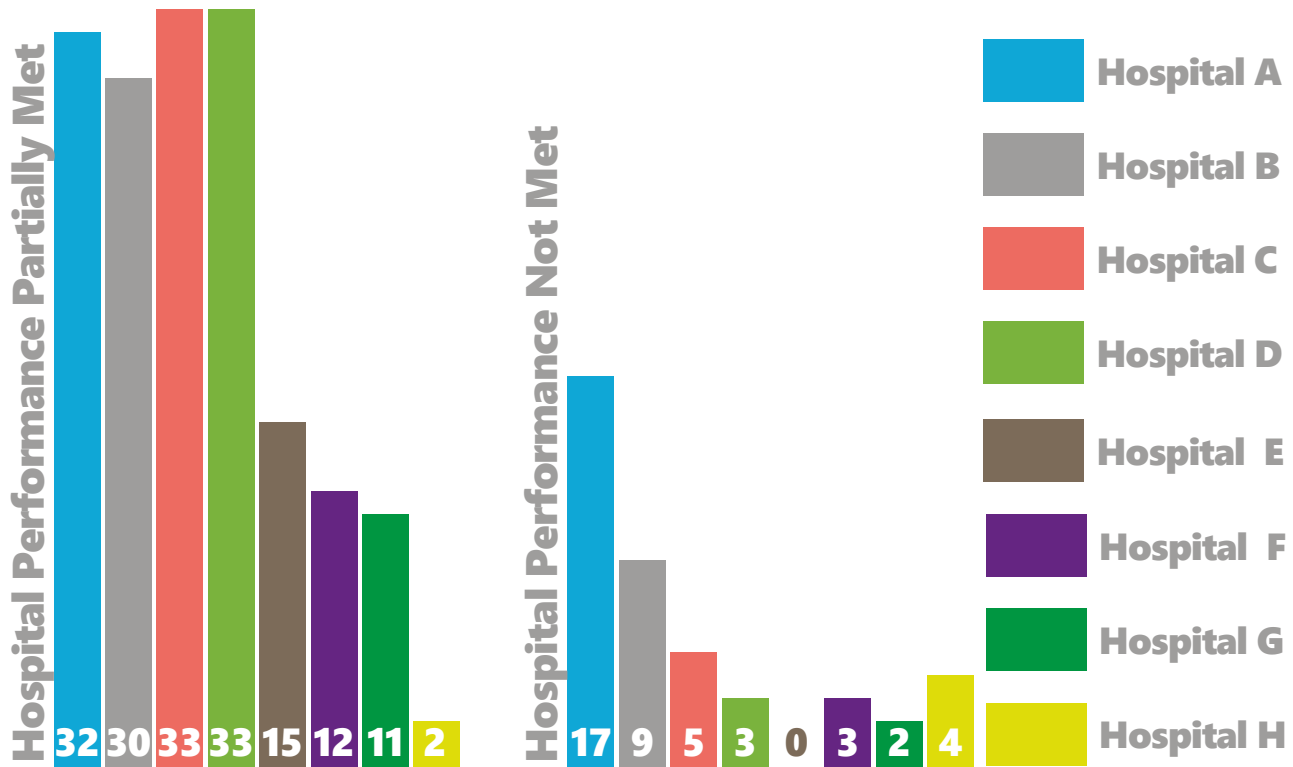
**Silver**

# Accreditation Outcome Analysis

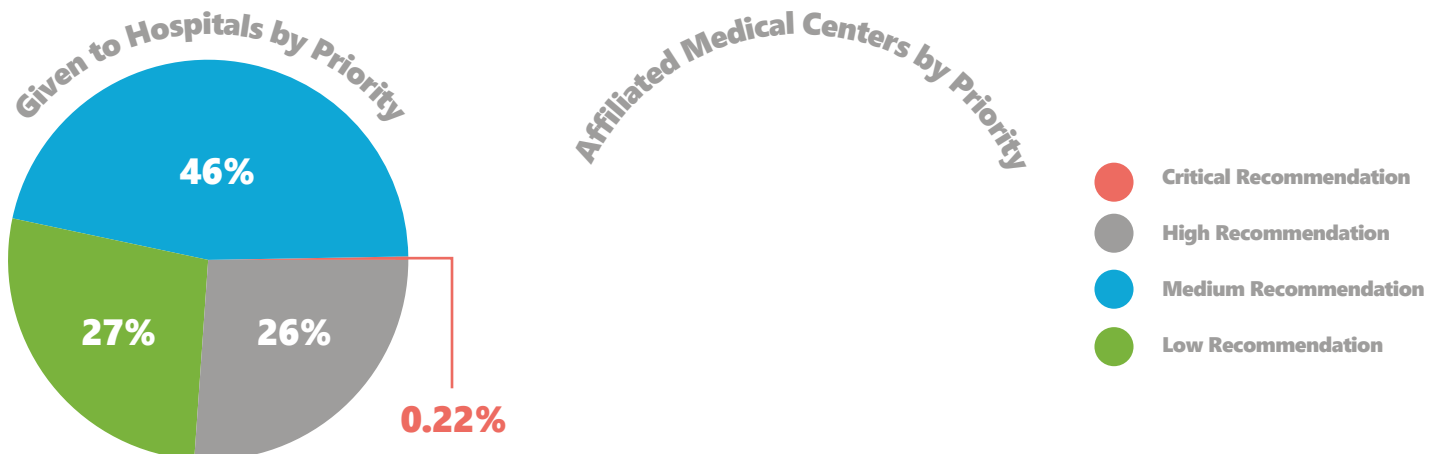
## Achievement of Core Elements



## Non Compliance Status in Private Hospitals



## Distribution of Recommendations



# Accreditation Standards Analysis

The Element with the most Not Met standards was Emergency Care

Total

6

Standard that was consistently Not Met within the element was the requirement of a Consultant Head of Emergency Department

Total

5

The Elements with the most Partially Met standards were:

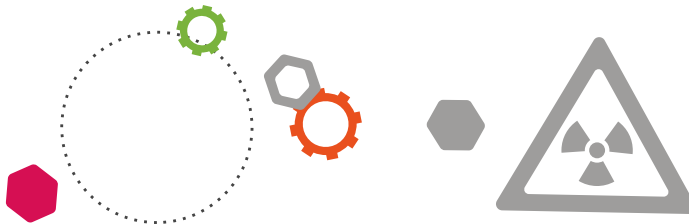
Governance

Management & Leadership

Infection Control & Prevention

Quality & Patient Safety

The Standard that was consistently **Partially Met** was in **Infection Control and Prevention** that required a system in place for the safe handling of internal and external waste.



Total

5

The Element with the most **High Priority Recommendations** is Infection Control and Prevention.



Total

12





## **The way forward**

In the year ahead, NHRA aims to strengthen our relationship with our clients in the Kingdom of Bahrain. One of the initiatives to achieve this aim is to develop a comprehensive IT platform.

This will facilitate the licensing applications, drug and medical devices registration and sentinel event reporting processes thereby enabling NHRA to improve the efficiency of our operations and achieve a higher standard of customer satisfaction.

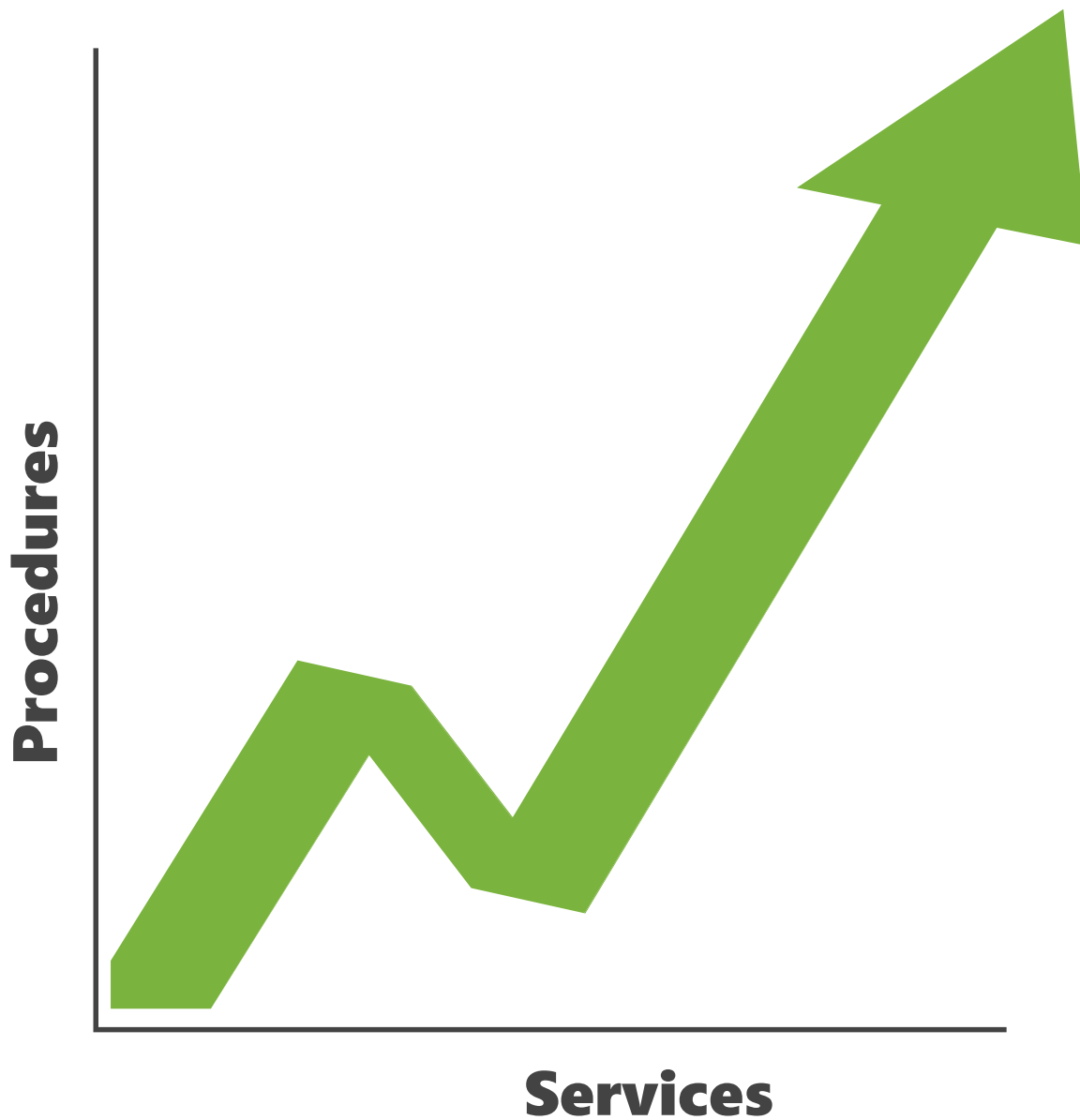
The way forward for some of our initiatives include:

- For Pharmaceutical Products Regulations: By May 2018 All pharmaceutical companies will be able to upload their products into our system to start the implementation of medication bar coding - A global standardized system for traceability of medication
- For Accreditation: Implementation of accreditation of medical centers and continue private / public hospital accreditation
- With the implementation of the national health insurance system in Bahrain, the role of NHRA will expand to include approving the private insurance companies providing the insurance coverage
- Review and update professionals' legislation, Law 21 for private care facilities and the Pharmacy and Drug legislations.

We strive to serve the people of Bahrain in the best way we can and gain the trust of our clients by continuously improving our procedures and policies.

# Our Ambition

**Reach global competitiveness in the regulation of health services**



**nhra**  
B A H R A I N



الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY

[www.nhra.bh](http://www.nhra.bh)