

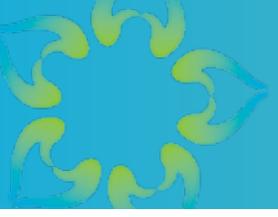
# Annual Report 2021



National Health Regulatory Authority



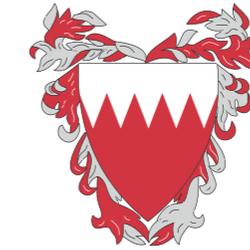
الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY



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



الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY



**His Royal Highness  
Sheikh Isa bin Salman  
Al Khalifa**



**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  
of the Kingdom of Bahrain



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

## Contents

Executive Summary	2
Message from the CEO	14
National Health Regulatory Authority Organizational Chart	16
NHRA Strategic Plan	18
NHRA Strategic Plan Achievements	19
NHRA Digital Transformation Program	22
Health Facilities Regulation	24
Health Profession Regulation	54
Regulating Alternative Medicine Facilities	78
Pharmacy & Pharmaceutical Control	84
Regulating Medical Devices	98
Clinical Trials & Continuing Professional Development Regulation	110
Accreditation & Quality Group	118
Medical Complaints & Investigation	136
Achievements of the Legal Affairs Unit	154
Activities of the Investors Office	158
Customer Engagement Activities	164
Human & Financial Resources	170
Committees Convened at NHRA	176
Equal Opportunities Committee at NHRA	178

The National Health Regulatory Authority (NHRA) was founded in 2010 by Law No. 38 of 2009. Our mission is to regulate the provision of healthcare in the Kingdom of Bahrain and to assure appropriateness, continuity, efficiency, and safety in the delivery of health services in both the public and private sectors. With the dynamic evolution of the country's strategy in dealing with the COVID-19 pandemic and its implications on healthcare systems, NHRA has continued to prove itself a pragmatic, progressive regulator. NHRA is pleased to present this annual report which reflects highlights of our organization's commendable achievements in 2021.

## 1. Proactive Response to COVID-19

The authority played a significant role in facilitating the rapid launch of clinical trials and timely access to critical medicinal products and diagnostic tests, as well as supporting national efforts to combat COVID-19. In 2021, after a thorough examination of their efficacy, the authority approved 7 vaccinations, 4 anti-COVID antibodies, and 12 rapid antigen tests. To provide Emergency Use Authorization for the new vaccines, NHRA's Pharmacy & Pharmaceutical Control Section (PPR) and the Clinical Trial Committee have coordinated with the

National Immunization Committee to evaluate their safety and efficacy before issuing the approval. This was a collaborative effort between the Pharmacy & Pharmaceutical Control Section (PPR), the Clinical Trial Committee as well as the National Immunization Committee. With this approval, Bahrain became the first country in the world to approve this number of COVID-19-related vaccinations and treatments, putting us at the forefront of international efforts to fight the pandemic. Additionally, NHRA's Healthcare Facilities Regulation Department (HCF) approved the operation of two private isolation facilities for positive cases and 77 private quarantine facilities for travellers. To supplement this work for COVID-19, 42 PCR testing laboratories were also inspected, and laboratories quality assessments were carried out accordingly, as well as evaluating Ministry of Health isolation and critical care premises.

## 2. Providing support for the health system

### Professional Licensing

With the emergence of variants in 2021, the demand for healthcare professionals continued to increase in order to support the healthcare system. In response to these extraordinary circumstances, the NHRA launched a new automated licensing service called Mehan in order to facilitate a more dynamic licensing process. By the end of the year, the Kingdom of Bahrain had a total of 25,076 licensed healthcare practitioners. Among which, 4,727 were physicians, 1,145 were dentists, 1,702 were pharmacists, 13,558 were nurses, and 3,944 were allied health professionals. In addition, the Health Professions Regulation department processed 3,478 new license applications, 10,783 license renewal applications, and a total of 1,889 professionals took the Licensure exam, with a 69 percent pass rate reported. To sustain the professional development of those healthcare practitioners and ensure they are up-to-date with the latest developments in their respective fields, the Clinical

The authority played a significant role in facilitating the rapid launch of clinical trials and timely access to critical medicinal products and diagnostic tests

The authority approved 7 vaccinations, 4 anti-COVID antibodies, and 12 rapid antigen tests



Trials and Continuing Professional Development Regulations department had received, reviewed and processed 20,108 CPD activities. The majority of these activities were in the form of lectures and online webinars followed by specialized workshops, general workshops and conferences.

### Licensing and Regulating Healthcare Facilities and Pharmacies

NHRA further supported the Kingdom of Bahrain's health system through the licensing of healthcare facilities. By the conclusion of the year 2021, the HCF department had licensed a total of 831 healthcare facilities throughout the country, comprising of 21 hospitals, 301 centers, and 96 clinics. The department processed 118 new applications for opening new facilities in various specialties and issued 80 new licenses and renewing the license of 689 healthcare facility. Moreover, in line with the government's 2030 strategic directions for digital transformation, NHRA implemented "Munshaat" which is a digital service which allows rapid application and regulation of healthcare facilities.

A total of 78 new pharmacies were licensed in 2021 by the pharmaceutical product regulation department, of which 8 were opened in a healthcare facility and 70 were public pharmacies, reflecting a 16% increase in the

number of licensed pharmacies compared to 2020. The total number of pharmacies licensed in the Kingdom of Bahrain are 396 of which 317 are operating as public pharmacies and 79 are operating in a healthcare facility. 6 New Warehouses were registered making it total of 22 Pharmaceutical Warehouse registered.



### Inspection Activities

By the end of 2021, the Healthcare facility department's inspection team had conducted 1,377 inspection visits, where 117 general violations were detected in healthcare facilities, whilst in 576 private health care facilities no violations were observed during those visits. Most of the observed violations represented violations in safety, sterilization, licensing, safety of medical devices, storage and general violations in promotional advertisements. The necessary measures were taken to correct them, as 82 notification letters were issued, 22 referrals to the Public Prosecution Office, 23 to disciplinary committees, and 12 violating facilities were closed.

On the other hand, the pharmaceutical department completed 421 inspection visits, with inspectors taking full precautions to carry out their duties. There were 375 violations found and remedied, with 40% of them involving pharmaceutical violations, followed by 24% involving temperature and humidity violations, 23% involving pharmacy set up, 7% involving price violations, and 6% involving licensing violations.

### 3. Regulating the Practice of Complementary and Alternative Medicine (CAM)

The National Authority continued its efforts to regulate complementary and alternative medicine (CAM) in the Kingdom, as twenty (20) applications for licensing alternative medicine facilities were approved. Thus, the number of licensed alternative medicine facilities in the Kingdom in 2021 reached 21 facilities specialized in alternative medicine, in addition to 31 health facilities providing alternative medicine within their medical services. The number of health professionals licensed in the various fields of alternative medicine reached 71 professionals. To expand its partnerships, the authority has collaborated with the Indian Embassy and the government agency, 'Ayush Ministry' of the Republic of India, to conduct several online meetings to exchange information

NHRA launched a new automated licensing service called Mehan in order to facilitate a more dynamic licensing process

In line with the government's 2030 strategic directions for digital transformation, NHRA implemented "Munshaat" which is a digital service which allows rapid application and regulation of healthcare facilities

and support the authority's efforts in organizing professionals' licensing and conducting licensing examinations. The first licensing exam for alternative medicine pharmacists was conducted in the Kingdom of Bahrain with the participation of five (05) pharmacists specialized in alternative Indian medicine (Ayurveda).

#### 4. Ensuring Early Access to Medicines

2021 was likely the most successful year for the pharmaceutical product regulation (PPR) department with the registration of 357 new medications, classification of 410 of them, as well as registration and renewal of 151 overseas manufacturing site applications. The total number of registered pharmaceutical products in the Kingdom stands at 3,643. The department continued to assist in preventing drug shortages in the country and ensuring that all necessary medicines are available to patients in Bahrain by processing temporary imports of 2004 non-registered products applications. Within the momentum of ensuring early access to medication, PPR department utilized the Drug Utilization Review System, which facilitated the department to process 9,532 electronic invoices (DUR). In addition, 584 manual invoices were



approved, 508 cold chain shipment releases were completed, on the (GS1) Portal, 508 cold shipment releases were completed, and 3,857 medicines were processed on Brand Sync Portal.

To implement Article (1) of Supreme Council of Health Resolution 41 for 2017, which grants the National Health Regulatory Authority the authority and obligation to implement the Track and Trace system for the supply chain of medicines within the Kingdom of Bahrain from the manufacturing site to the patient, NHRA partnered with MVC to provide the Kingdom with the world's most advanced and secure system. The system significantly reduced the risk of counterfeit and fraud in the marketplace. By the end of December 2021, 73 % of the 247 marketing authorization holders had registered with MVC, accounting for 94 % of all pharmaceuticals imported into the Kingdom.

To respond to the public health emergency caused by the Covid-19 pandemic, the authority has established a new pathway to approve the emergency use authorization for submitting applications for vaccines and medicines with the aim of accelerating and simplifying the evaluation and licensing of promising vaccines and treatments. The main objective was to assist manufacturers in obtaining a license for the emergency use of vaccines and medicines, which contributed to making the Kingdom of Bahrain among the first countries to introduce new vaccines and medicines to combat the Covid-19 virus.

#### 5. Providing Support for the Safe Conduct of Clinical Research

In 2021, the Clinical Trials and Continuing Professional Development Regulations department had received 13 Clinical Trial applications. Out of the 13 Clinical Trial Application packages, 9 CT applications have been approved, 2 are pending amendments and 2 were rejected. A vast majority of the approved Clinical Trials were from the government sector, as part of the initiative to tackle COVID-19.

To supplement this work for COVID-19, 42 PCR testing laboratories were also inspected, and quality assessments were carried out accordingly

The 3rd edition of Clinical Trials Regulations was also issued in the Kingdom of Bahrain with agreements of commitment and compliance to these regulations and monitoring requirements instated between Sponsors-PIs-Applicants and NHRA. Additionally, introduction of ICH Good Clinical Practice certification requirement for researchers with the instatement of NHRA algorithm regarding the review of clinical trials has cemented the importance of safeguarding patient's rights, well-being and safety in the context of research.

## 6. Resolving Medical Complaints

In line with our goals of preserving health rights and ensuring safe health services, the complaints department continued to investigate allegations of medical errors, as the department received 213 cases for investigation in 2021. Of these, 146 were individual complaints, while 25 were reported by health care facilities, and 41 were referrals by the prosecution or the courts and one case that was reported by the inspection team.

The Department investigated 176 cases and completed investigations in 114 of them, 44 of the cases were closed either due to irrelevance to NHRA or for lack of evidence, and the investigation is still ongoing in 18 of them.

A medical error / violation of the principles, obligations, requirements, or ethics were only found in 30.7% of the investigated cases, while no medical error/ violation of principles, obligations,

or requirements were identified in 69.3% of them. In 42% of the cases, the treating physician was responsible for the error, while in 52% of them, the facility was responsible for the error, and in 6% of them the error was the responsibility of either nurses, pharmacists, or other allied professions.

In the year 2021, 57 disciplinary measures were issued by the Disciplinary Committees and the Accountability Committee, including 30 decisions to suspend the licenses of professionals, 15 warning notices, revocation of the licenses of four professionals, and the issuance of 4 monetary fines for healthcare facilities, while 4 professionals were acquitted based on the decision of the appeal committee.

## 7. Regulating and monitoring medical devices

In keeping with the regulation of medical devices, the Medical Device Regulation department licensed ten new medical device businesses and registered 523 medical devices. The department's biomedical engineers also reviewed a total of 9,644 new medical device applications, of which 7,996 were granted approval through the Electronic System of Customs (OFOQ). Because of the detection of a fraudulent certificate or a counterfeit device, the authority denied 17% of all import applications (1,648). The total cost of the imported equipment released from customs was 35,245,050.47 BHD.

## 8. Maintaining quality of medical services and accreditation of facilities

NHRA became one of the very few certifying authorities in the world to successfully automate its operations and adopt the hybrid format of accreditation. N H R A conducted 30 hybrid surveys while accrediting healthcare facilities in the last year alone. Besides this, the Authority was able to accredit 21 hospitals and 28 medical centers, as well as renew the accreditation of 18 healthcare facilities. With the conclusion of the year, 100% of all eligible hospitals have been accredited.

831 healthcare facilities licensed in the Kingdom of Bahrain

The Kingdom of Bahrain had a total of 25,076 licensed healthcare practitioners



Furthermore, a total of 7,100 hospital standards and 5,230 medical center standards were investigated and assessed, with about 4,000 recommendations made to both hospitals and medical centers. The most encouraging part of all of these figures is that facilities have implemented and completed more than 80% of the survey team's recommendations.

In line with our strategic aim to be recognized internationally, NHRA has planned to obtain the International Society for Quality in Healthcare (ISQua) recognition of our accreditation program, NHRA is also working towards achieving ISO 9001 certification to ensure credibility, improving our processes for clients, and delivering high-quality services.

### 9. Innovating for a better patient and public experience

Due to increased interest in investing in the Kingdom of Bahrain's growing healthcare industry, the NHRA investors' office provides guidance and assistance to investors. The office has received 31 queries for various healthcare investments from markets in the GCC,



Europe, and Asia. 10% of the inquiries were about opening hospitals, 58% about opening medical facilities, and 32% were about the pharmaceutical and medical device businesses. The office works closely with the Economic Development Board, the Labor Market Regulatory Authority and TAMKEEN to provide support to new investors.

### 10. Improving Authority Performance and Investing in Staff

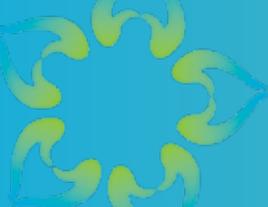
Whilst ensuring the provision of the best quality of care in the Kingdom, as part of the Fiscal Balance Program targets, the NHRA raised its revenues by 13% compared to the previous year and by 7% compared to the allocated budget in 2021, while reducing its actual recurrent non-manpower expenses by 4% of the projected budget. The NHRA financial sufficiency score has significantly improved over the last five years, growing from 45% in 2016 to 98 % in 2021.

In line with our wellbeing initiatives and after the proposal raised by the equal opportunities committee, a nursing mothers room was established at NHRA. Moreover, according to evaluation results, the Authority's institutional performance was ranked fourth out of 45 participating government entities and NHRA was granted the Princess Sabeeka bint Ibrahim Al Khalifa Award for the Advancement of Bahraini Women.

The Authority was dedicated to meet its 2021 recruitment goals, and as such, 16 new employees were hired in several departments. Acknowledging the role of NHRA's esteemed staff in the success of the Authority, 19 employees were promoted and 46 were given incentives and special rewards, while training and development of all NHRA employees became a top priority throughout the year. In line with our wellbeing initiatives and after the proposal raised by the equal opportunities committee, a nursing mothers' room was established at NHRA. Moreover, according to evaluation results, the Authority's institutional performance was ranked fourth out of 45

100% of all eligible Hospitals have been nationally accredited.

NHRA conducted 30 hybrid surveys while accrediting healthcare facilities in the last year



participating government entities and NHRA was granted the Princess Sabeeka bint Ibrahim Al Khalifa 2021 Award for the Advancement of Bahraini Women.

### 11. NHRA Digital Transformation Program

To implement the government direction towards digital transformation, NHRA IT Vision was initiated in 2021 which is set to enable NHRA to be a Digital Health Regulator Model in the Gulf Cooperative Council (GCC). The NHRA Digital Transformation Program has enabled NHRA to offer end-to-end Health Regulatory eServices using state-of-the-art Amazon Cloud Services and features.

After 11 months of intense focus and dedication, Phase 1 of the Program was successfully implemented and consists of five systems that integrate with a number of public and private entities. The five systems are as follows:

1. Healthcare Professionals (HCP) Regulation System “mehan”
2. Healthcare Facilities (HCF) Regulation System “Munshaat”
3. Accounting System
4. HCP Professional Mobile App
5. HCF Inspectors Mobile App

Integration / Interfacing with LMRA, Sijilat, iGA-CPR, NPA (e-Payment Gateway), i-Sehati/NEMR Prometric, DataFlow/Quadrabay and the e-Notification system (SMS/SNS). Phase 1 has provided many advanced features such as being AWS Cloud-native, ability to scale and elasticity, self-care, service mobility etc.

### 12. Legislation activities

In 2021 the legal unit prepared more than 130 resolutions that included directions to form committees, referrals for investigations, and decisions for disciplinary sanctions. The legal unit also prepared legal views in cases before the judicial authorities, where the verdict was passed in favor of the Authority in more than 20 cases so far.

The unit cooperated with other government agencies such as the Engineering Professions Council and provided them with legal expertise in the field of work, especially the laws of practicing professions and the system of work of the disciplinary committees in the authority.

The unit have also worked on developing health laws and decisions in coordination with the Legislative and Legal Opinion Authority, ministerial committees, and the Physicians Society.

In conclusion: The year 2021 was a year of achievements, development and digital transformation, and these achievements would not have been accomplished without the dedication and efforts of our employees and their belief in the vision and mission of the authority. As our response to the pandemic has allowed us to forge innovative ways of working that have been improved to ensure response to the challenges, we will move forward to complement our digital services in other departments and seek international recognition of the authority by gaining recognition from the International Society for Quality in Healthcare (ISQua) for our accreditation program and work towards obtaining ISO 9001 certificate to ensure credibility, improve our operations for clients and provide high quality services.

16 new employees were recruited to various departments in 2021

NHRA was granted the Princess Sabeeka bint Ibrahim Al Khalifa Award for the Advancement of Bahrain Women



**Dr Mariam Al Jalahma**  
Chief Executive Officer NHRA

To begin, I would like to extend my profound gratitude to all the staff at the National Health Regulatory Authority for their tireless efforts throughout the pandemic and facilitating a remarkable year for the organization. Not only has the authority made a significant contribution in facilitating the rapid launch of clinical trials and timely access to critical medicinal products and diagnostic tests, but we have also continued to support national efforts to combat COVID-19. In 2021, the authority had approved a total of 7 vaccines, 4 anti-COVID antibodies, and 12 quick antigen tests after a thorough examination of their efficacy. The Kingdom was at the forefront of international efforts to combat the pandemic by being one of the first countries in the world to approve this many Covid-19 therapies. Additionally, the authority has continued monitoring healthcare facilities as well as isolation and quarantine facilities in order to guarantee adherence to national procedures to suppress the transmission of COVID-19.

During this national crisis with many staff members working from home, I was very pleased that colleagues throughout the authority stepped up to support the organization in these challenging conditions, thus ensuring the continuity of our authority's essential role. Last year, the NHRA was granted the Princess Sabeeka bint Ibrahim Al Khalifa Award for the Advancement of Bahraini Women, which recognizes the governmental bodies and private facilities in the fields of assisting and strengthening Bahraini working women. Moreover, in line with the economic development wheel of the Kingdom of Bahrain, and to implement the government's strategic directions for digital transformation, NHRA successfully implemented 2 major digitalized services "Mehan" and "Munshaat", which created new potential for regulating healthcare personnel and facilities.

Our response to the pandemic has also allowed the NHRA to form collaborative ways of working that have been refined to ensure that the organization is well positioned to rebuild better in the future. In

doing so, we will move forward to complete our digitalized services in other departments and aim to be recognized internationally by obtaining the International Society for Quality in Healthcare (ISQua) recognition of our accreditation program and work towards achieving ISO 9001 certification to ensure credibility, improving our processes for clients, and delivering high-quality services.

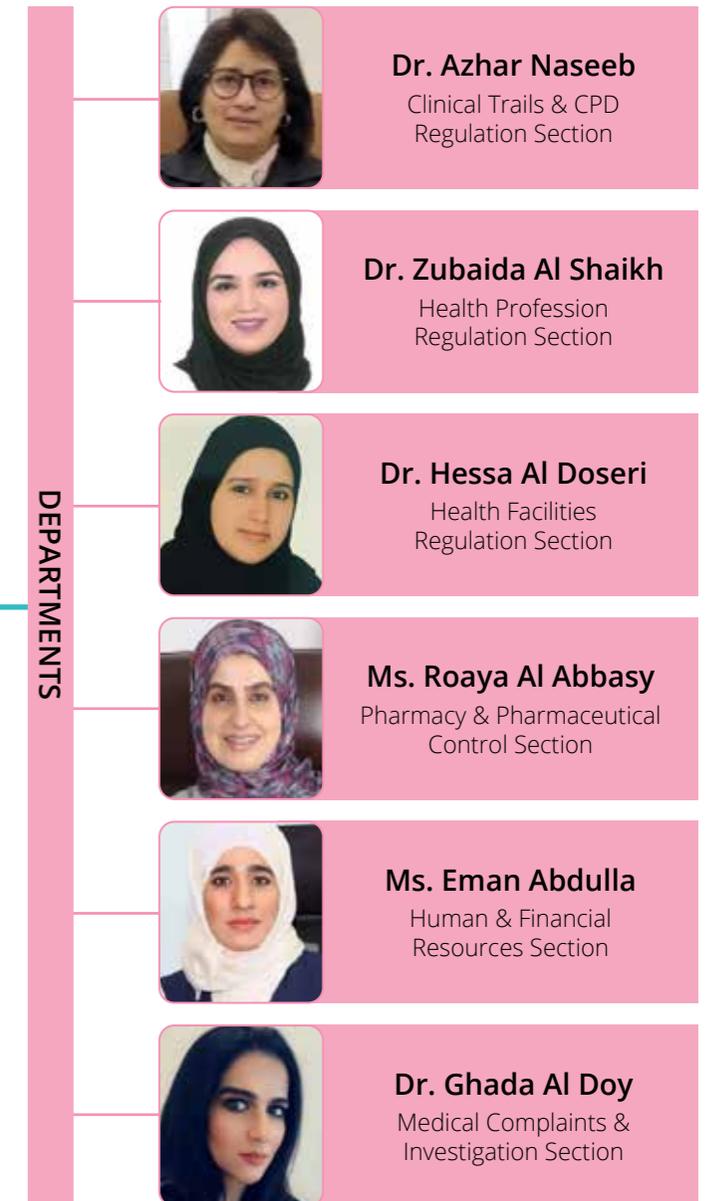
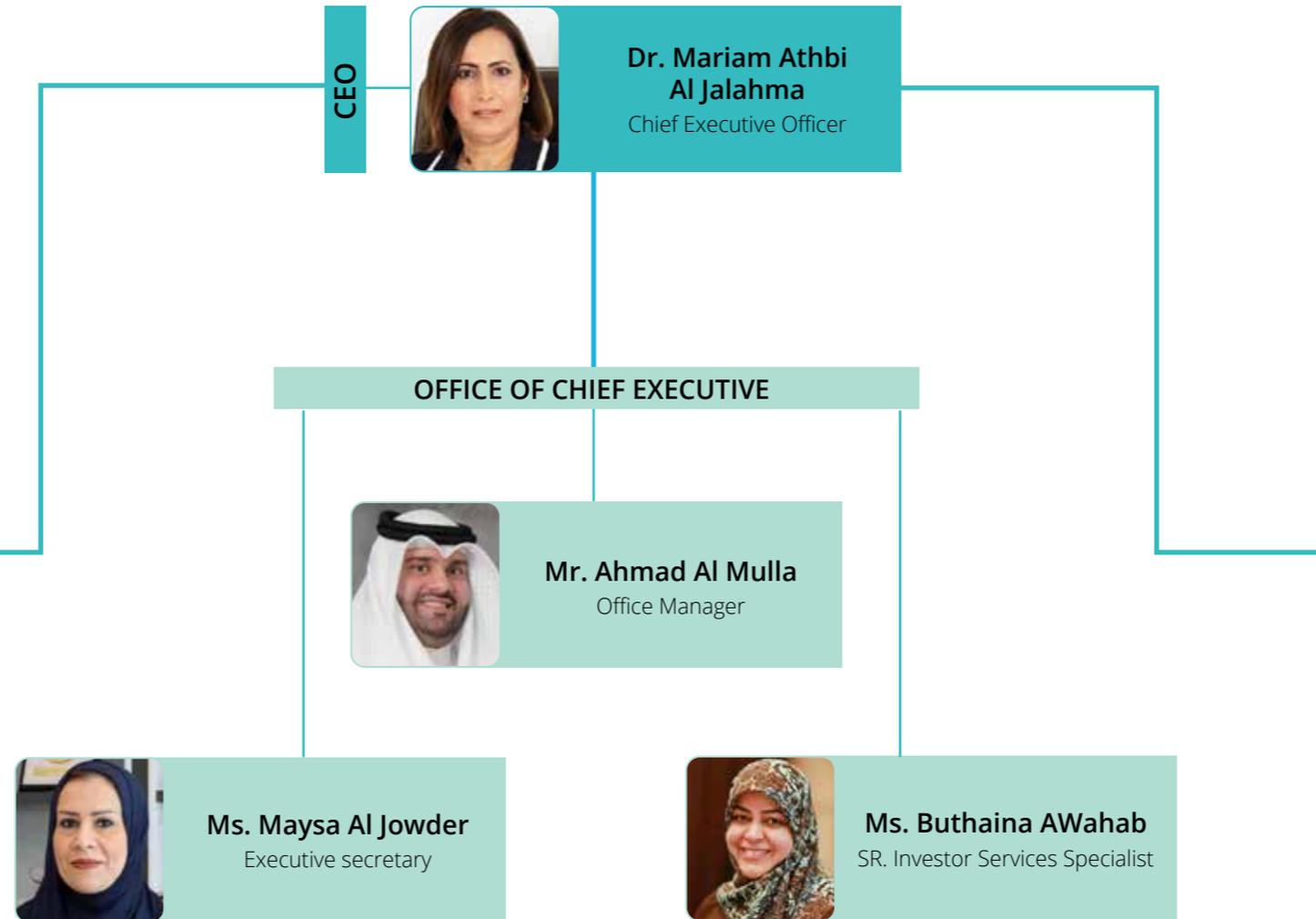
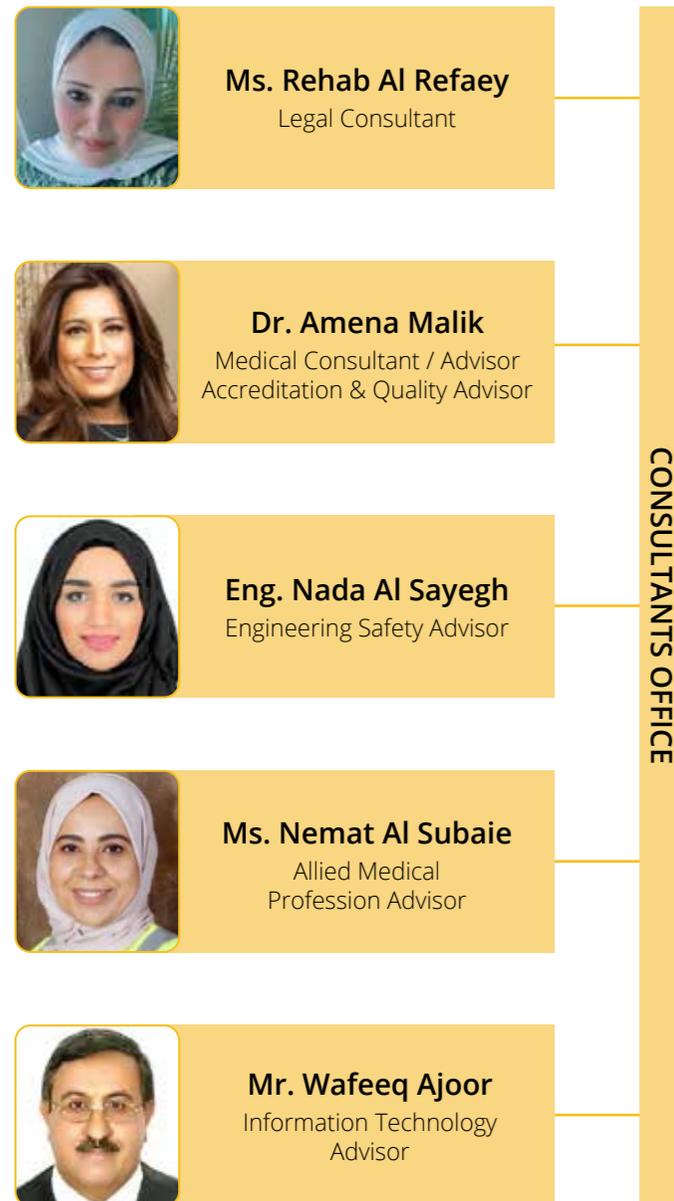
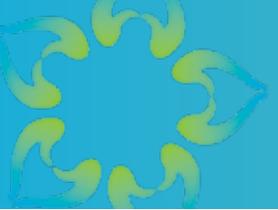
None of our authority's accomplishments, would have been without our supportive and knowledgeable personnel. As such, staff retention, talent development, and employee well-being have become our top priorities. The NHRA continues to evolve its organizational chart, forming new departments. As such in 2021, 16 new employees were hired across the authority. We have also increased our revenue through regulatory services, with the revenue-to-recurring-expense ratio reaching 93% in 2021, up from 91% in 2020.

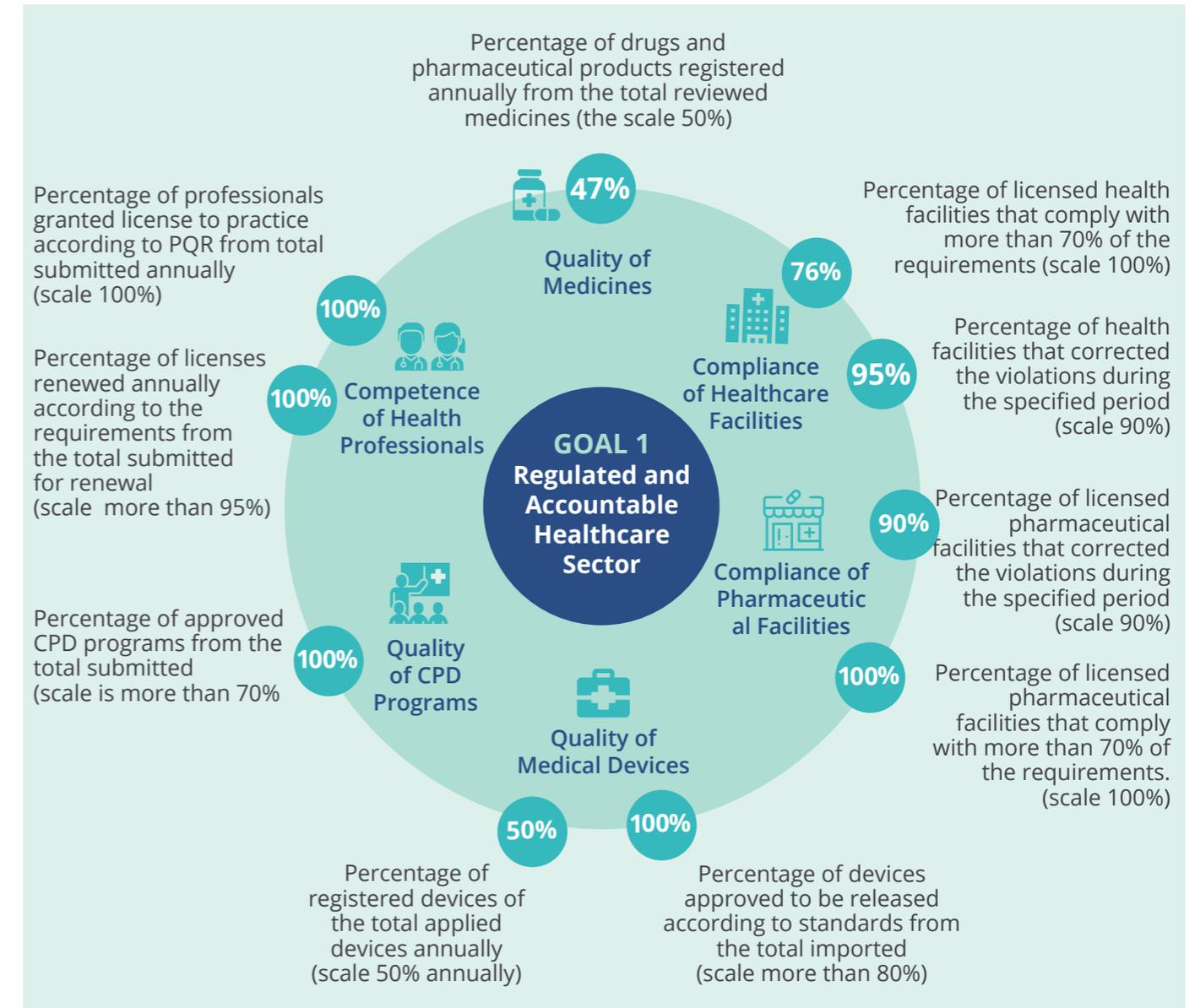
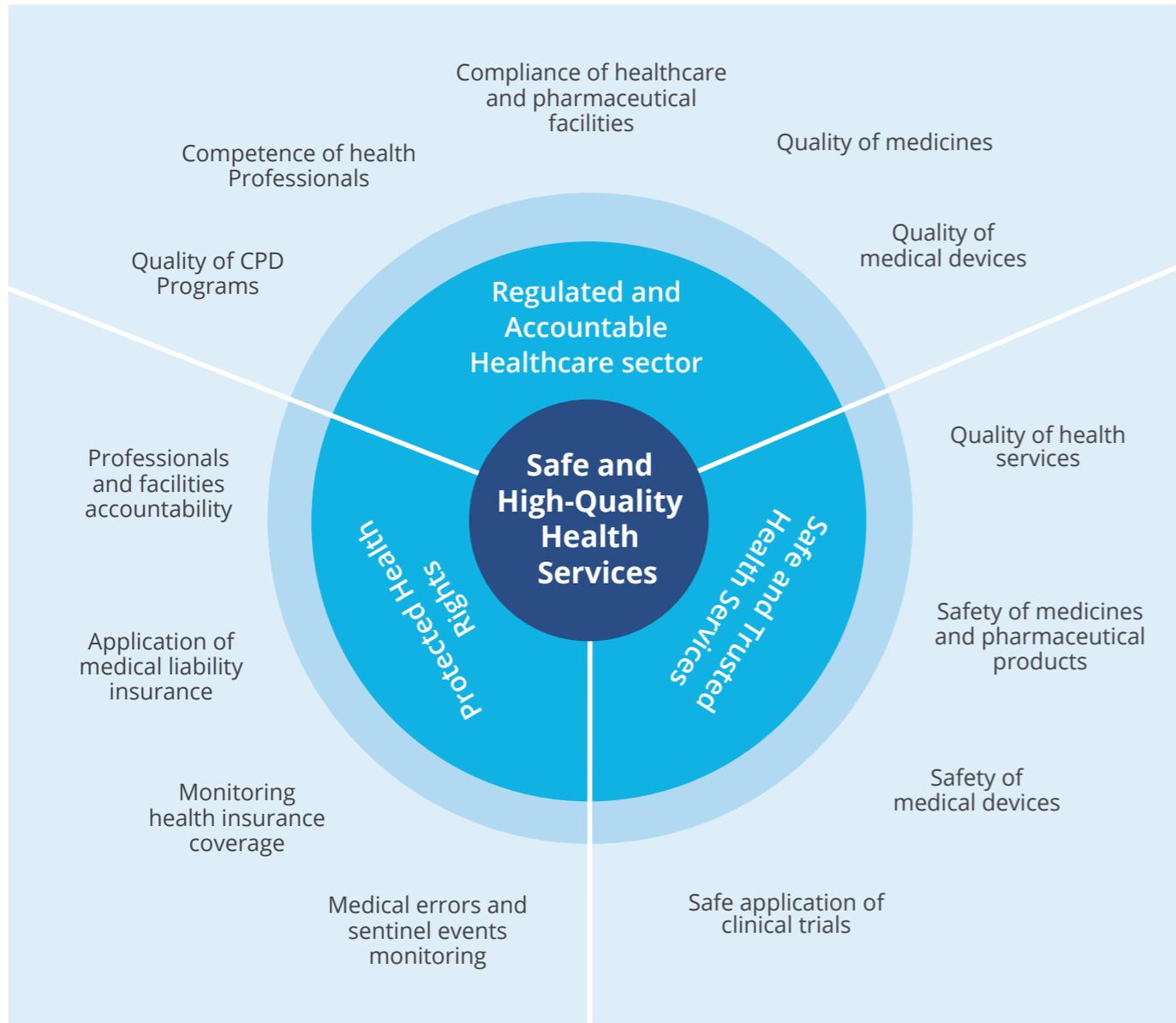
Our mental health and wellbeing initiative, as well as our equal opportunity committee, is being expanded as we strive to create a culture of inclusion and achievement for everyone. Finally, the combination of the demonstrable excellence of the National Taskforce for Combatting the Coronavirus and the evolution of NHRA as a pragmatic regulator during this pandemic, has paved the way for transformational change, with clear emphasis on innovation around the provision of safe and high quality health services.

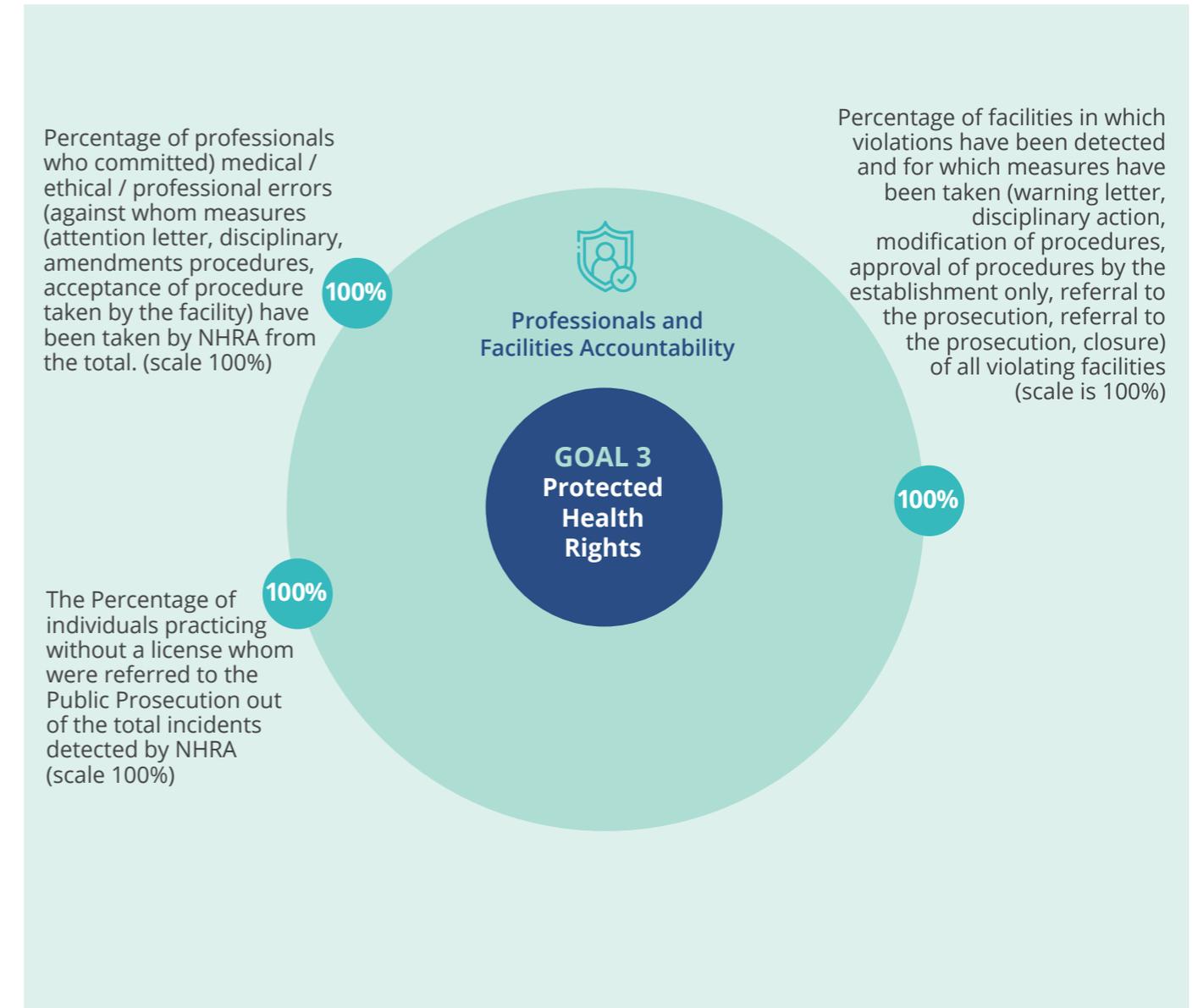
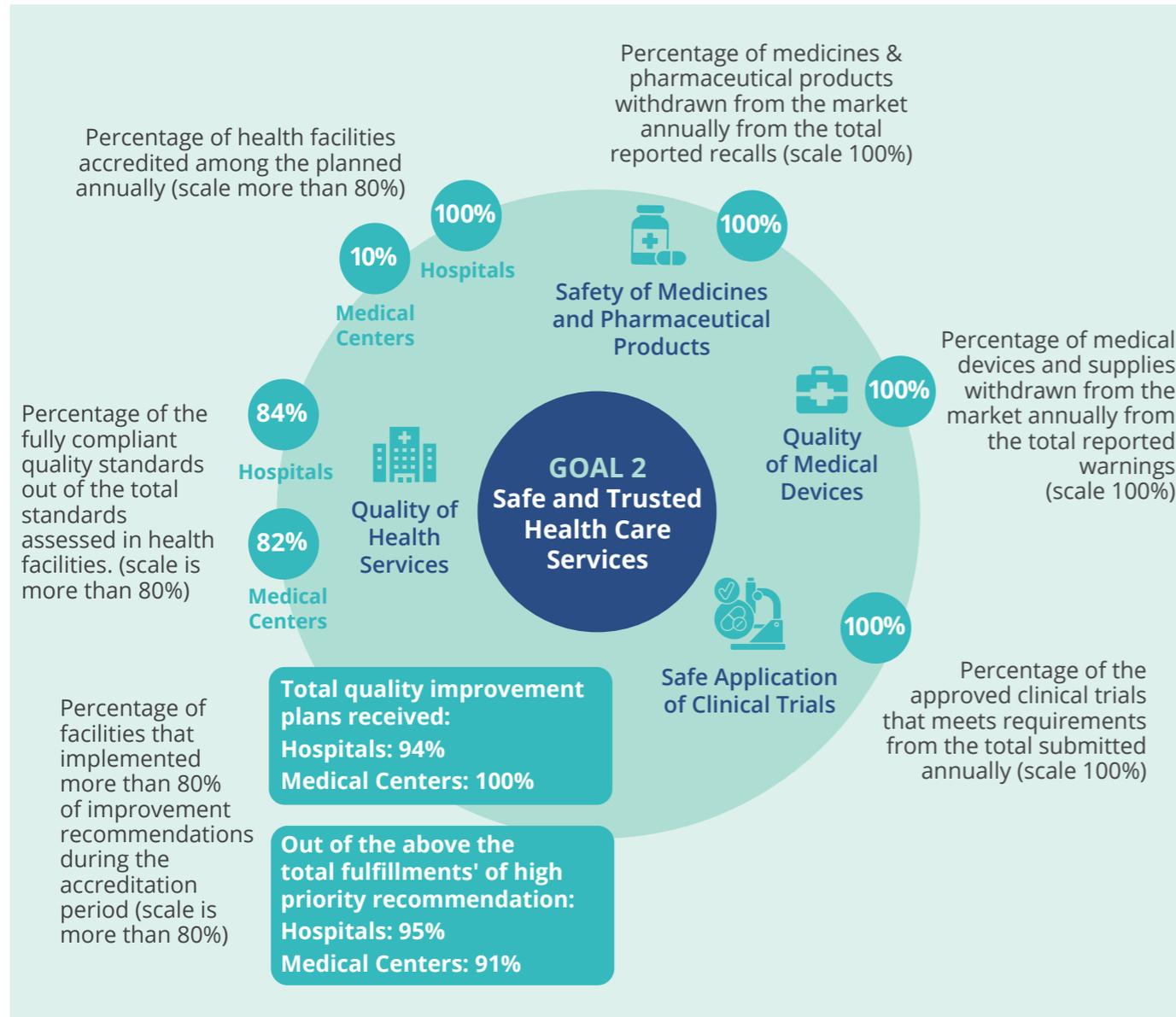
God Bless us All

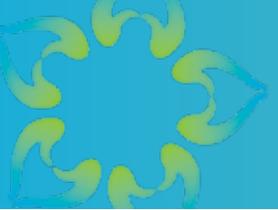
*Sincerely,*  
**Mariam Al Jalahma**  
Chief Executive Officer NHRA











## NHRA Digital Transformation Program

The NHRA IT Vision was initiated in 2021 which is set to enable NHRA to be a Digital Health Regulator Model in the Gulf Cooperative Council (GCC). The NHRA Digital Transformation Program has enabled NHRA to offer end-to-end Health Regulatory eServices using state-of-the-art Amazon Cloud Services and features.

After 11 months of intense focus and dedication, Phase 1 of the Program was successfully implemented and consists of five systems that integrate with a number of public and private entities. The five systems are as follows:

1. Healthcare Professionals (HCP) Regulation System "mehan"
2. Healthcare Facilities (HCF) Regulation System "Munshaat"



3. Accounting System
4. HCP Professional Mobile App
5. HCF Inspectors Mobile App

The system encompasses intervention / interfacing with LMRA, Sijilat, iGA-CPR, NPA (e-Payment Gateway), i-Sehati/NEMR Prometric, DataFlow/Quadrabay and the e-Notification system (SMS/SNS).

Phase 1 has provided many advanced features such as being AWS Cloud-native, ability to scale and elasticity, self-care, service mobility etc.





**301**

total number of registered centers

**96**

total number of registered clinics

**21**

total number of licensed private hospitals

**831**

total number of licensed facilities in the Kingdom of Bahrain

**58**

total number of private facilities providing pre-marital check up

**39**

total number of private facilities providing pre-employment examination

**576**

total number of no violation 'Appreciation Letter'

**21**

total number of pre-application engineering consultations

**187**

total number of violations identified

**1377**

total number of inspection visits 2021





### Digitalization of Services (munshaat.nhra.bh)

In line with NHRA's initiative to deliver quality healthcare services, the Healthcare Facilities Regulation section was fully engaged in automating all its services through the newly launched electronic system, "Munshaat". In 2021, all the available data was verified and mapped onto the new digitalized system to automate and facilitate all transactions related to healthcare facilities' operations. Within this system, all licenses are issued electronically with a unique barcode for each facility. Thus, allowing facilities to have their own exclusive self-services account.

### Licensing Activities

In 2021, the Healthcare Facilities Regulation Department (HCF) had a total of 831 licensed healthcare facilities, including 21 hospitals, 301 centers, and 96 clinics in the Kingdom of Bahrain. An addition to this, the department processed 118 new applications for opening healthcare facilities in various specialties, ranging from hospitals to health centers, and issued 80 licenses to new healthcare facilities. The department was successful in granting licenses for 28 government primary healthcare centers and renewing the licenses of 689 healthcare facilities.

### Inspection Activities

By the end of 2021, the authority's inspection team had conducted 1,377 inspection visits, where 117 general violations were detected in healthcare facilities, whilst in 576 private health care facilities no violations were observed during those visits. Most of the observed violations represented violations in safety, sterilization, licensing, safety of medical devices, storage, and general violations in promotional advertisements. The necessary measures were taken to correct them, as 82 notification letters were issued, 22 referrals to the Public Prosecution Office, 23 to disciplinary committees, and 12 violating facilities were closed.



### COVID-19 Activities

In 2021, the HCF department approved the operation of two private isolation facilities for positive cases and 77 private quarantine facilities for travellers. This was in the context of 105 applications received for private quarantine facilities for employees arriving from overseas, and 44 applications for healthcare facilities to run private quarantine for personnel arriving from abroad. The department continued to monitor the private sector's adherence to national COVID-19 regulations as instated by the National Taskforce for Combating the Coronavirus. A total of 37 visits were conducted.

In collaboration with the Public Health Laboratory, 42 PCR testing laboratories quality assessments were carried out accordingly, as well as evaluating Ministry of Health isolation and critical care premises.



Licensed Facilities



Licensed Facilities

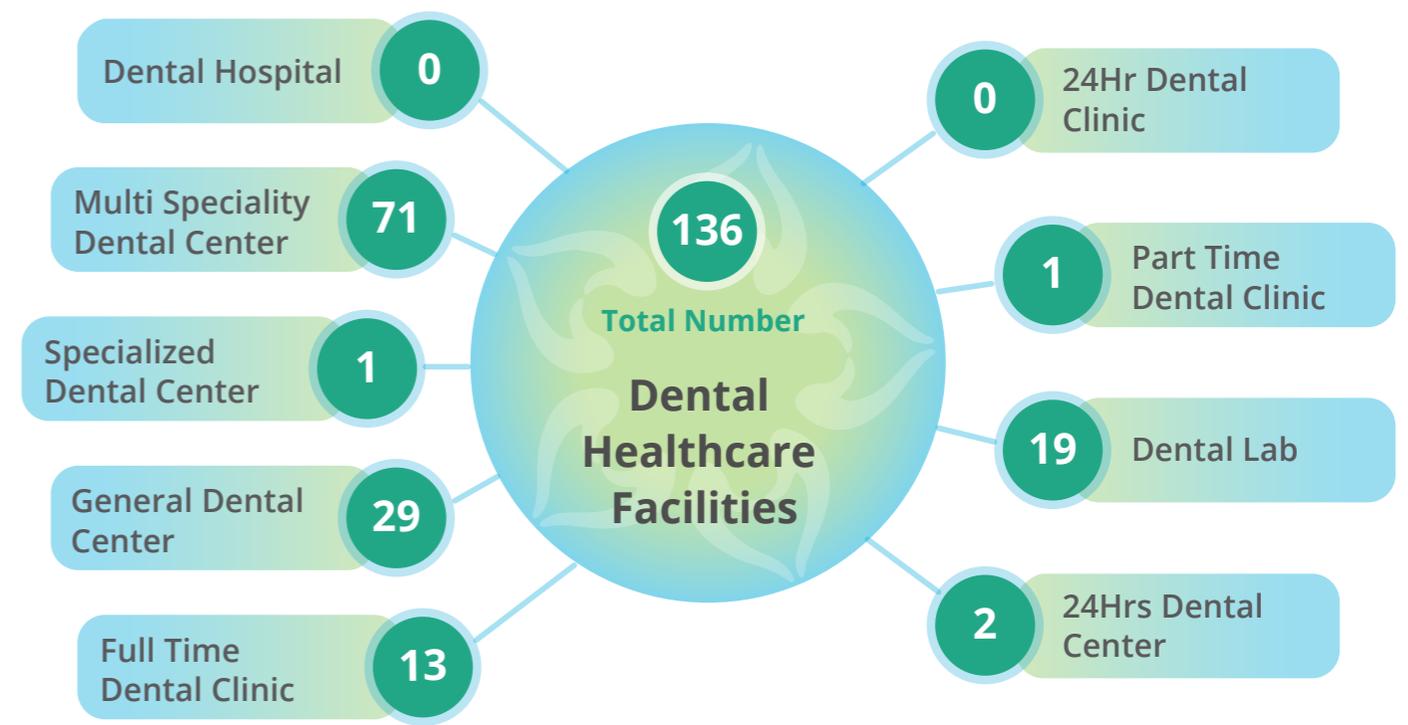




## Number of Registered Centers

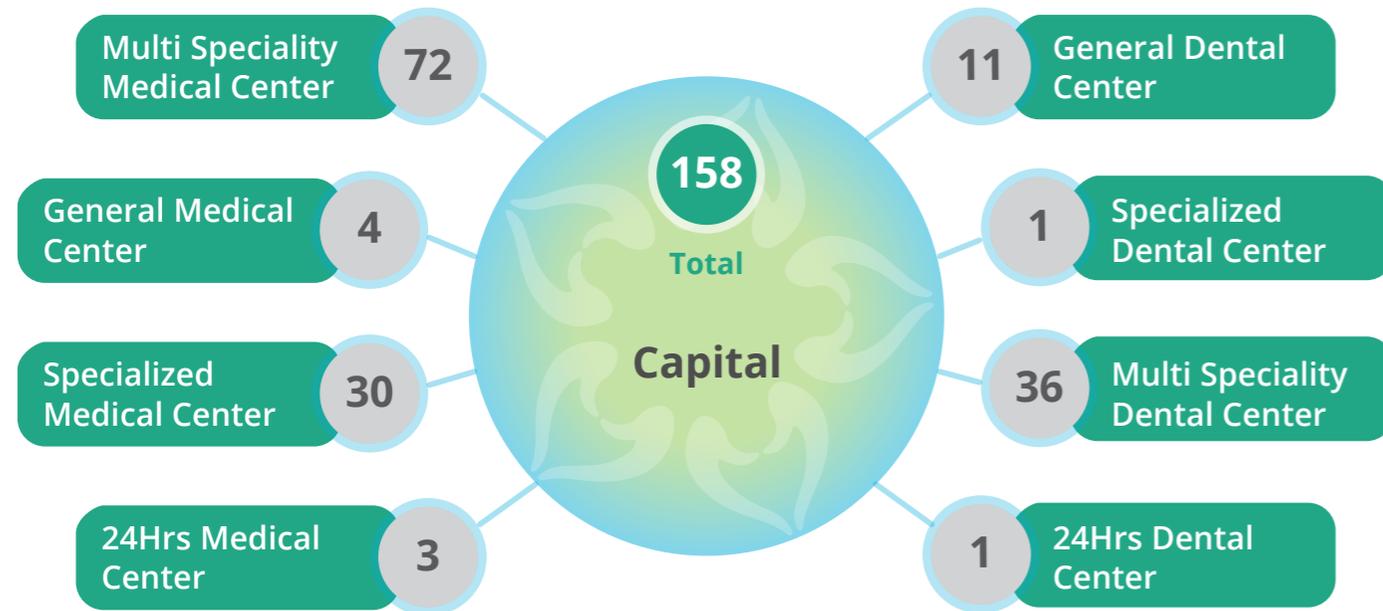


## Registered Dental Healthcare Facilities

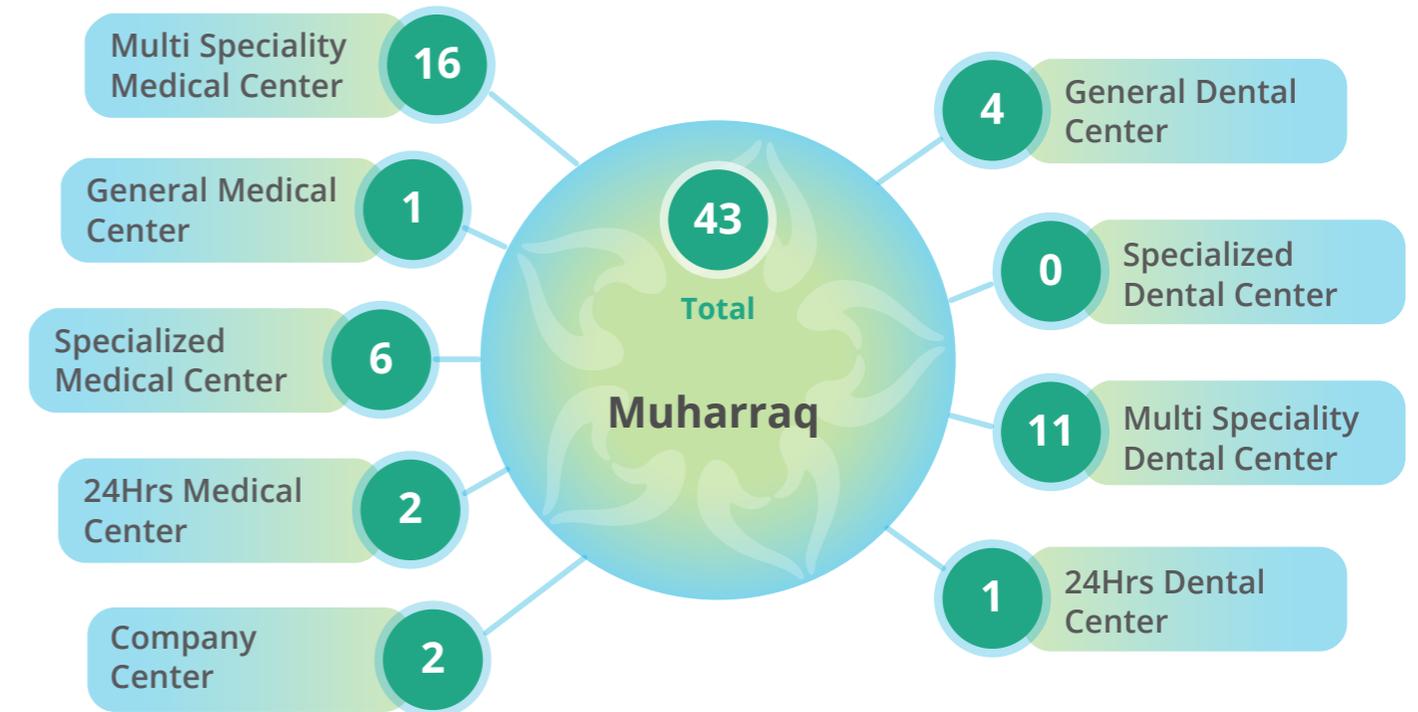




## Geographic Distribution of Registered Centers

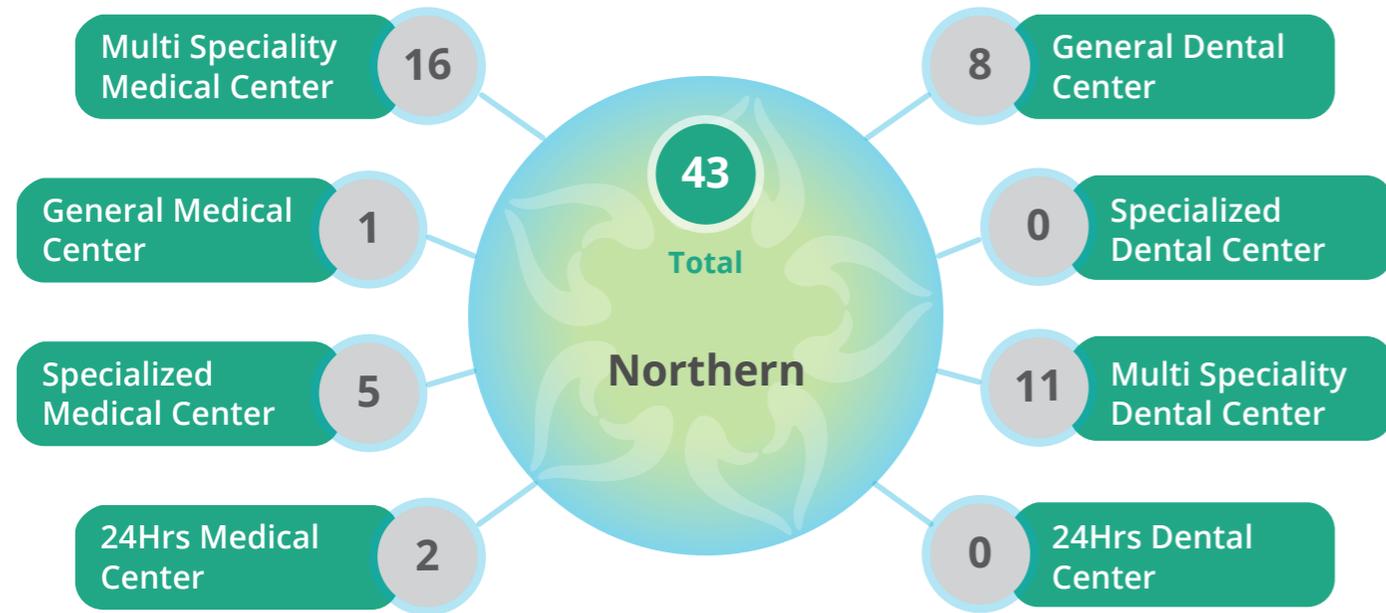


## Geographic Distribution of Registered Centers

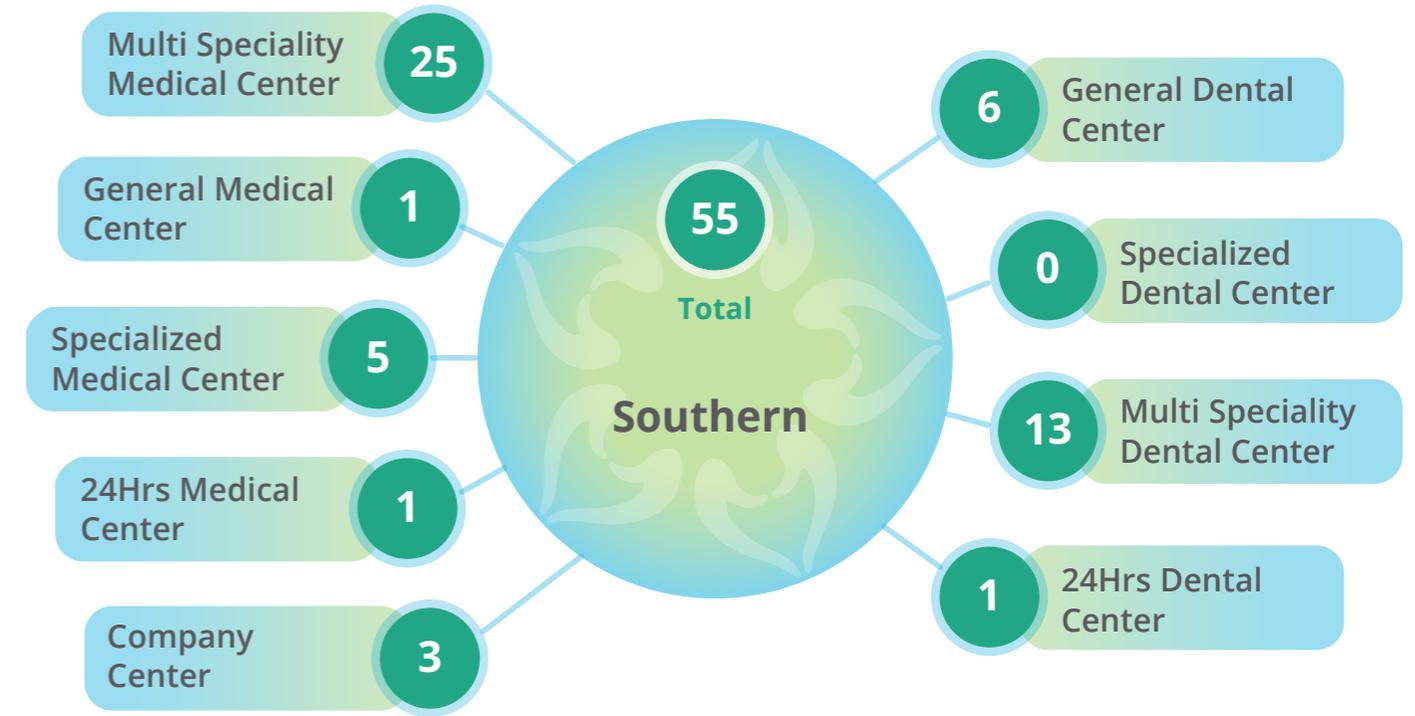




## Geographic Distribution of Registered Centers

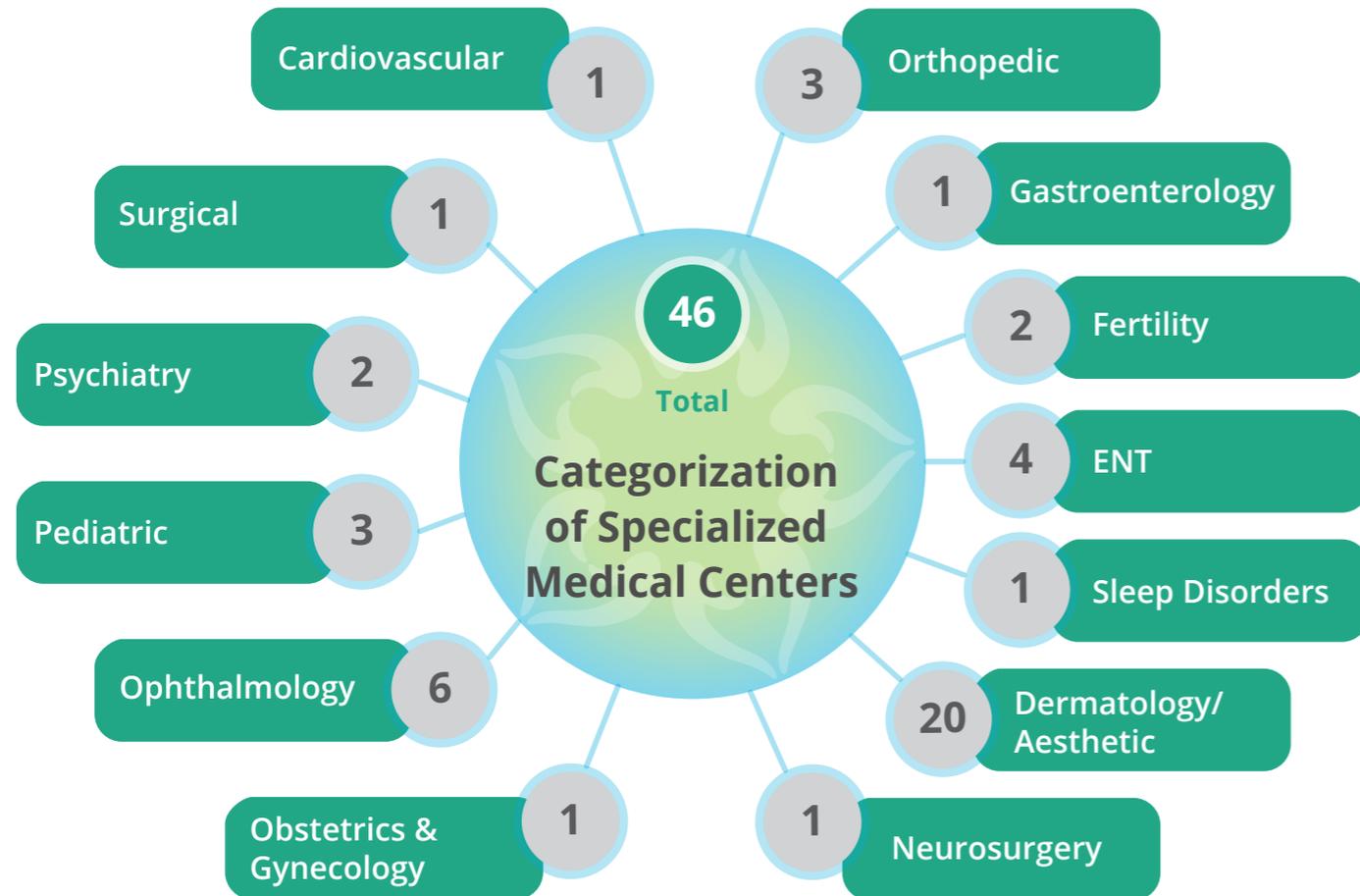


## Geographic Distribution of Registered Centers





## Categorization of Specialized Medical Centers

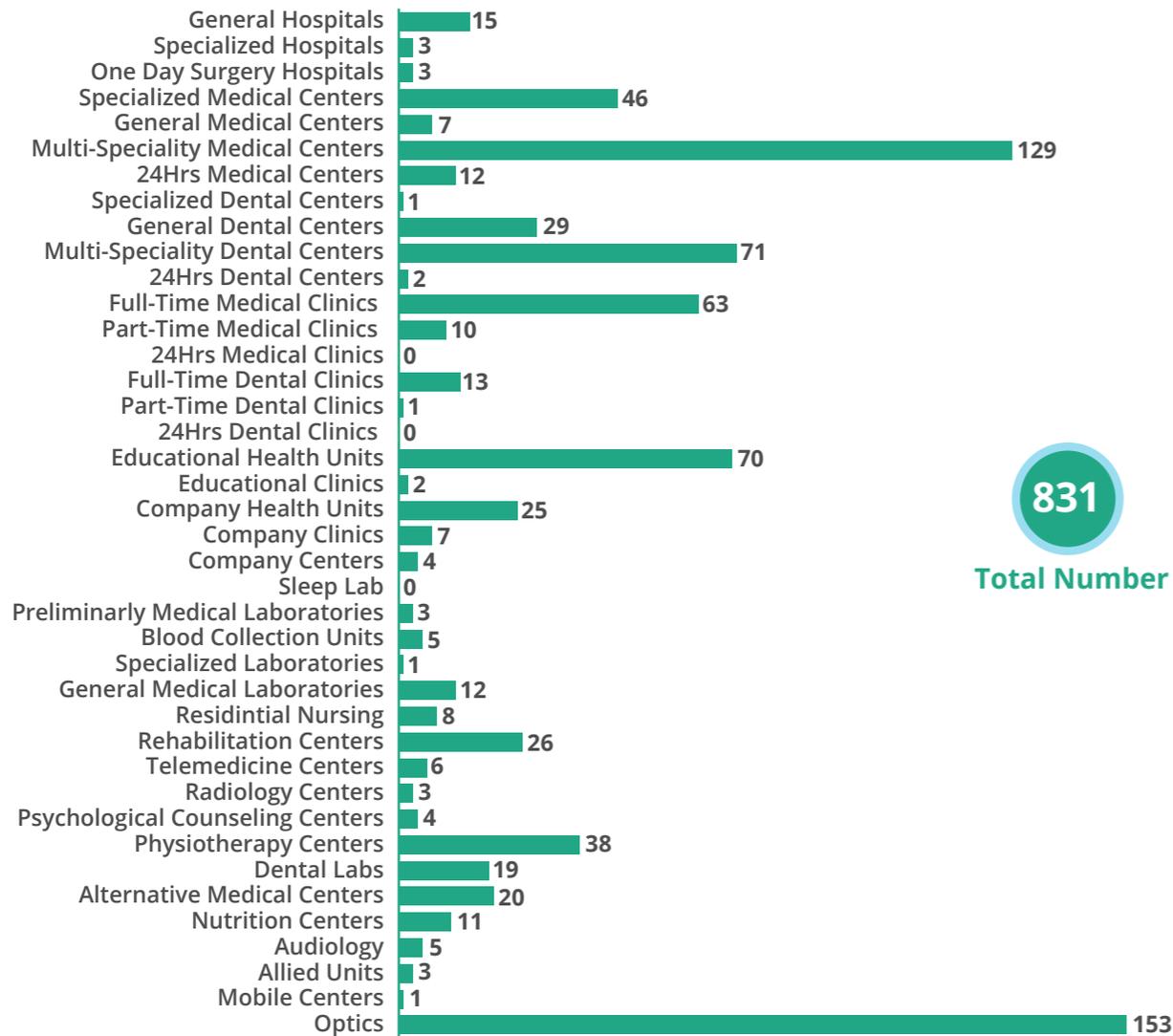


## Registered Medical Clinics

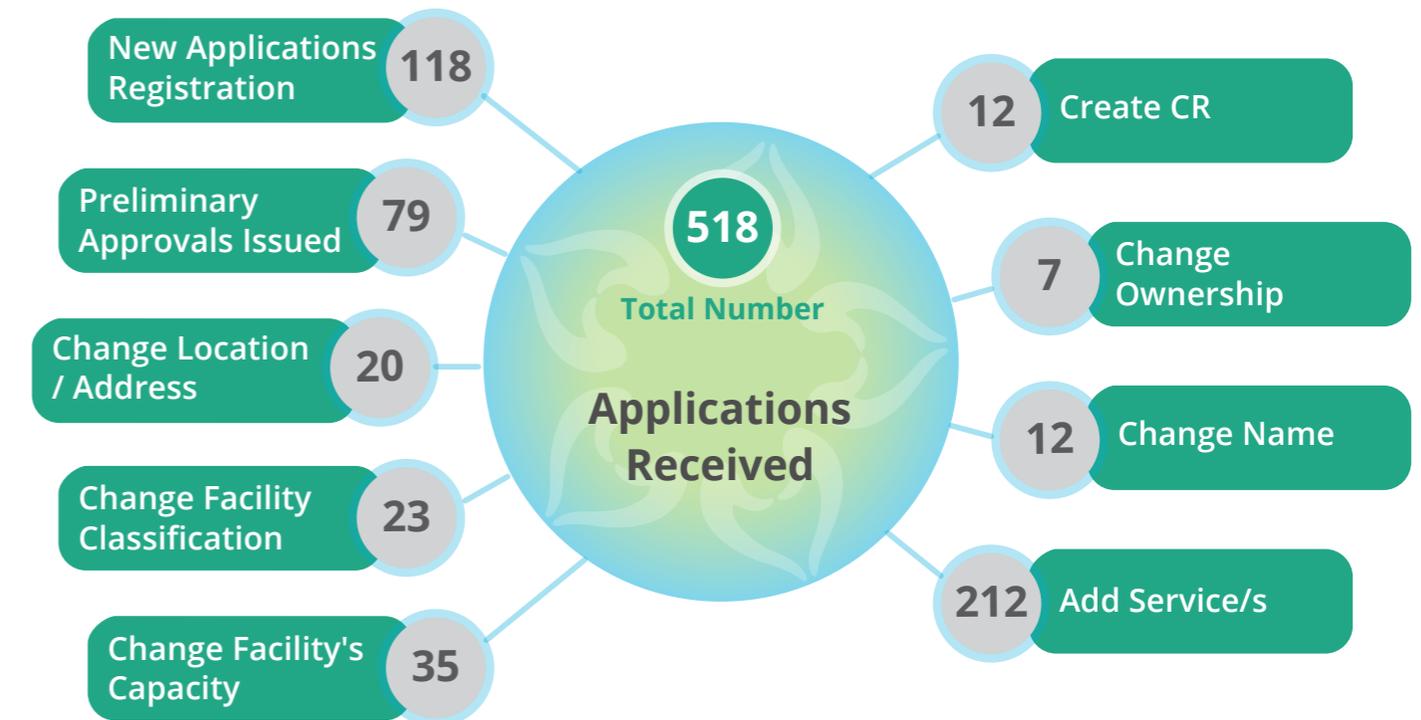




## Classification of Facilities

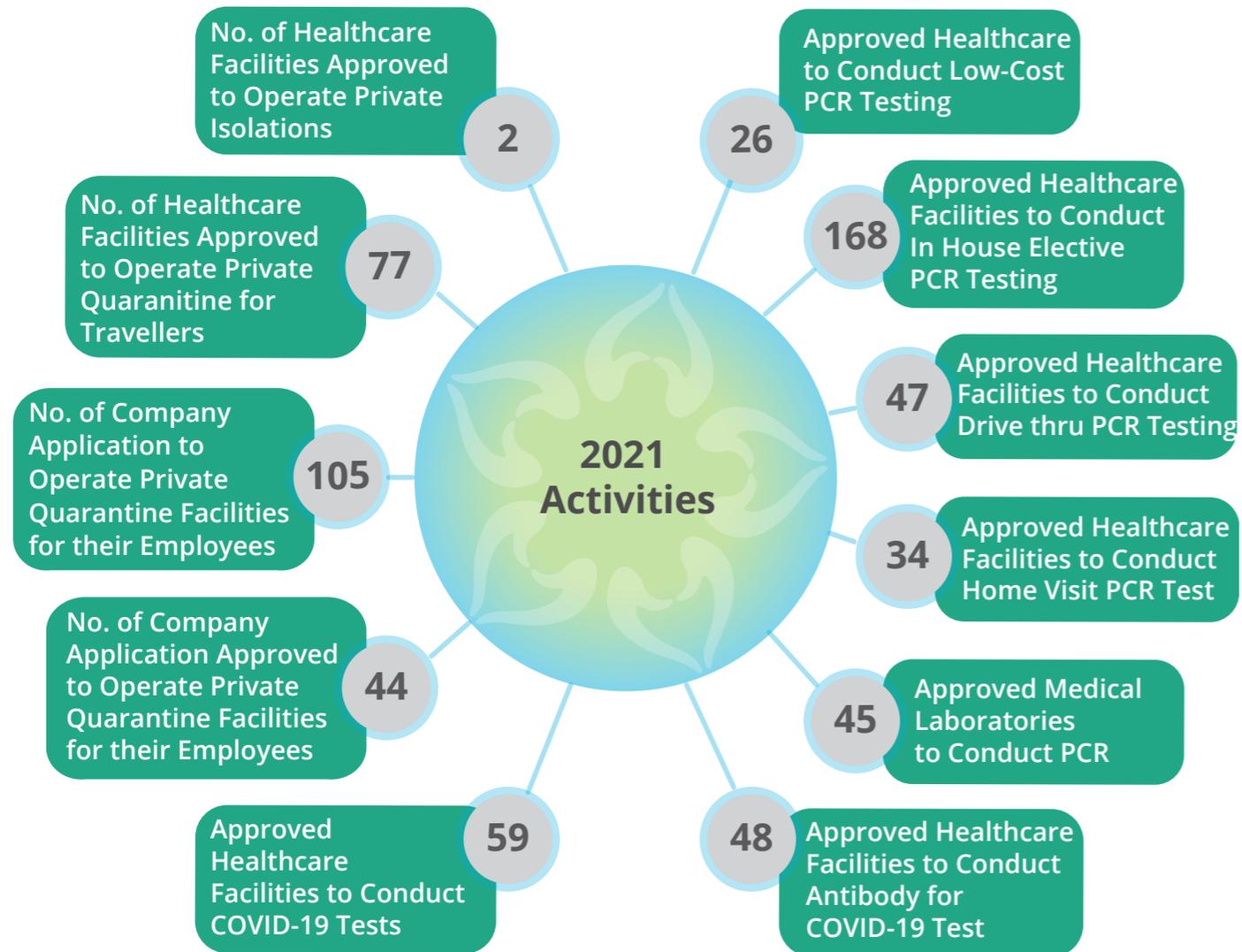


## Applications Received





## 2021 Activities



## Licensing Activities





## Private Facilities Providing Vaccination Services



## Total Private Facilities Providing Pre-Marital Checkup



## Private Facilities Providing Pre-employment Examination for Expatriates





## Inspection Visits 2021



## Inspection Violations

**117** total number of general violations

**62** number of infection control violations

**8** number of medication violations

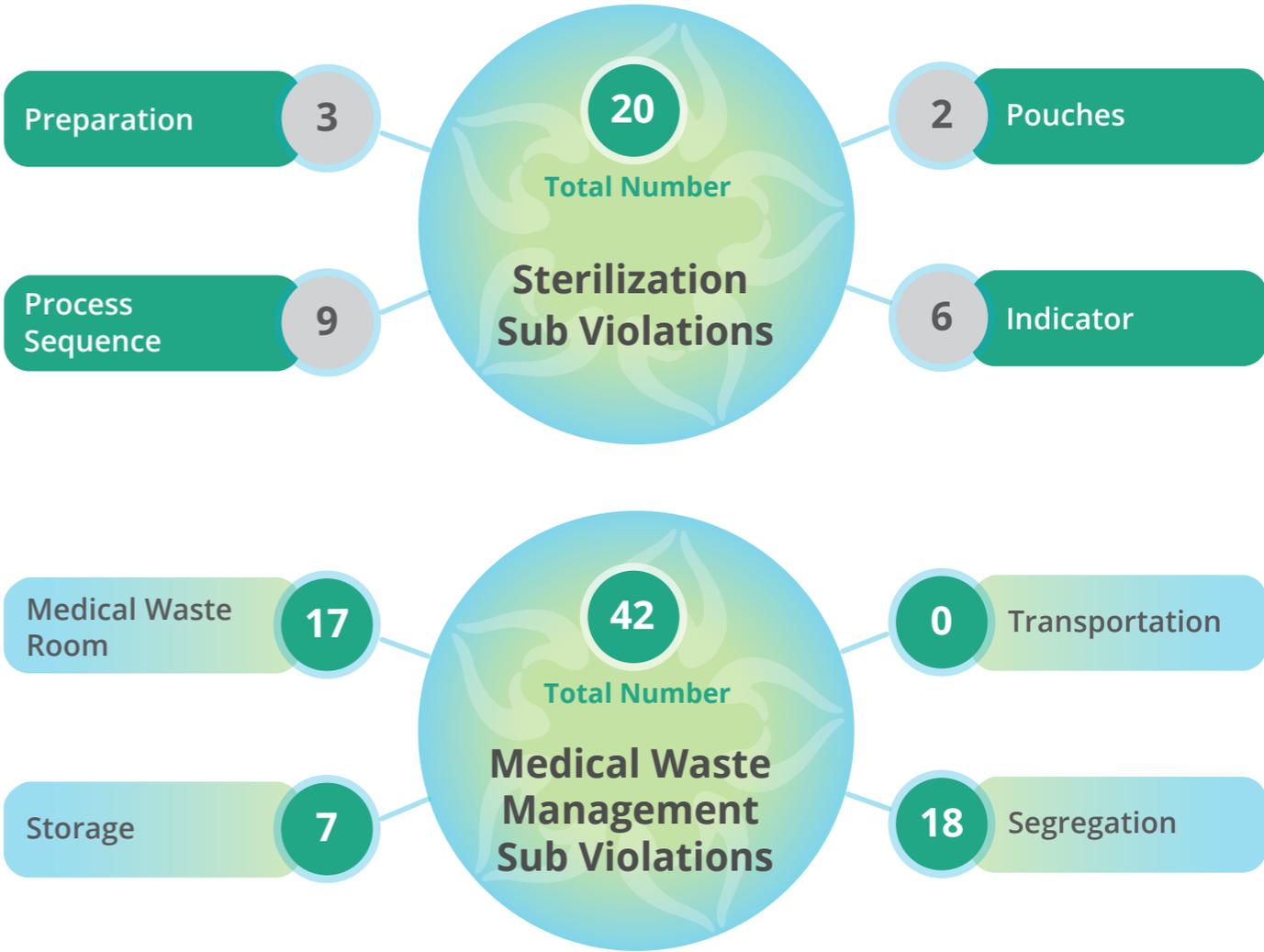
**576** number of no violation "appreciation letter"



General Violations

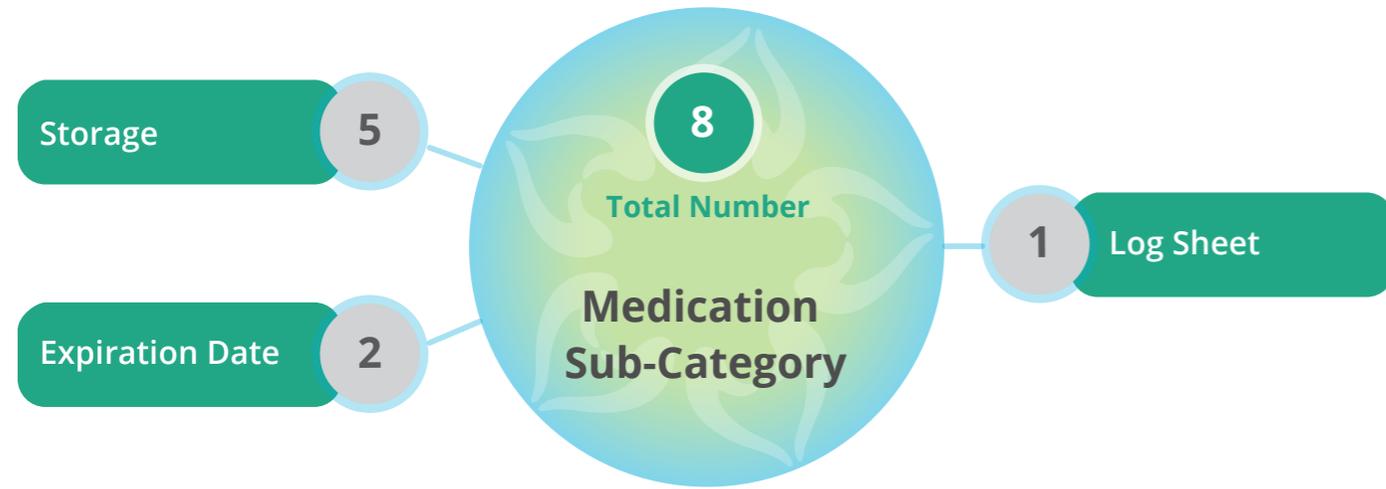


Infection Control Sub-Category Violations





## Medication Sub-Category Violations





Facility Safety Sub Violations



Licensing Violations



Device Safety Sub Violations

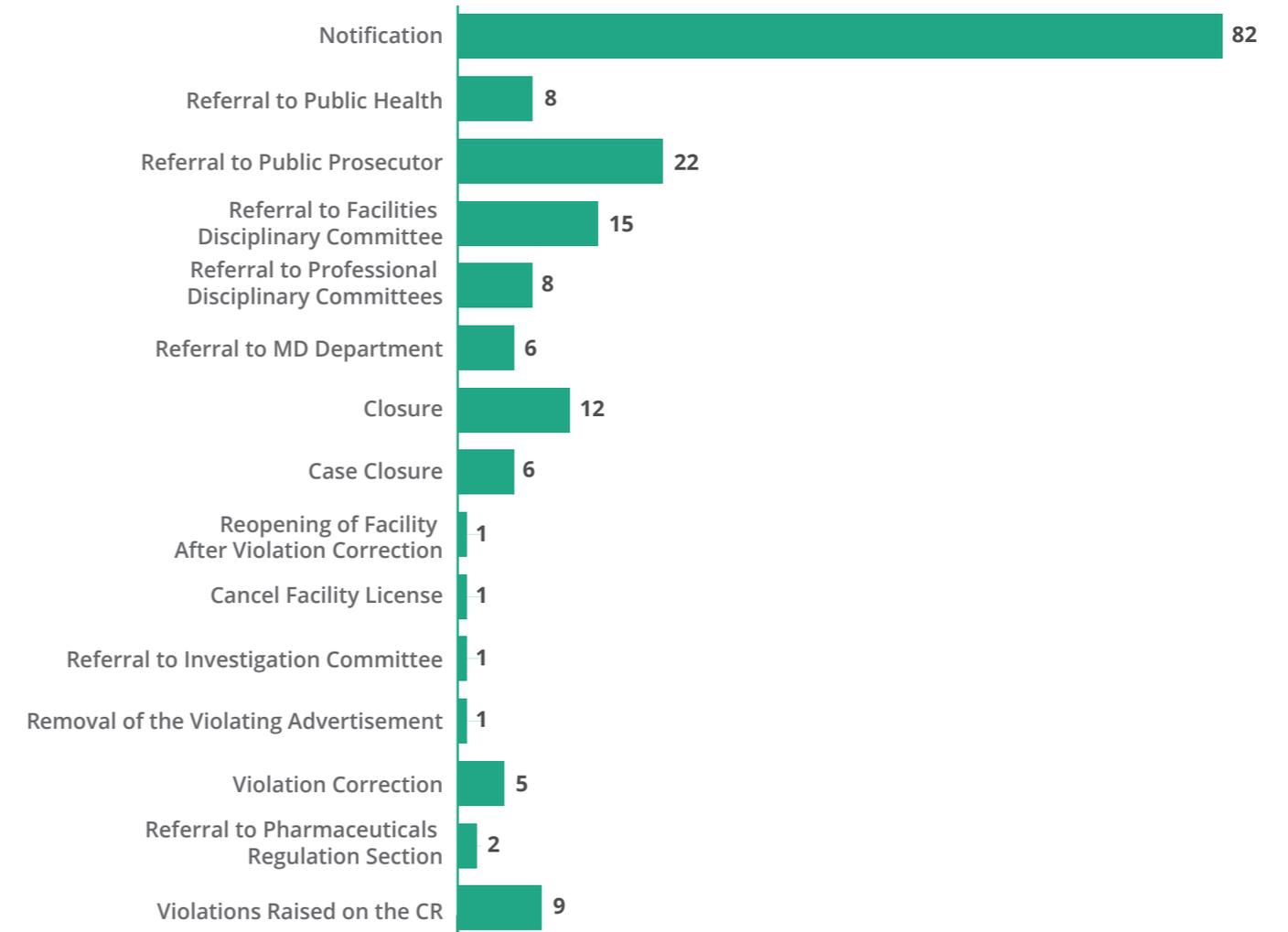




## Quality Control Assessment



## Actions Taken Against Violations Detected





### Digitalization of Services (Mehan.nhra.bh)

The department was fully engaged in fully automating its services in 2021 with the launch of its new system "Mehan". The system was launched in line with NHRA's 'Go Green' initiative, with the aim of benefiting all healthcare professionals. This considerable advancement allows professional licenses to be issued electronically with unique barcodes encoding for all the practice's pertinent information. To prevent penalties, the system also generates an alert notification to alarm healthcare professionals of upcoming license expiry, further allowing them to promptly upload the required CME certificates to facilitate renewal.

# 25,076

total number of healthcare licensed professionals active in the Kingdom of Bahrain

# 14,261

total number of new and renewal applications processed

### Licensing Activities

In 2021, the Kingdom of Bahrain had a total of 25,076 healthcare professionals holding an active license. Among these, 4,727 of which were physicians, 1,145 were dentists, 1,702 were pharmacists, 13,558 were nurses, and 3,944 were allied health professionals. The Health professions Regulation department also handled 3,478 new license applications and 10,783 license renewal applications. A total of 1,889 people took the licensure exam, with a 69% pass rate.



## Total Active Health Professionals

physicians **4727**

dentists **1145**

nurses **13,558**

pharmacists **1702**

allied **3944**

## New License Application Processed

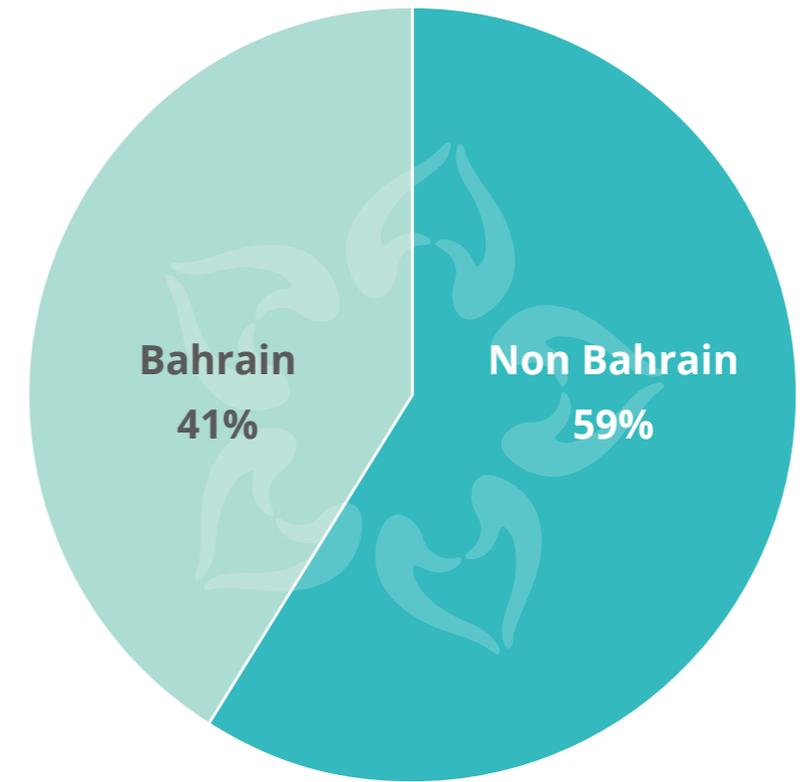




## Renewal License Applications Processed

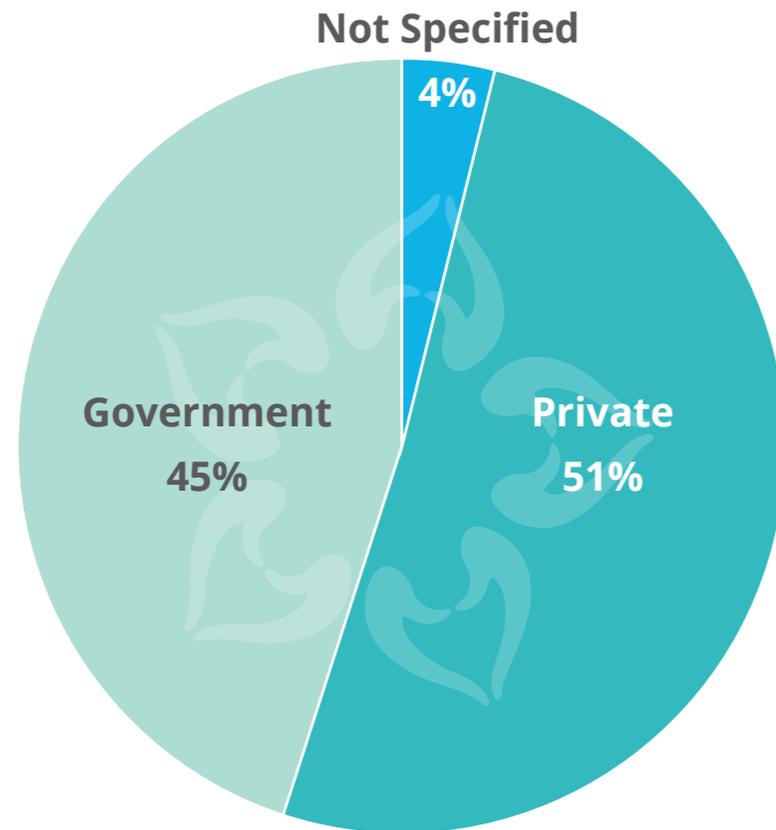


## Healthcare Workforce by Nationality





## Healthcare Workforce by Place of Work





### NHRA Licensed Physicians by Professional Category



### NHRA Licensed Dentists by Professional Category



### NHRA Licensed Nurses by Professional Category

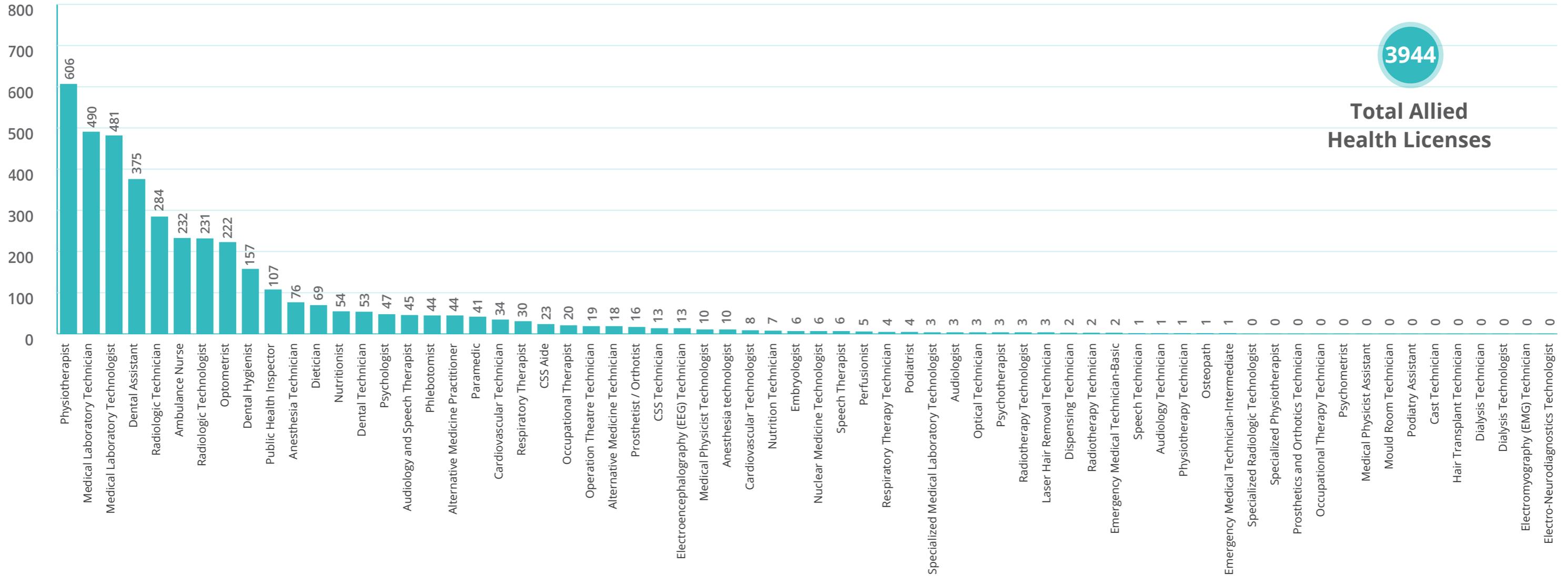


### NHRA Licensed Pharmacists by Professional Category



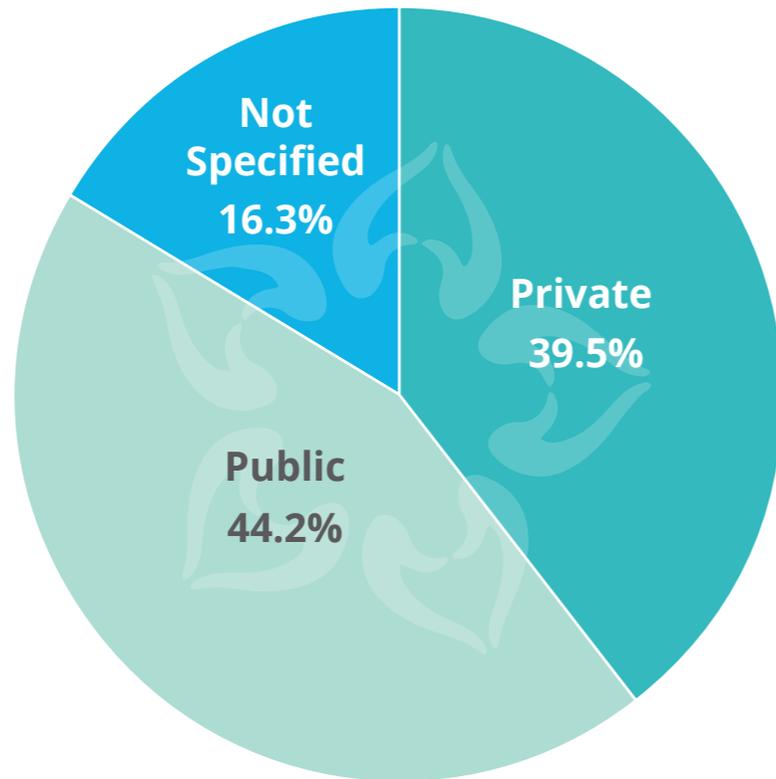


## NHRA Active Allied Health Professionals

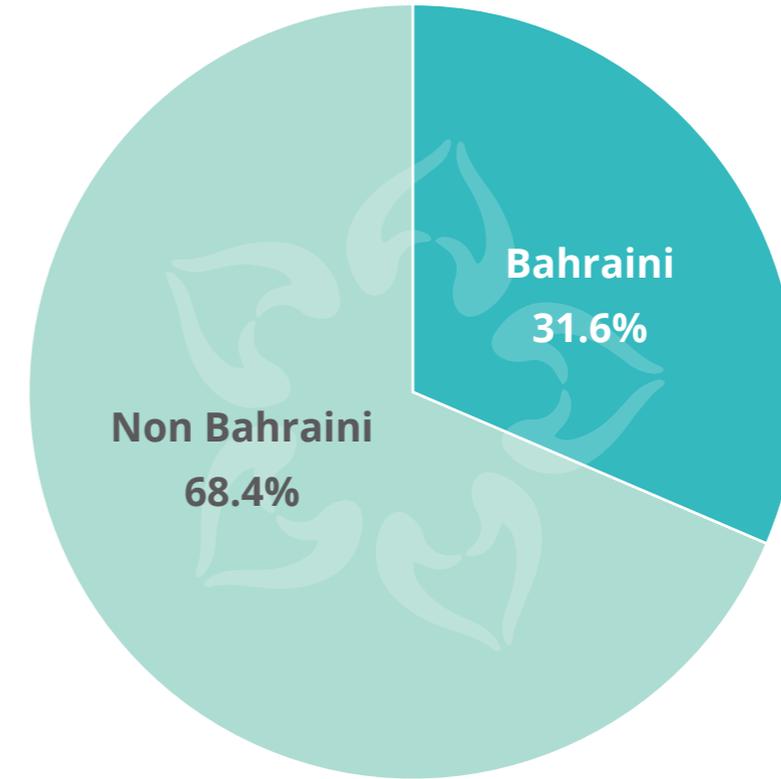




### Distribution of Physicians Place of Work

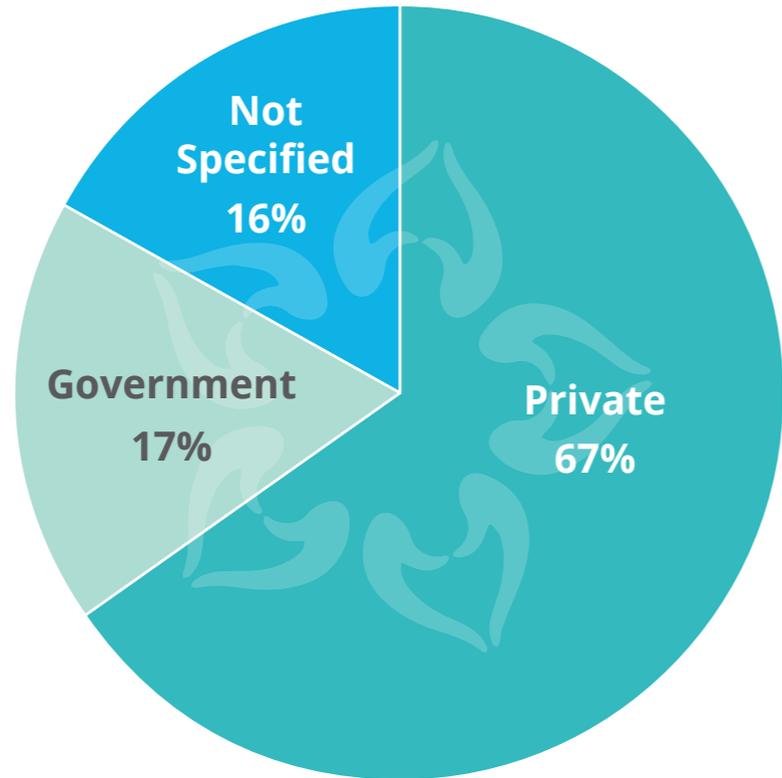


### Distribution of Physicians Nationality

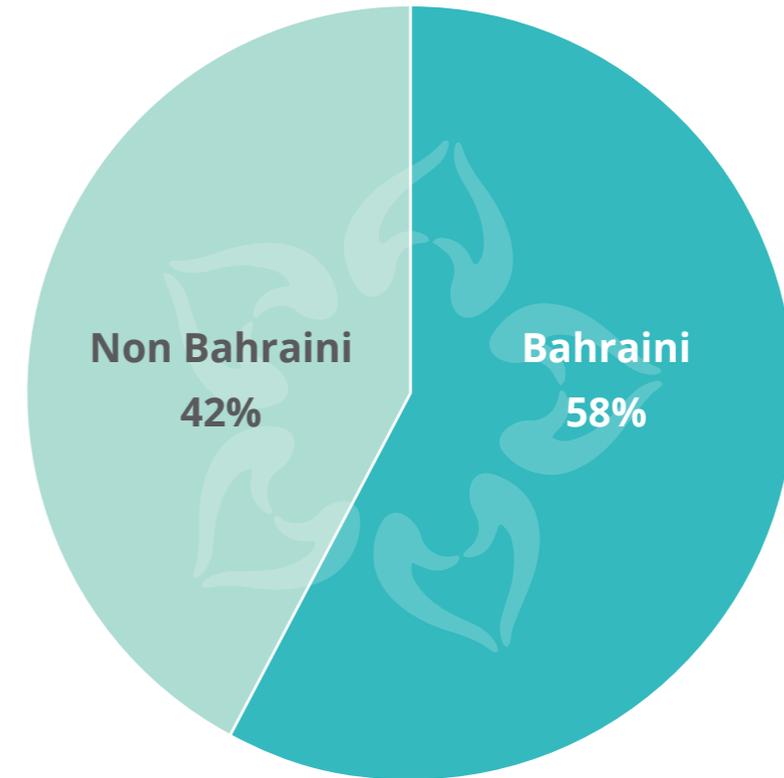




### Distribution of Dentists by Work Place

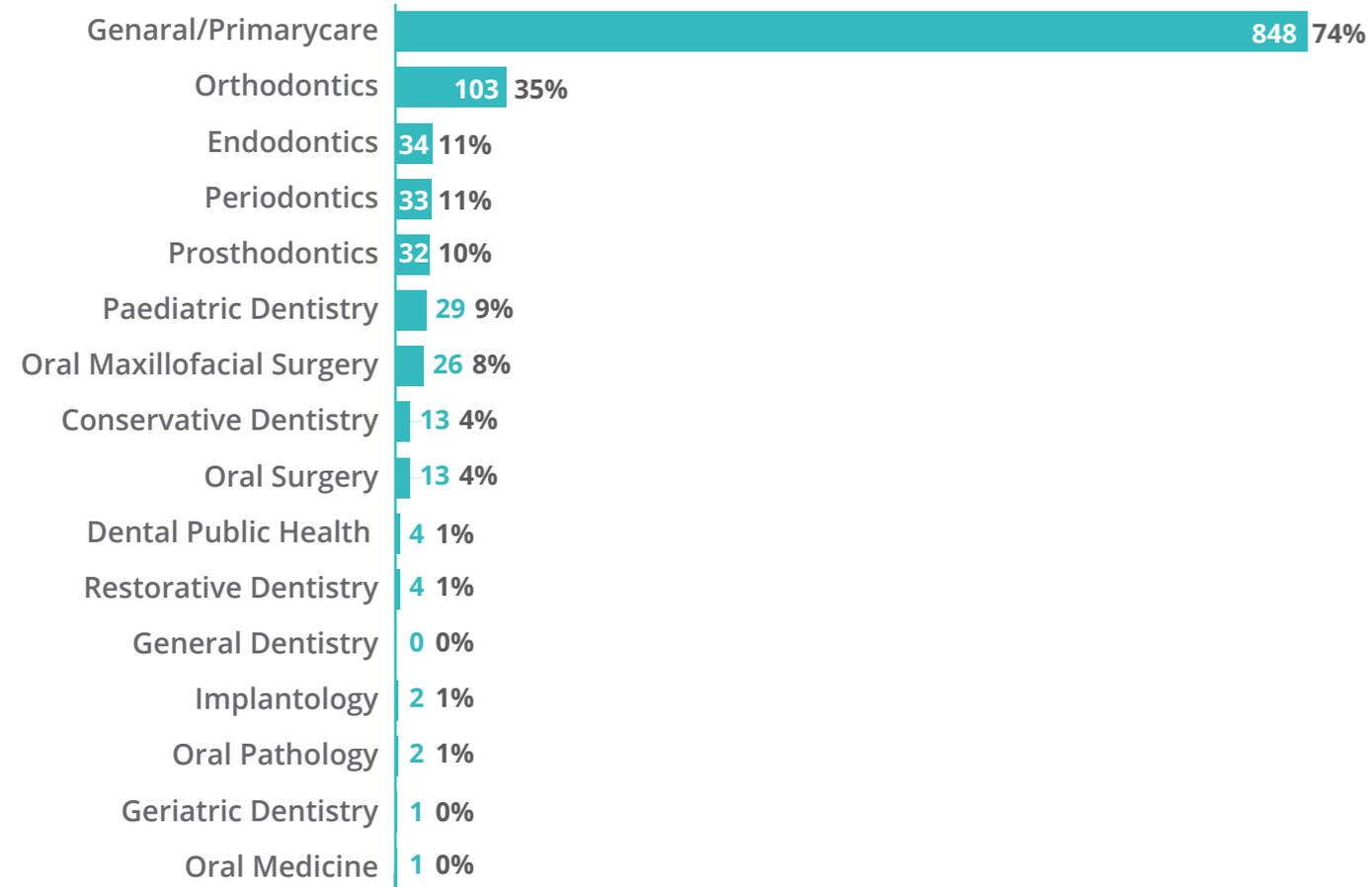


### Distribution of Dentist by Nationality



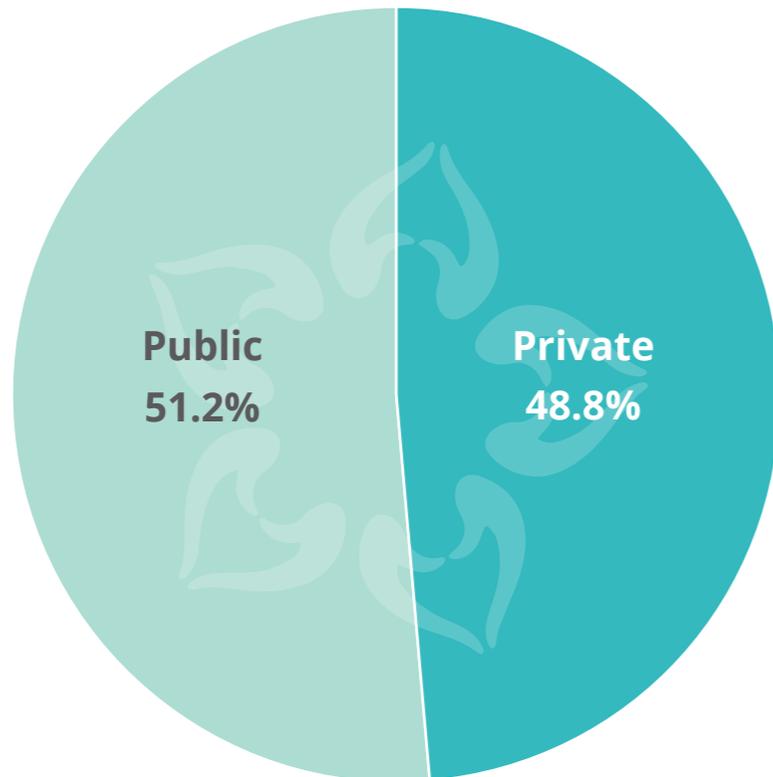


## Dentists by Speciality

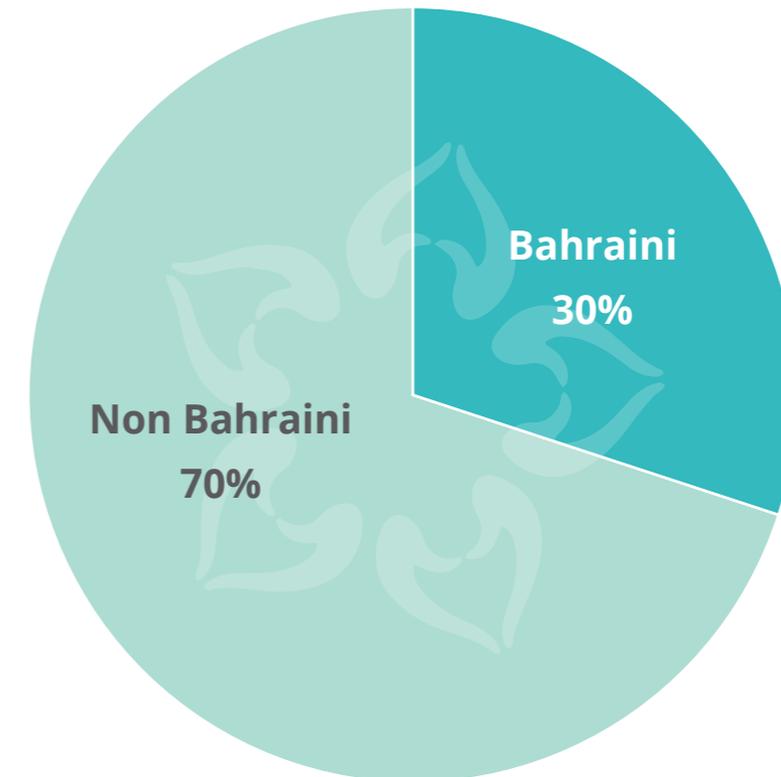




## Distribution of Nurses Place of Work

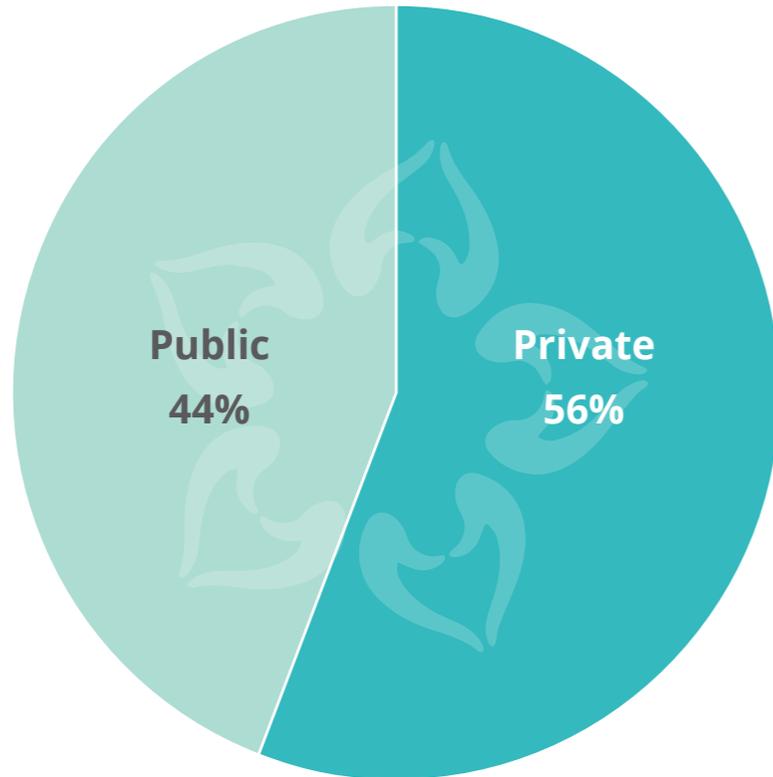


## Distribution of Nurses Nationality

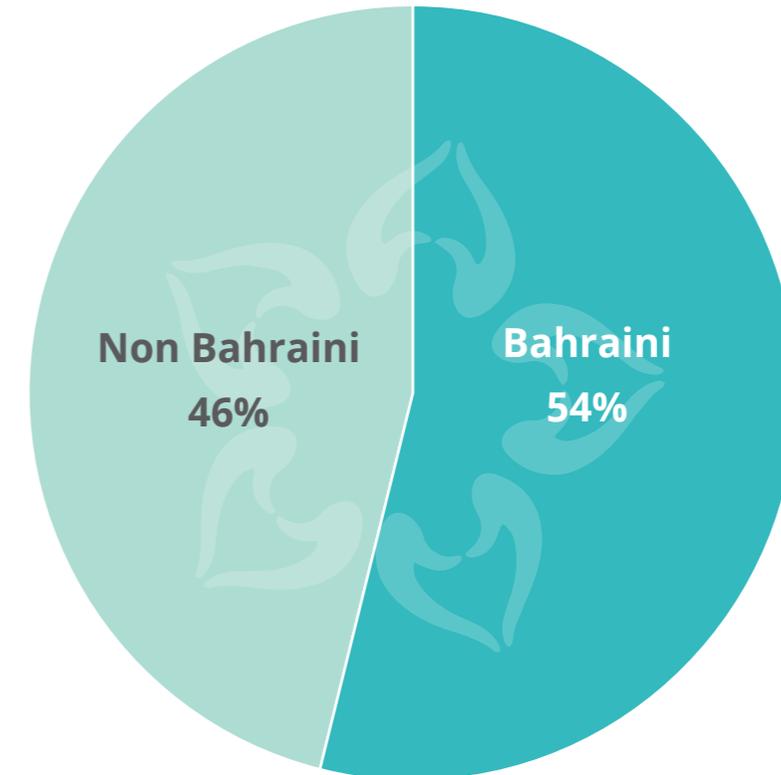




### Distribution of Allied Health Place of Work

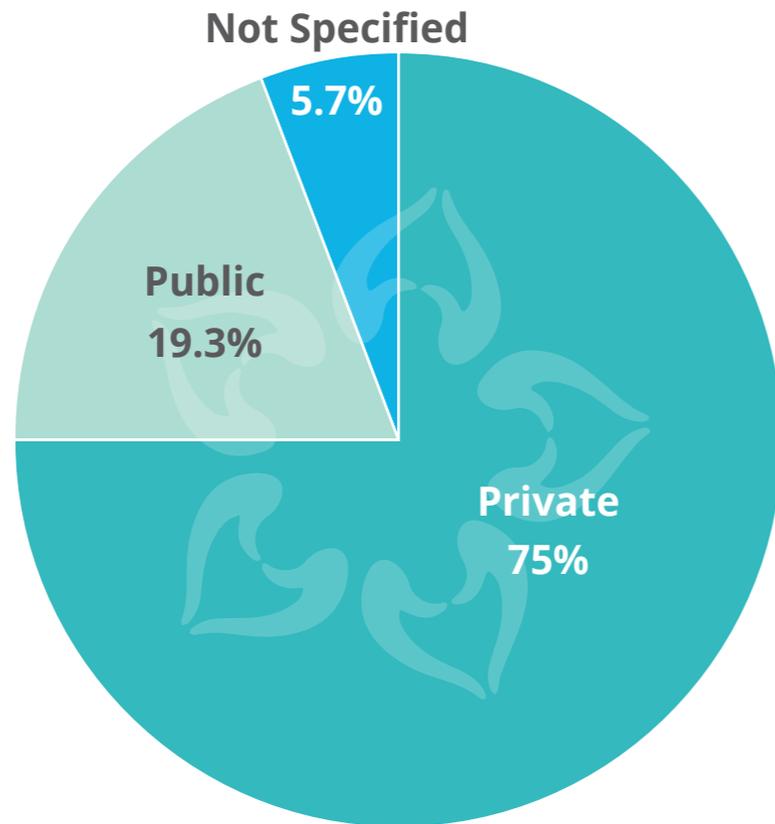


### Distribution of Allied Health Nationality

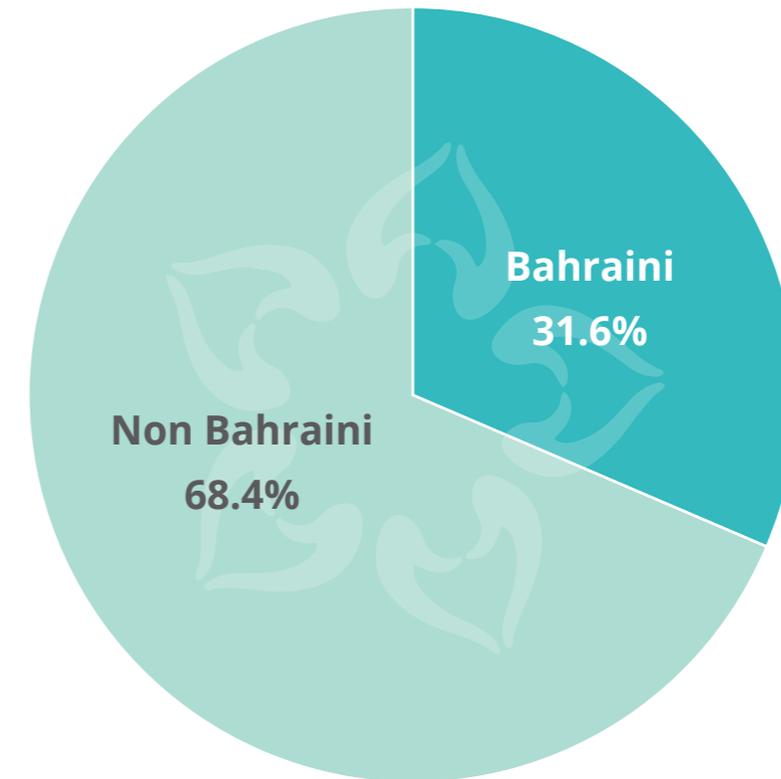




### Pharmacists by Specialty by Place of Work



### Pharmacists by Specialty by Nationality





**44**

number of licensed alternative medicine practitioners

**18**

number of licensed alternative medicine technicians

**9**

total number of licensed alternative medicine physicians

**21**

total number of licensed alternative medicine facilities

**31**

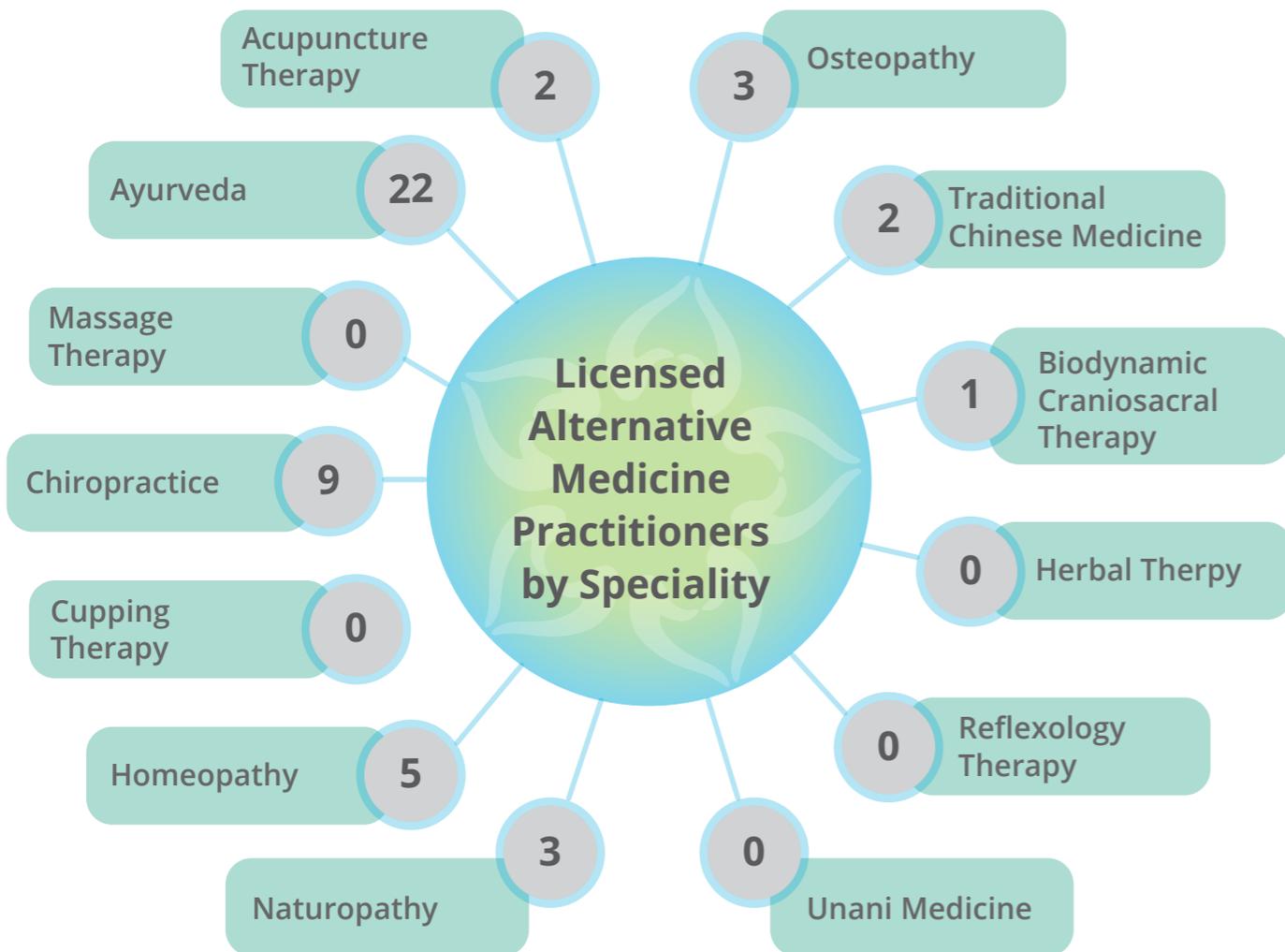
total number of facilities providing alternative medicine services

The National Authority continued its efforts to regulate complementary and alternative medicine (CAM) in the Kingdom, as twenty (20) applications for licensing alternative medicine facilities were approved. Thus, the number of licensed alternative medicine facilities in the Kingdom in 2021 reached 21 facilities specialized in alternative medicine, in addition to 31 health facility providing alternative medicine within their medical services. The number of health professionals licensed in the various fields of alternative. medicine reached 71 professionals. To expand its partnerships, the authority has collaborated with the Indian Embassy and the government agency, 'Ayush Ministry' of the Republic of India, to conduct several online meetings to exchange information and support the authority's efforts in organizing professionals' licensing and conducting licensing examinations. Where the first licensing exam for alternative medicine pharmacists was conducted in the Kingdom of Bahrain with the participation of five (05) pharmacists specialized in alternative Indian medicine (Ayurveda).

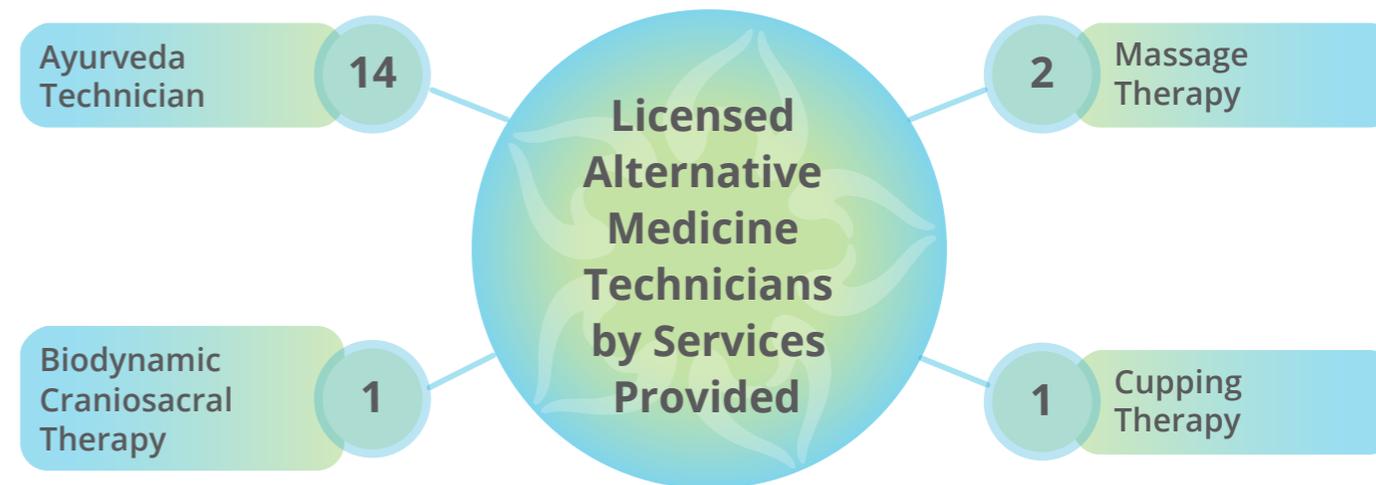




Licensed Alternative Medicine Practitioners by Speciality



Licensed Alternative Medicine Technicians by Services Provided





**3** total number for new applications for alternative medicine facilities

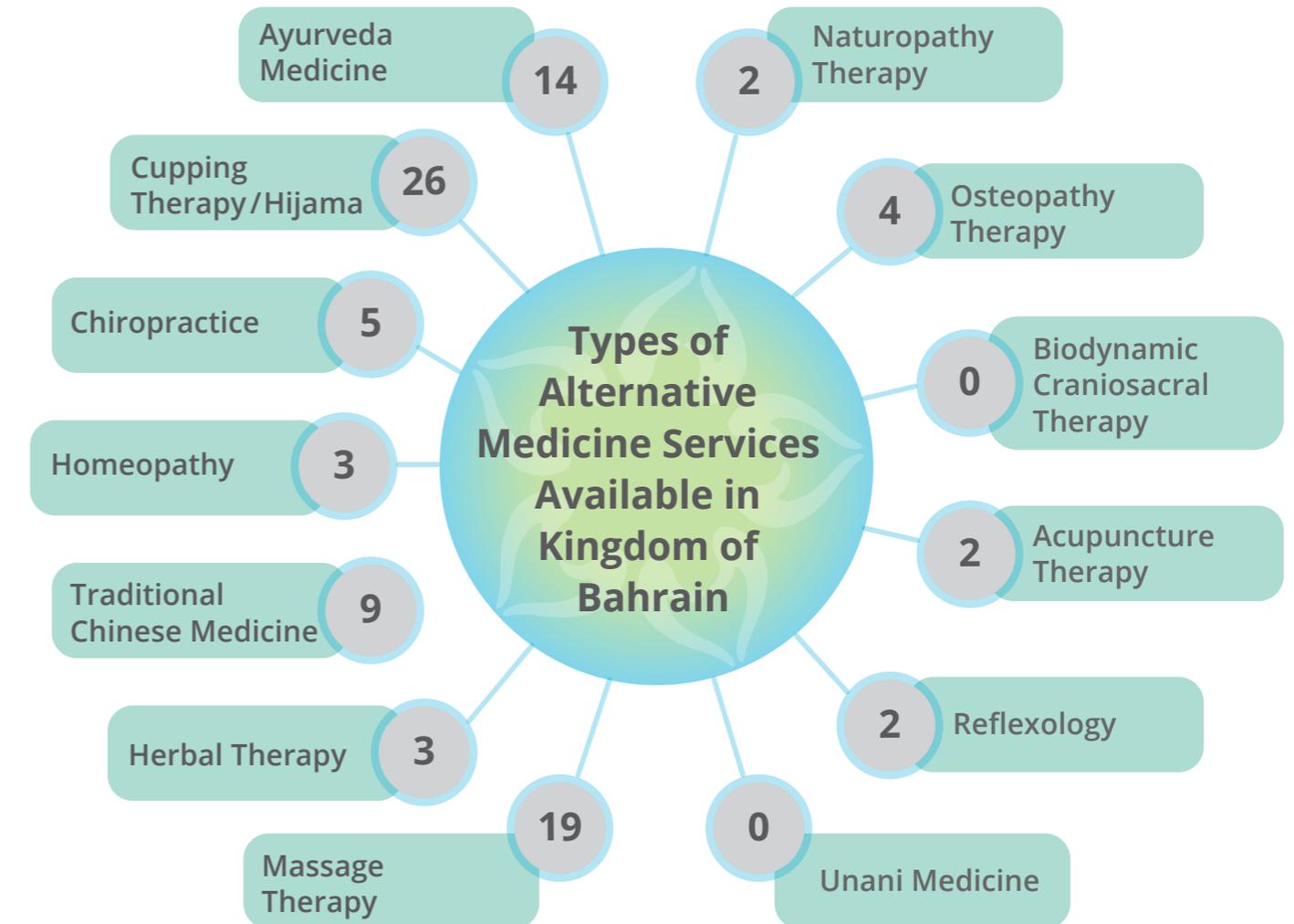
**145** total number of licensed alternative medicine facilities products approved

## ACM (Alternative and Complementary Medicine)

**19** total number of products received in 2021

**13** total number of products approved

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





**593** total number of health products registered in the Kingdom

**7** total number of COVID-19 vaccines emergently authorized

**145** number of alternative and complementary medicines approved

**357** total number of new medications registered

**3643**

total number of medications registered in the Kingdom

## Registration Activities

This year was the departments most successful year with the registration of 357 new drugs bringing the total number of registered pharmaceutical products to 3,643. The department processed 575 medicine licensing renewals, 1,431 medicine variation applications, and 461 drugs were priced by the department. The department also classified 410 Pharmaceutical Products. 151 overseas manufacturing site applications and 16 agency transfer applications were continued to follow through registration and renewal.

By 2021, registration of 3643 pharmaceutical products, 593 health products, and 3,857 medicine was processed on Brand Sync (GS1) Portal, and 3,233 total Medicine Baseline applications were imported.



## Pharmaceutical products Custom Release Activities

The department continued to assist in preventing medicine shortages in the country and ensuring that all necessary medicines are available to patients in Bahrain, by processing 2004 temporary importations of non-registered items applications.

The department processed 9,532 electronic invoices using the Drug Utilization Review System (DUR). 584 manual invoices were approved, 508 cold chain shipment releases were made, and 3,857 medicines were processed on Brand Sync Portal.

## Emergency Use Authorization

To respond to the public health emergency caused by the coronavirus (Covid-19) pandemic, the authority has established a new pathway to approve the emergency use authorization for submitting applications for vaccines and medicines with the aim of accelerating and simplifying the evaluation and licensing of promising vaccines and treatments. The main objective was to assist manufacturers in obtaining a license for the emergency use of vaccines and medicines, which contributed to making the Kingdom of Bahrain among the first countries to introduce new vaccines and medicines to combat the Covid-19 virus.

## Pharmaceutical Track and Trace (GS1) on Blockchain

To implement Article (1) of the Supreme Council of Health's Resolution 41 for 2017, which grants the National Health Regulatory Authority, the authority and obligation to apply the Track and Trace system for the supply chain of medicines within the Kingdom of Bahrain from the manufacturing site to the patient, NHRA has partnered with MVC to provide the Kingdom of Bahrain with the world's most advanced and secure system. The SmartPass platform provides an auditable cryptographically verified solution.



SmartPass is the world's first blockchain-based track-and-trace platform, featuring dual notarization of smart contracts for compliance, customs clearance, supply chain finance, and cross-border payments. SmartPass is powered by AWS and leverages the immutable Hyperledger Fabric blockchain with Hedera Hashgraph consensus and governance. The system includes the following features:

- Significantly reduces the risk of counterfeit and fraud in the marketplace (benefits the Kingdom of Bahrain, its residents, pharmaceutical companies, and their supply chains), as well as the return of unused drugs.
- Facilitates Supply Chain Financing from Local and International Banks.
- Reduces the manpower needs for both government and private workers, and reduces errors.

By the end of December 2021, 73% of the 247 marketing authorization holders had registered with MVD, accounting for 94% of all pharmaceuticals imported into the Kingdom. The system has registered 69 % of agents and 57.7% of pharmacies. The deadline for full registration has been extended to May 2022, with track and trace on Blockchain likely to go live by the fourth quarter of 2022.

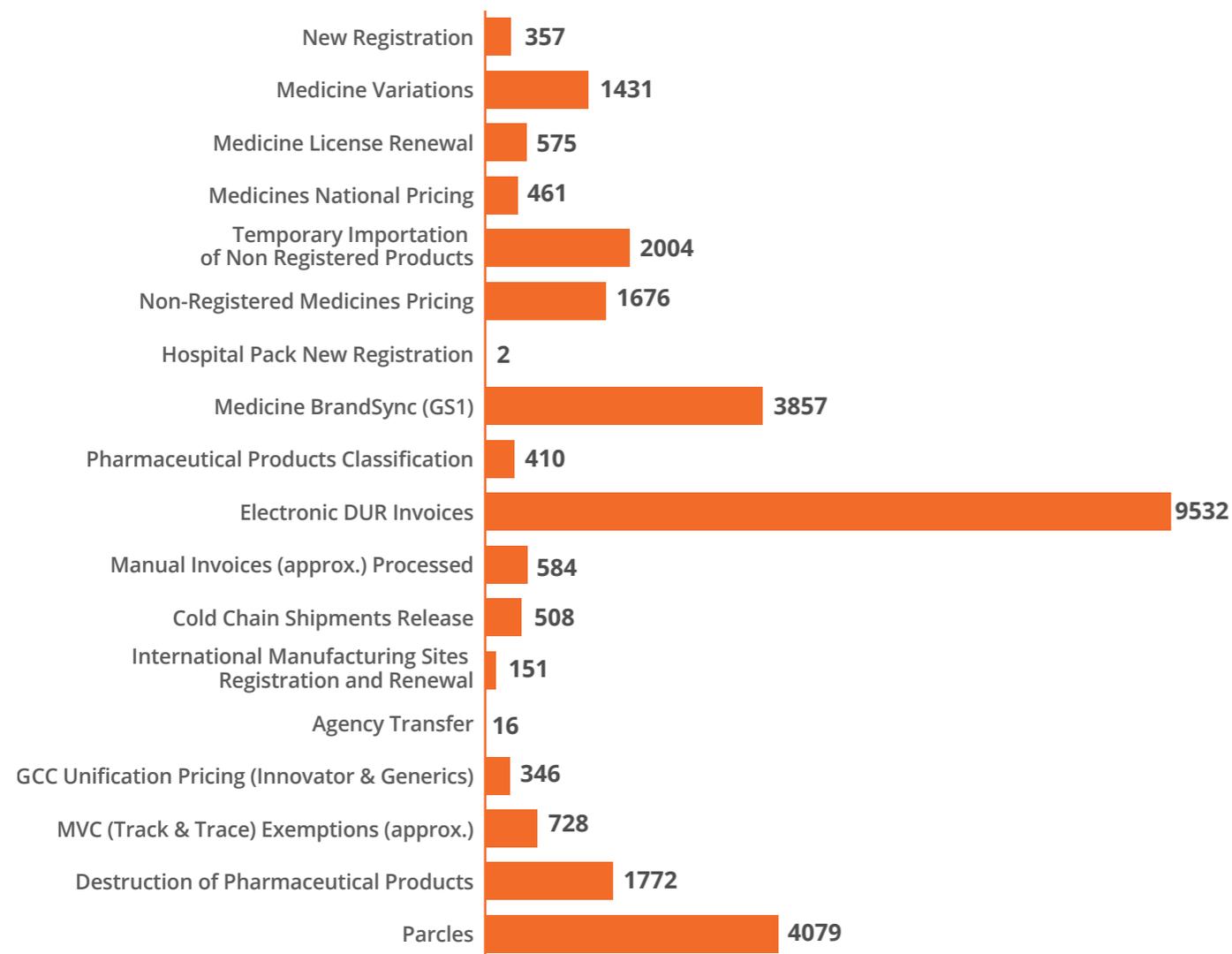


## Inspection Activities

Despite the country's pandemic crisis, the department completed 421 inspection visits, with inspectors taking full precautions to carry out their duties. There were 375 violations found and remedied, with 40% of them involving pharmaceutical violations, followed by 24% involving temperature and humidity violations, 23% involving pharmacy set up, 7% involving price violations, and 6% involving licensing violations.



## Regulatory Activities



**18**

number of new alternative medicines applications processed

**60**

number of new health products registered

**55**

number of health products license renewed

**29**

number of variations of health products

**3233**

electronic Common Technical Document (eCTD)

number of baseline importation status of applications

**2304**

number of drug mapping

**COVID- 19**

**2841**

number of safety evaluation of vaccines and communications

**6**

number of emergency use authorization of COVID-19 medicines



## Licensing Activities

A total of 78 new pharmacies were licensed in 2021, of which 8 were opened in a healthcare facility and 70 were public pharmacies, reflecting a 16% increase in the number of licensed pharmacies compared to 2020. The total number of pharmacies licensed in the Kingdom of Bahrain are 396 of which 317 are operating as public pharmacies and 79 are operating in a healthcare facility. 6 New Warehouses were registered making it total of 22 Pharmaceutical Warehouse registered.

**396** total number of licensed pharmacies

**79** total number of private pharmacies

**317** total number of public pharmacies

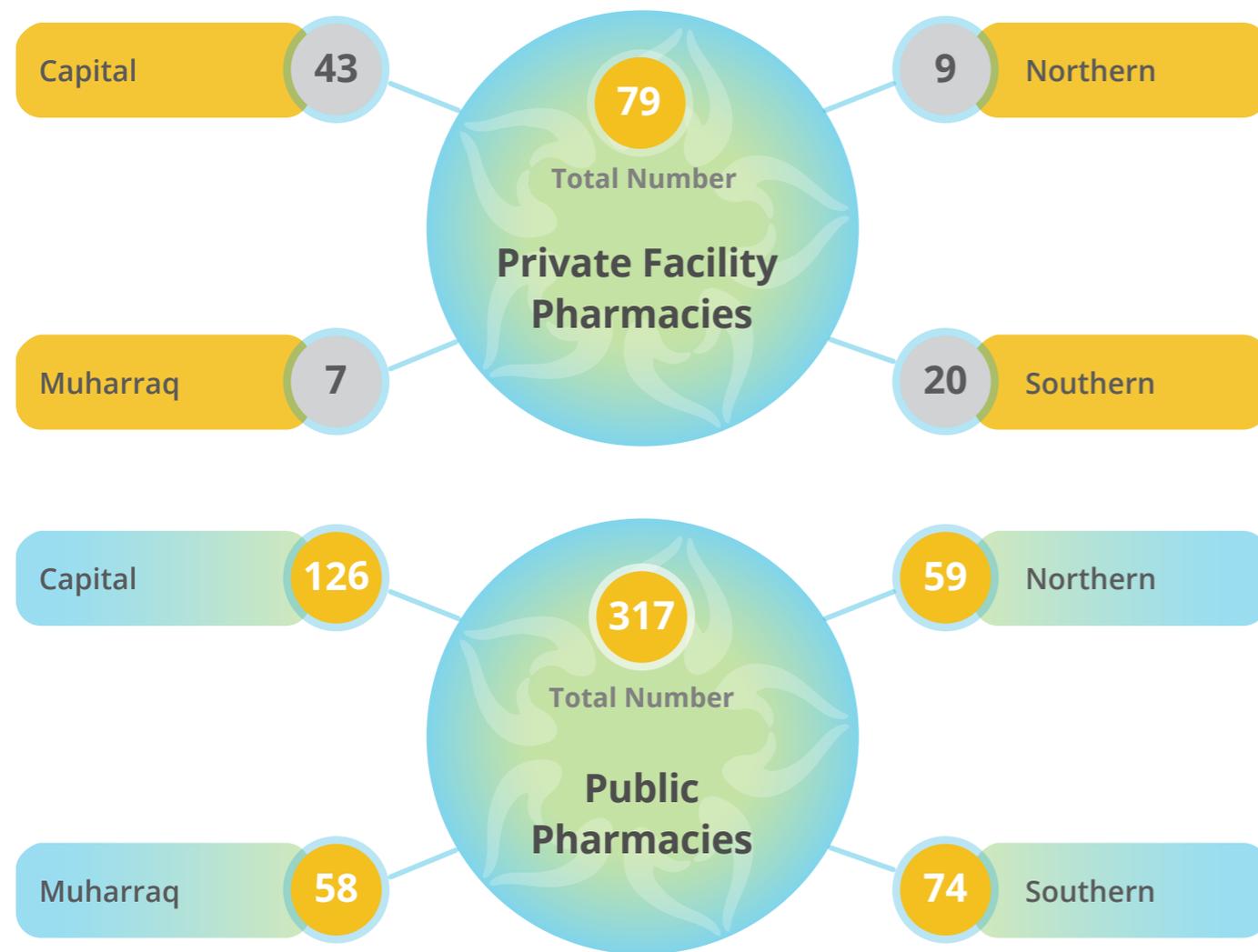
## Inspection Activities

The department conducted 421 inspection visits, despite of the pandemic situation facing the country, the inspectors with full precautions took the risk to carry their duty.

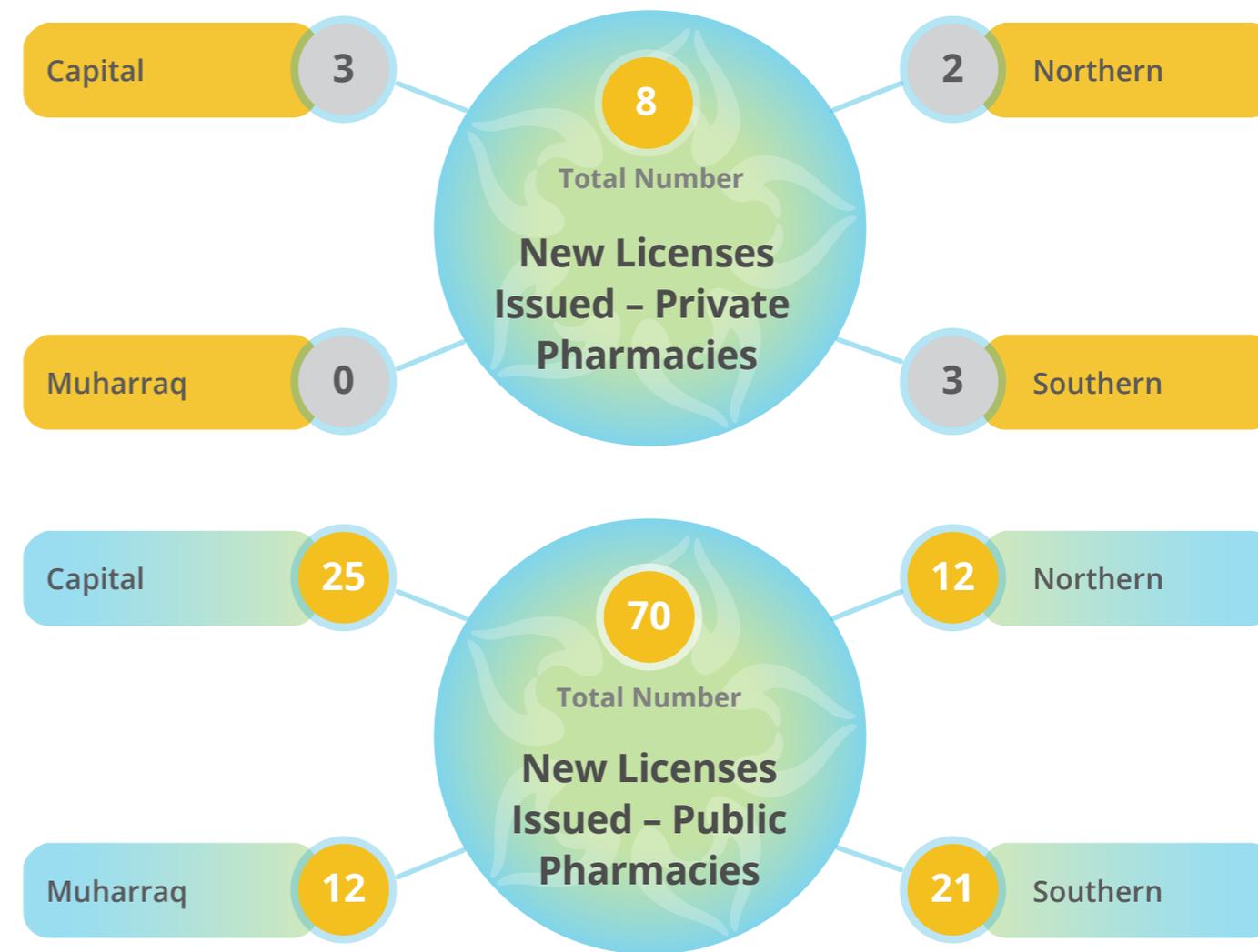
375 violations were identified and corrected out of which 40% were related to medicine violations, followed by 24% related to temperature and humidity violations, 23% related to pharmacy set up, 7% related to price violations and 6% related to licensing violations.



## Pharmacy Licensing



## New Licenses Issued





## Geographic Distribution of Public Pharmacies with Special Services



## Inspection Activities



**421** total number of inspection visits conducted

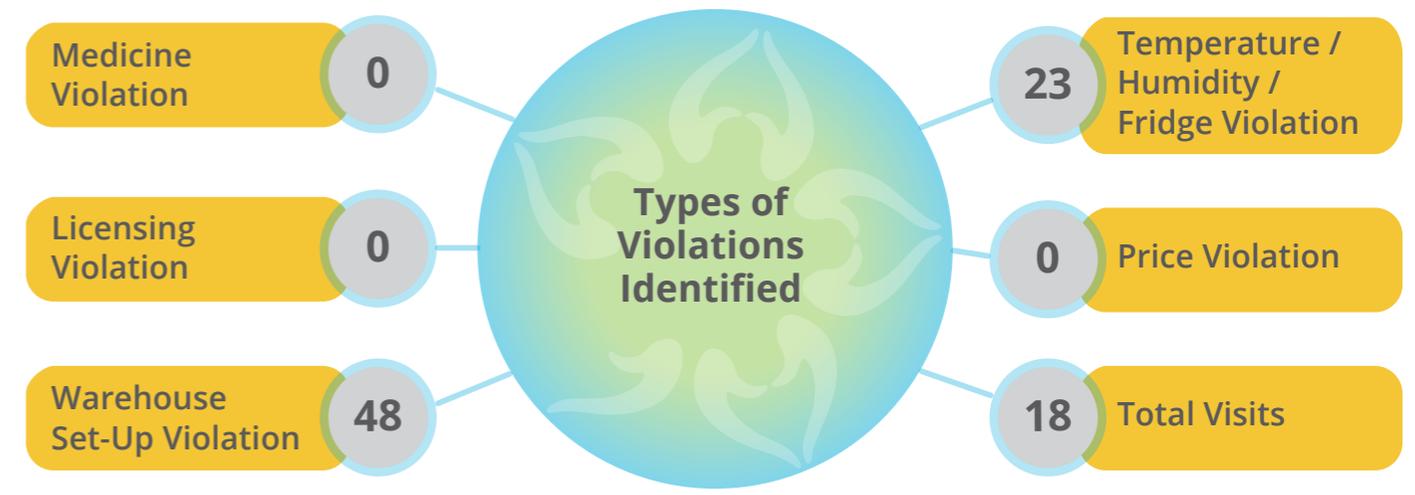
**22** total number of licensed warehouses



## Approvals Issued to Facilities



## Inspection Activities for Warehouse





**35,245,050.47** BHD  
total value of medical devices imported

**19** total number of inspection

**134**  
total number of new companies request (sijilat)

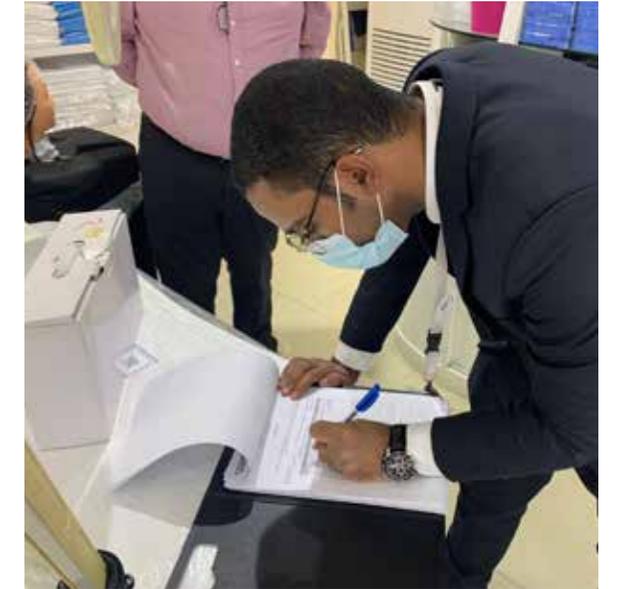
**9644**  
total number of new medical device applications assessed

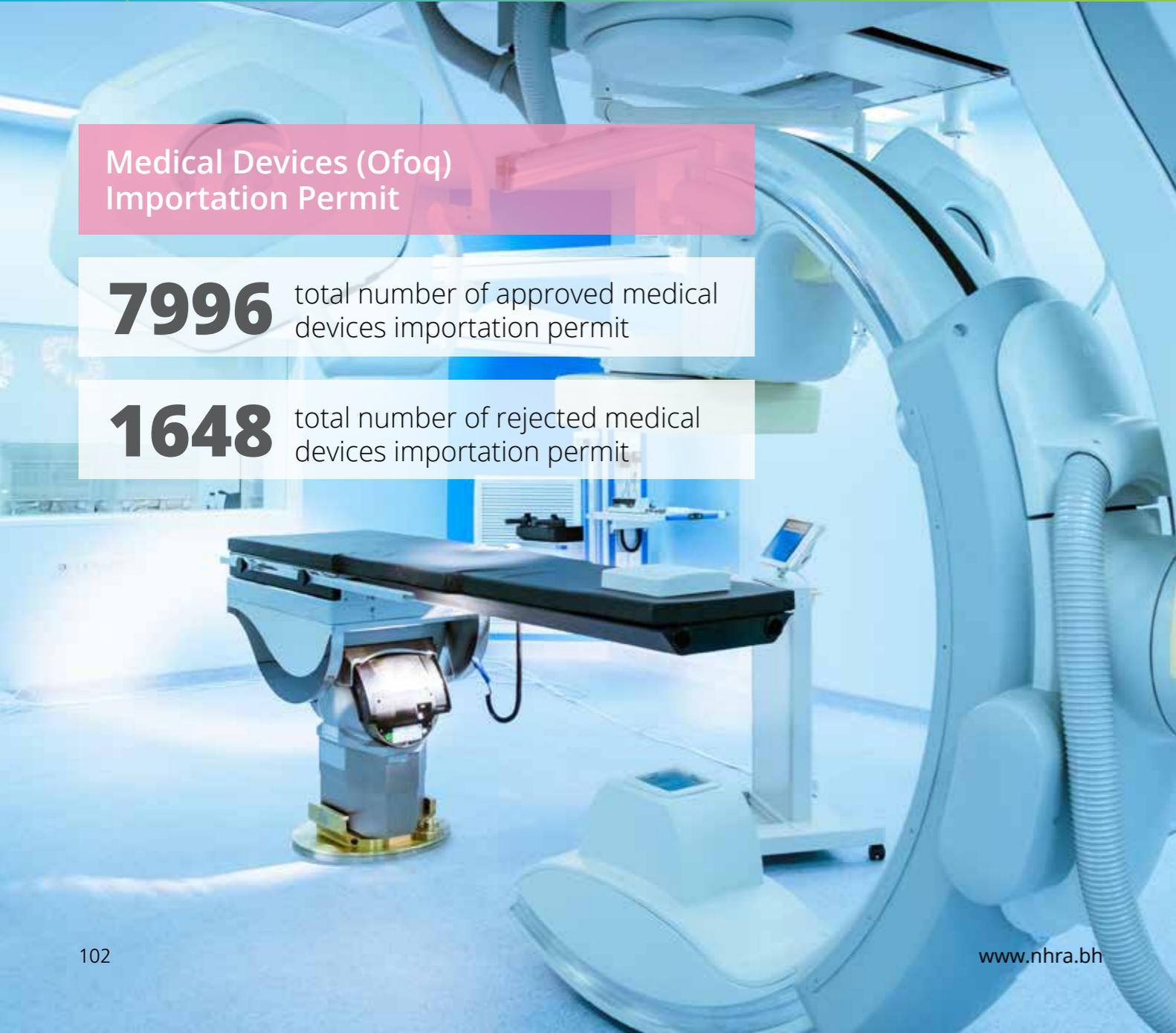
**Registration Activities**  
The Medical Device Regulation department successfully licensed 10 new MD companies and registered 523 medical devices in 2021. The purpose of the registration procedure is to assess whether or not the products meet the safety, performance, and quality requirements set forth in the applicable regulations and standards.



## MD Custom Release Activities

The department's biomedical engineers evaluated a total of 9,644 new medical device applications, of which 7,996 were approved through the Electronic System of Customs (OFOQ). The authority turned down 17 % of all import applications (1,648) either due to the discovery of a forged certificate or a counterfeit device. The imported devices released from customs cost a total of 35,245,050.47 BHD.



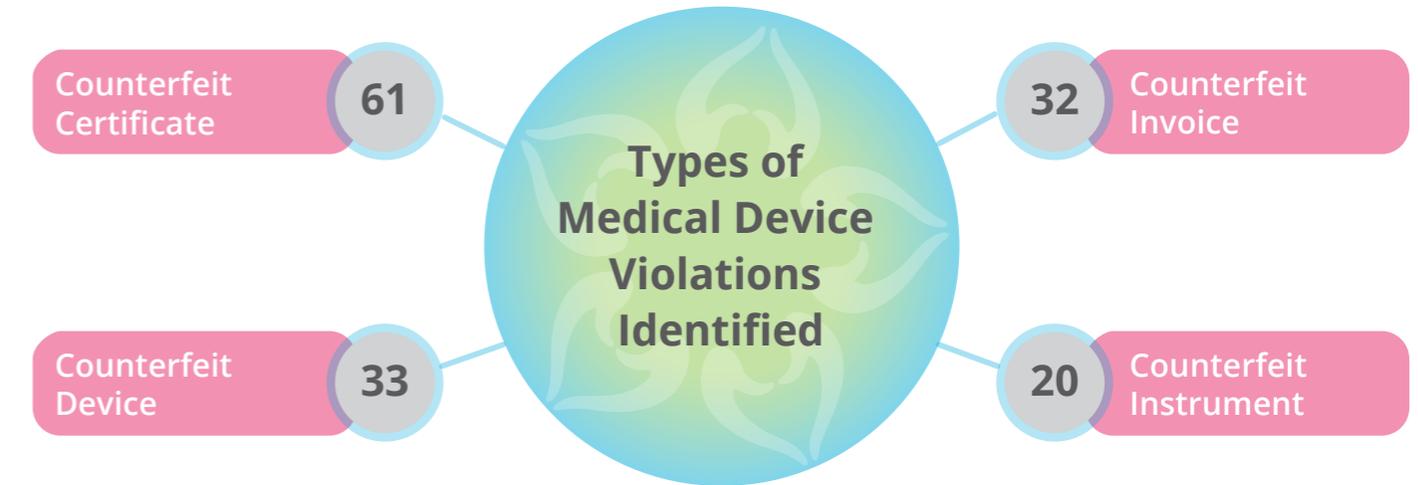


## Medical Devices (Ofoq) Importation Permit

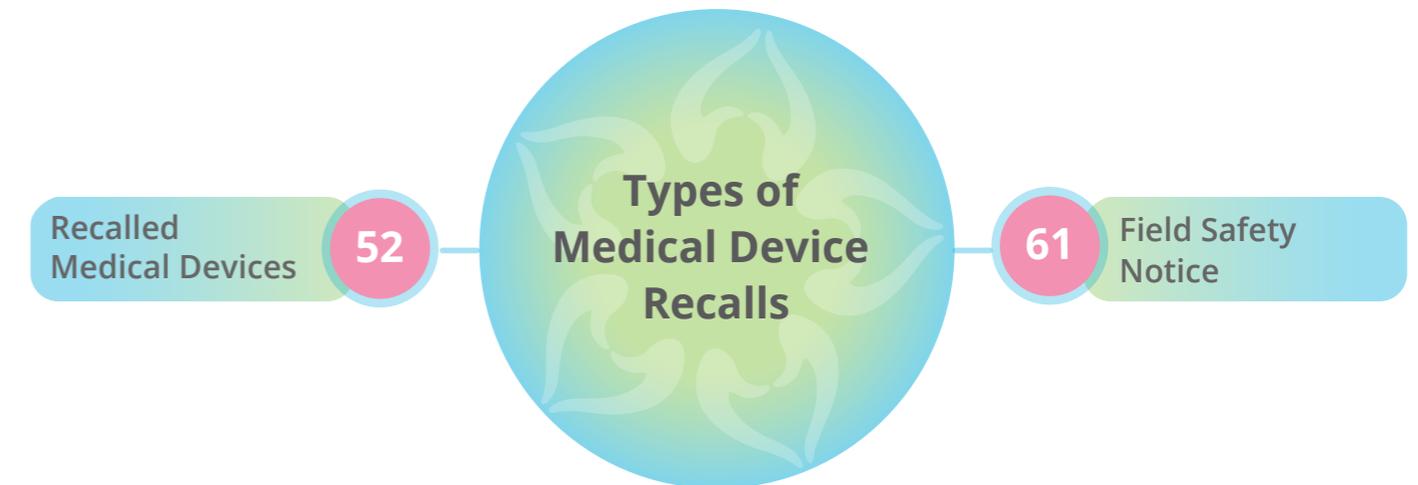
**7996** total number of approved medical devices importation permit

**1648** total number of rejected medical devices importation permit

## Types of Medical Device Violations Identified

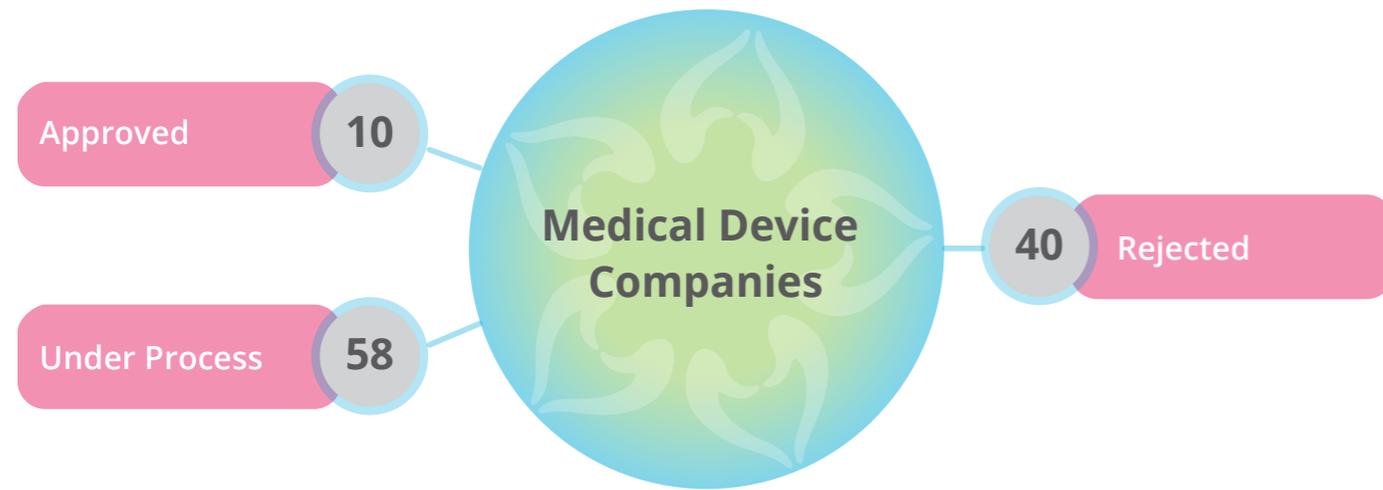


## Types Of Medical Device Recalls

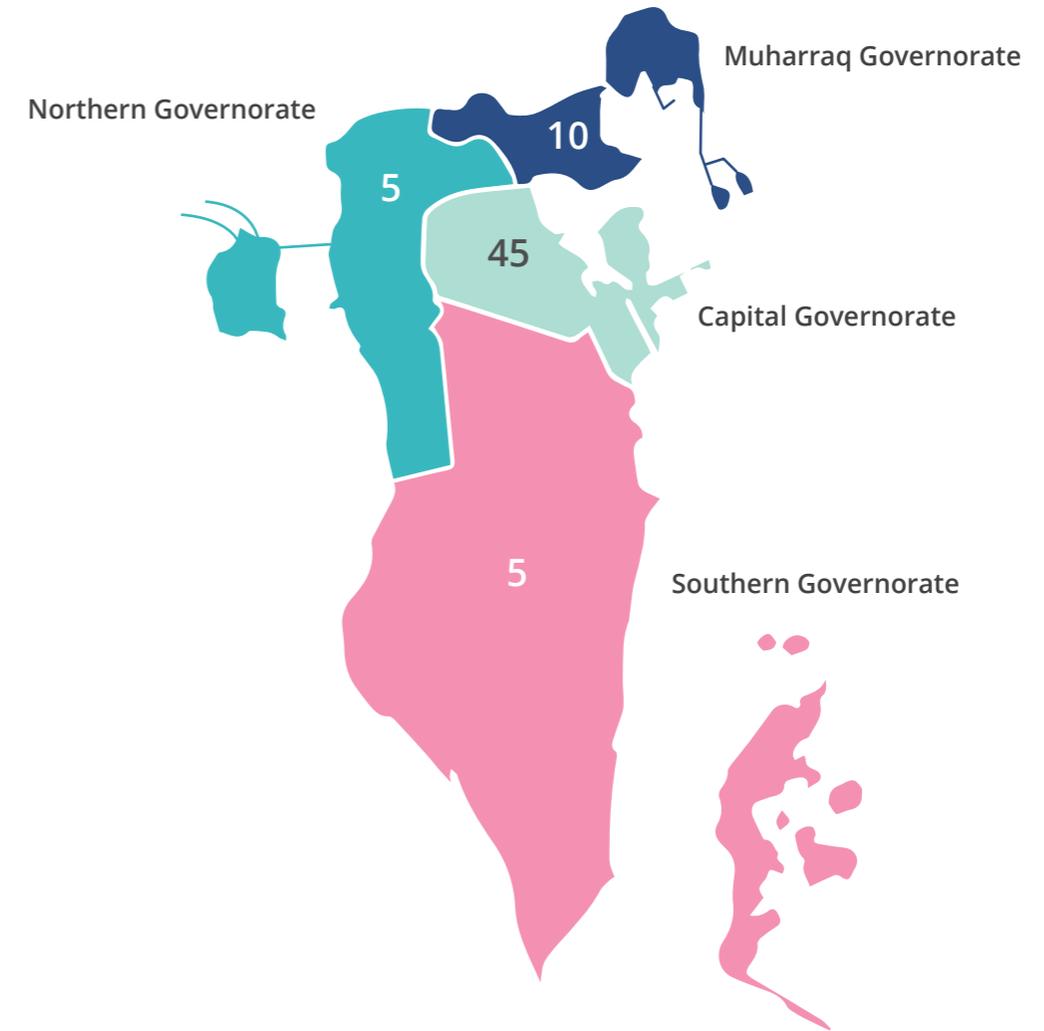




## Medical Devices Authorized Representative Registration

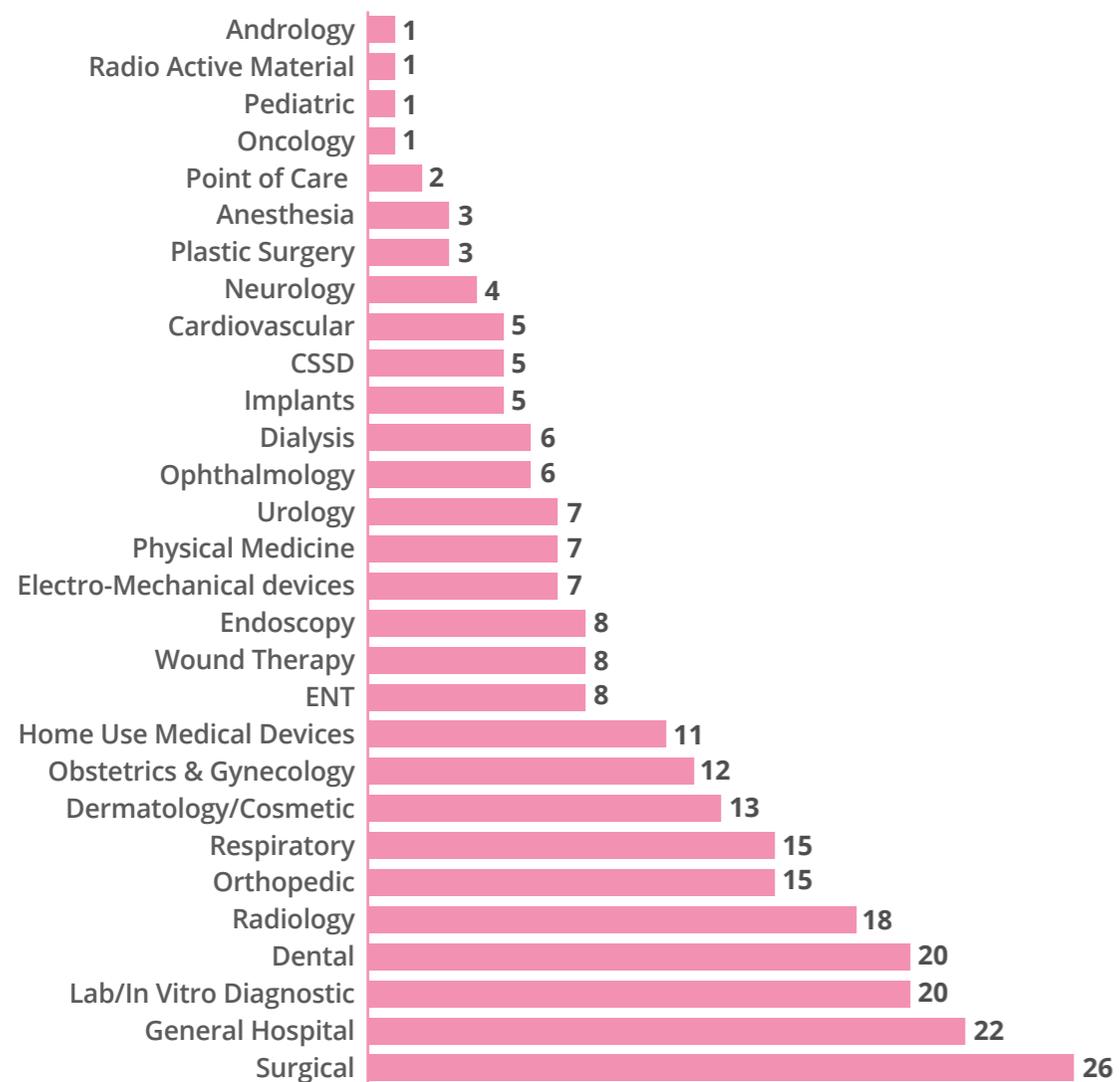


## Distribution of Authorized Representatives for Medical devices in the Kingdom of Bahrain as per the Governorates

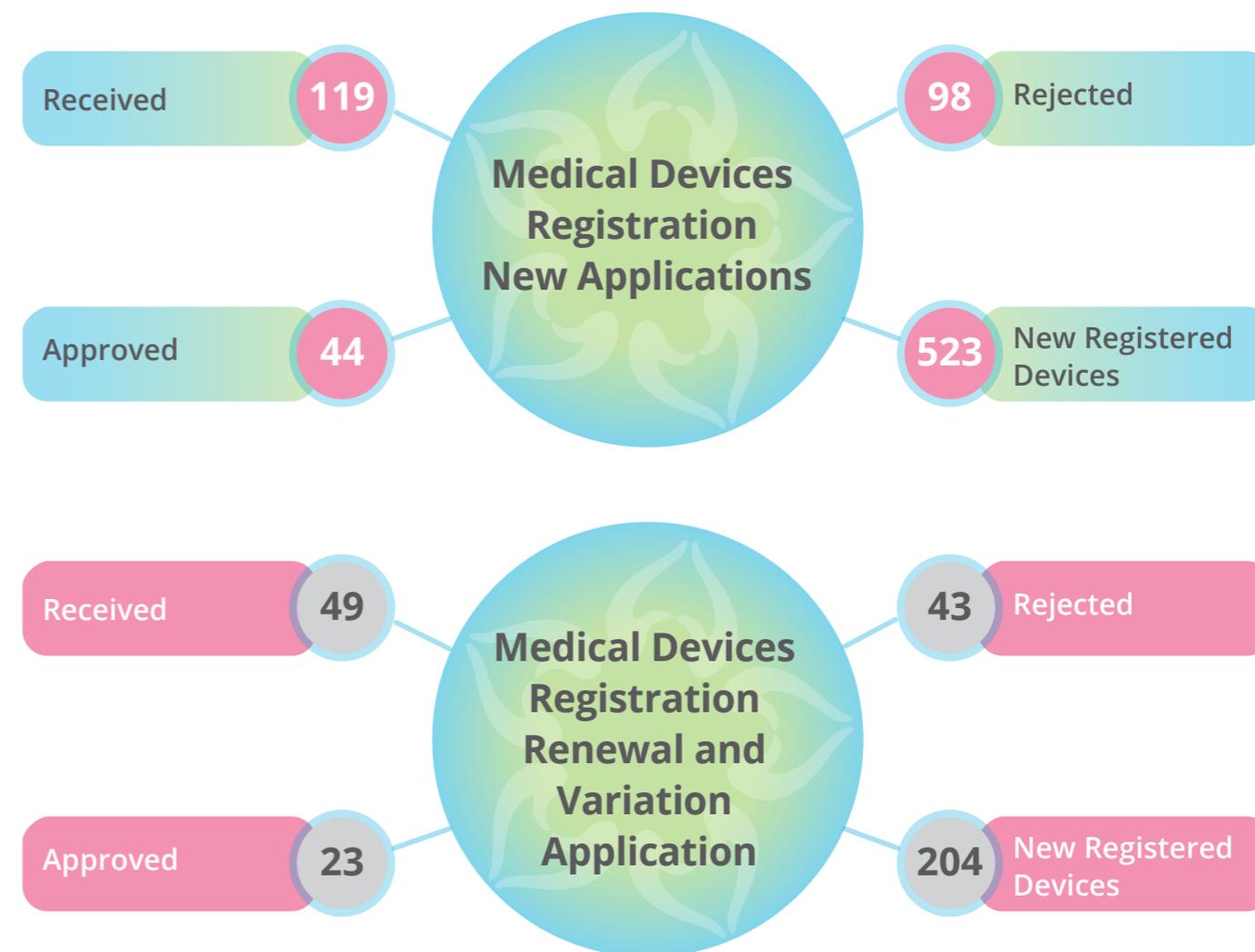




## Authorized Representatives 2021 Scopes Statistic



## Medical Devices Registration





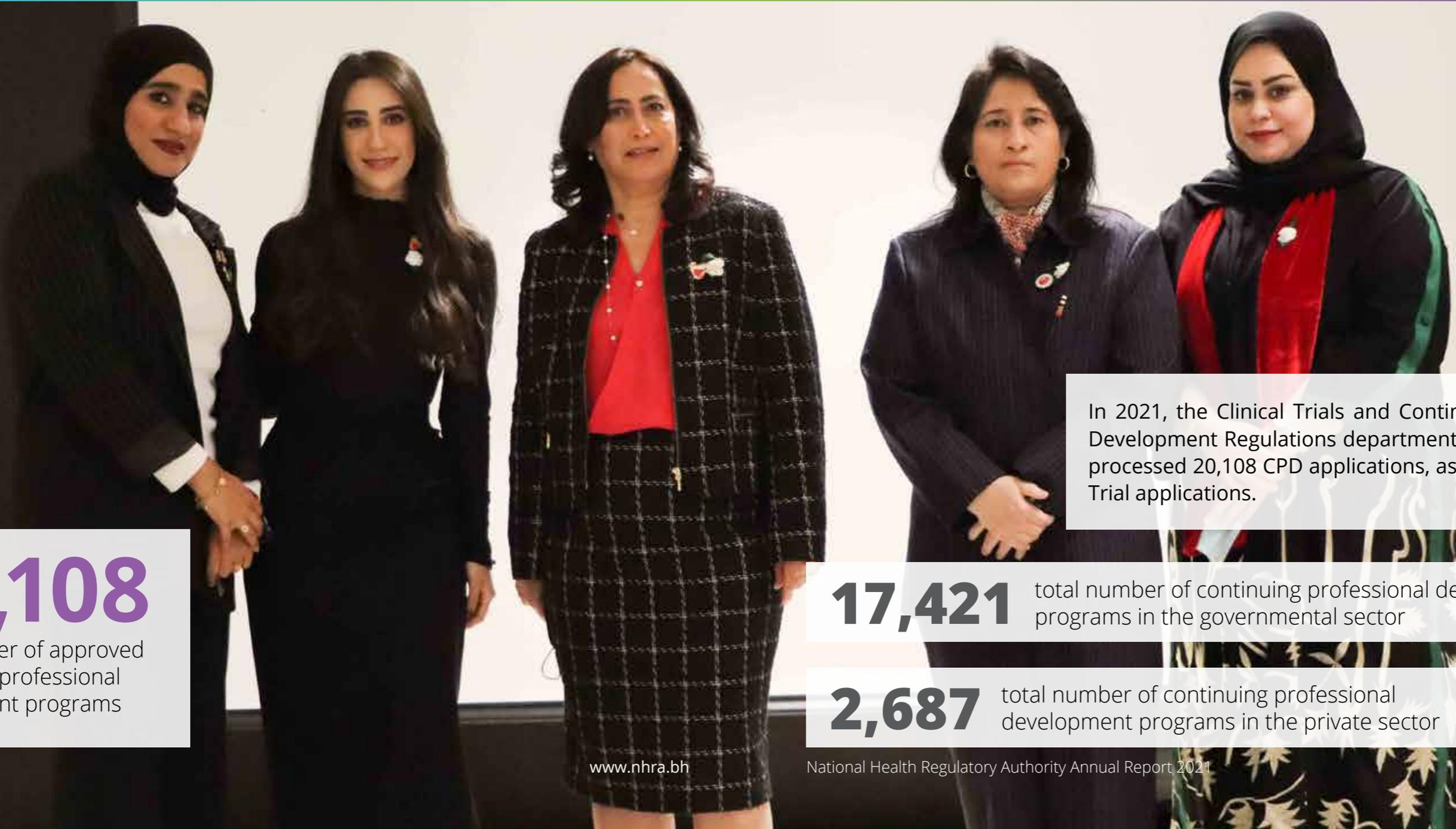
## Medical Devices Approval for Use



## Medical Devices Classification



**22** total number of medical MOH cosmetic devices classification requested



**20,108**

total number of approved continuing professional development programs

In 2021, the Clinical Trials and Continuing Professional Development Regulations department had received and processed 20,108 CPD applications, as well as 13 Clinical Trial applications.

**17,421**

total number of continuing professional development programs in the governmental sector

**2,687**

total number of continuing professional development programs in the private sector



## Clinical Trials

Out of 13 Clinical Trial Application packages, nine (9) CT applications have been approved, two (2) of which were pending amendments and two (2) were rejected. A vast majority of the approved Clinical Trials were from the government sector, as part of the initiative to tackle COVID-19. The clinical trials applications were seemingly focused in the field of infectious diseases and pulmonology, with eight (~61%) total clinical trials reviewed. The remainder of the clinical trials were distributed as one (~8%) in Endocrinology, one (~8%) in Hematology, and one (~8%) in Dentistry, one (~8%) in Rheumatology and one (~8%) in Dermatology.

## CPD

In 2021, the CPD unit had received and processed 20,108 CPD applications. The reviewed CPD activities were offered by both private and governmental sectors. The majority of these activities were in the form of lectures and online webinars followed by specialized workshops, general workshops and conferences. The highest prevalence of CPD activities conducted in year 2021 fall under the Laboratories & Pathology specialties with 3,847 (19%) activities approved, followed by nursing 2,892 (14%), neurology 1592 (8%), and Plastic Surgery 638 (3%) sectors.



The following accomplishments were witnessed for the CT & CPD Regulations Department:

CT	CPD
Re-review, update and issuance of the 3rd edition of Clinical Trials Regulations in the Kingdom of Bahrain.	Re-review, update and publication of the 2nd edition of CPD Regulations Charter.
Review and formulation of requirements for the import and export of stem cells in the Kingdom of Bahrain.	The Memorandum of understanding was signed between the National Health Regulatory Authority and the Ministry of Labor and Social Development regarding the adoption of health training programs in May 2021, with the establishment of a joint committee for review and approval of the same program as well as training centers.
Instatement of NHRA algorithm for the review of clinical trials to instruct applicants of NHRA's clinical trials regulatory scope.	Review and update of all CPD Accreditation forms and processes.
Review and update of all CT application forms, processes and flowcharts.	Agreements of commitment and compliance to CPD Regulations were instated between CPD activity providers and NHRA.
Agreements of commitment and compliance to CT Regulations and monitoring requirements were instated between Sponsor-PI-Applicant and NHRA.	NHRA Regulatory & Accreditation Workshops were conducted.
Thirteen Clinical Trial Packages were reviewed, out of which Nine clinical trials packages were approved.	The professional certification program for dental assistants at Seef Health Training Center was launched in collaboration with the Ministry of Labor and Social Development.
Eight clinical summary report, scientific data reviews were conducted to support Emergency Use Approval of the Covid-19 Vaccines and medicines in collaboration with PPR department & national immunization committee.	Cardiopulmonary Resuscitation Programs accredited by the American Heart Association (AHA) were launched at the Gulf Aviation Academy.
Re-formulation of NHRA's Clinical Trials & Research Ethics Committees to include members from academia & NHRA.	The 1st round of Manama Health Conference & Expo was coordinated and arranged to be held in 2022.



## Distribution of Approved CPD Activities According to Speciality

Anesthesiology	335	Occupational Medicine	164
Aviation Medicine	157	Oncology	411
BLS, ACLS & PALS	429	Ophthalmology	693
Cardiology	354	Orthopedic	288
Dentistry	553	Patient Safety & Management	218
Dermatology	286	Pediatric	445
Emergency Medicine	235	Pharmacology	474
Endocrinology & Diabetology	264	Physiotherapy	269
ENT	209	Plastic Surgery	638
Forensic Medicine	79	Primary Health Care	457
G. Medicine	430	Psychiatry	48
General Surgery	574	Pulmonology	470
Genetic	8	Radiology	422
Health Care Accreditation	107	Rheumatology	8
Health Care Mangmt, Quality & Ethics	237	Gatroeneterology	82
Health Research	189	Urology	47
Hematology	266	Aviation Medicine	12
Infection Control & Prevention	522	Bariatric Surgery	2
Internal Medicine	561	Vascular Surgery	0
Laboratories & Pathology	3487	Pathology	6
Medical Education	201	ICU	6
Neurology	1592	Gatroeneterology	1
Nursing	2892	Speech therapy	6
Nutrition	337		
Obs & Gyn	637	<b>Total</b>	<b>20,108</b>

## CPD

**17,091** total number of CPD activities opted for virtual mode of delivery

**3017** number of CPD activities opted for physical mode of delivery





## Types of Approved CPD Activities



## Distribution of Clinical Trials

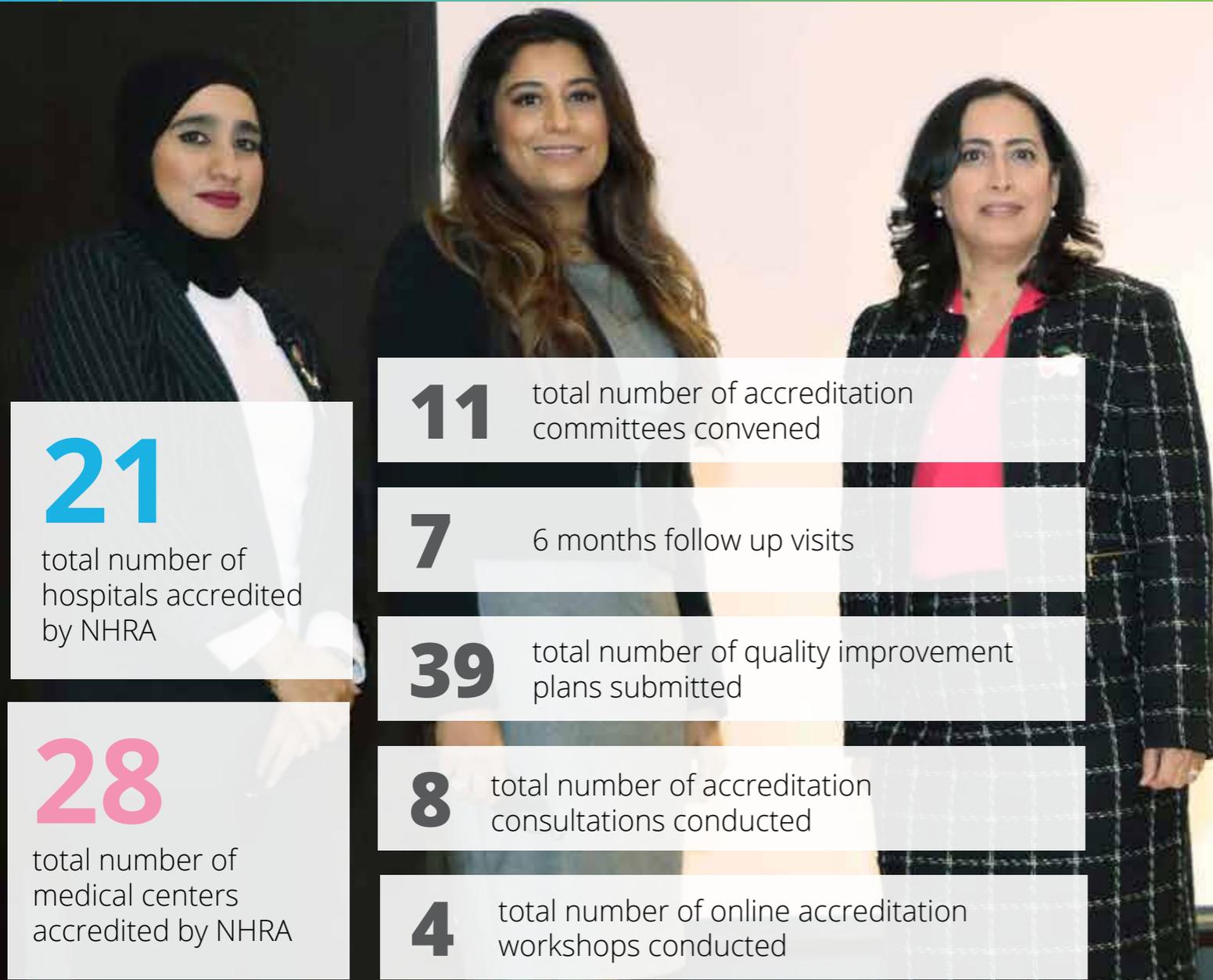


## Distribution of Clinical Trials / Organization



## Distribution of Clinical Trials According to Speciality





**21**  
total number of hospitals accredited by NHRA

**28**  
total number of medical centers accredited by NHRA

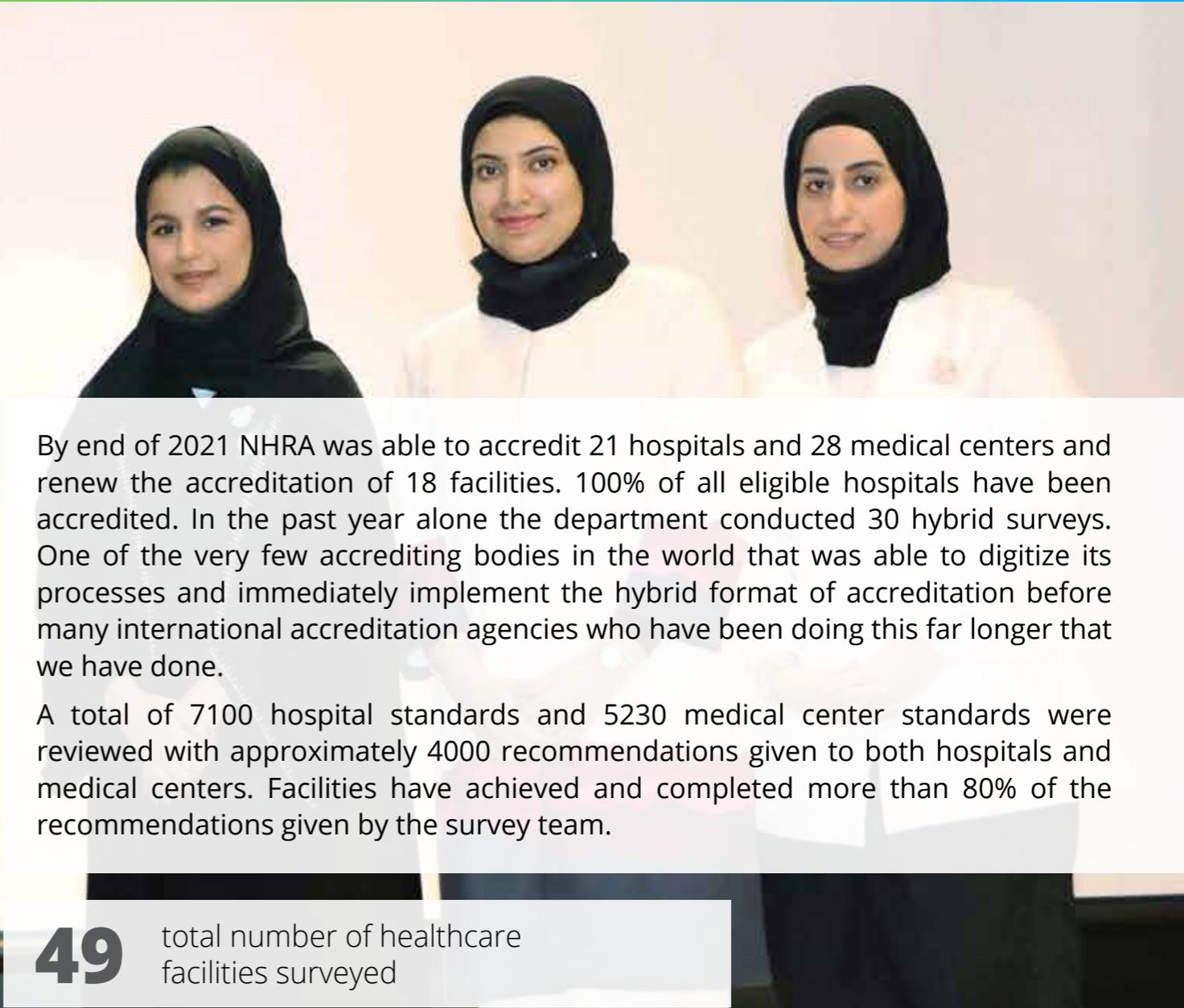
**11** total number of accreditation committees convened

**7** 6 months follow up visits

**39** total number of quality improvement plans submitted

**8** total number of accreditation consultations conducted

**4** total number of online accreditation workshops conducted



By end of 2021 NHRA was able to accredit 21 hospitals and 28 medical centers and renew the accreditation of 18 facilities. 100% of all eligible hospitals have been accredited. In the past year alone the department conducted 30 hybrid surveys. One of the very few accrediting bodies in the world that was able to digitize its processes and immediately implement the hybrid format of accreditation before many international accreditation agencies who have been doing this far longer that we have done.

A total of 7100 hospital standards and 5230 medical center standards were reviewed with approximately 4000 recommendations given to both hospitals and medical centers. Facilities have achieved and completed more than 80% of the recommendations given by the survey team.

**49** total number of healthcare facilities surveyed



## Goals and Objectives

1. Increasing quality of healthcare services.
2. Enhancing competitiveness between healthcare facilities
3. Raising the confidence of citizens and residents in health services.
4. Attracting Health investments.
5. Implementing the initiatives of the national health plan.

## Future Plan

1. Set a time plan for the next five years
2. Apply accreditation every 4 years with annual follow up
3. Increase evaluation capacity
4. Increase staff capacity

## Accreditation and Quality Group Achievements

1. 30 hybrid surveys conducted between Oct 2020 to Dec 2021.
2. Facilities have been granted 4-year accreditation validity rather than 3 years.
3. Updating existing standards and policies within the department.
4. Preparation and reviewing for international accreditation.
5. Converting consultation visits into virtual consultation.
6. Issuance of Online Accreditation Certificate.
7. Restructuring of Surveyors Team by adding and training 19 new surveyors in March 2021.
8. Recruitment of staff as Health Quality Assurance Specialist to the department
9. Training of two external members in quality and safety.
10. Additional training for another 10 new surveyors in December 2021.
11. Accreditation Ceremony for all surveyors, committee members and other supportive people in December 2021.





## Distribution of Hospital Awards



## Distribution of Medical Center Awards





2021 Performance



Total Hybrid Surveys October 2020–December 2021



Quality Improvement Plans Submitted by Accredited Facilities

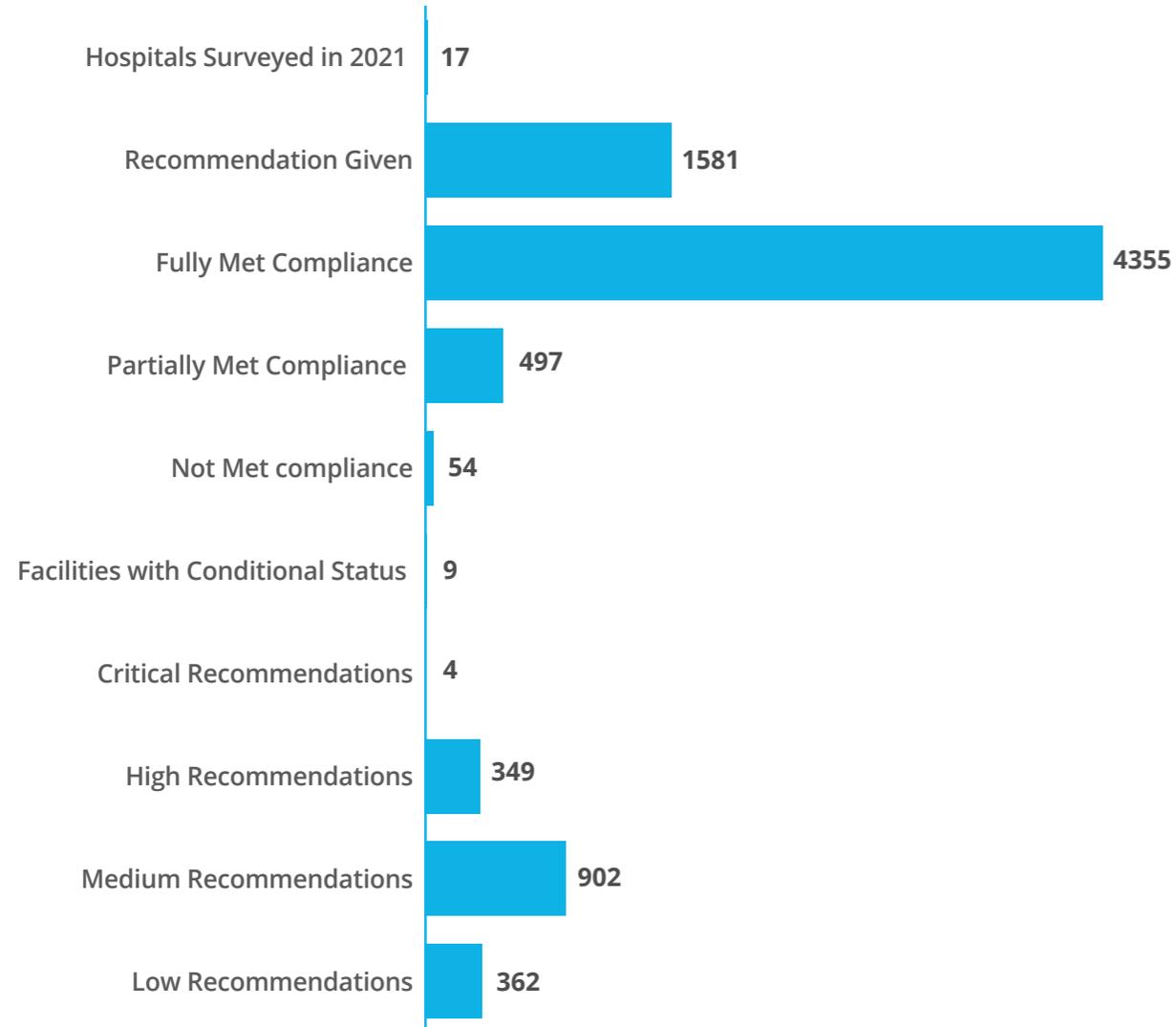


Actions Taken by Facilities in Regards to Fulfill High Priority Recommendations

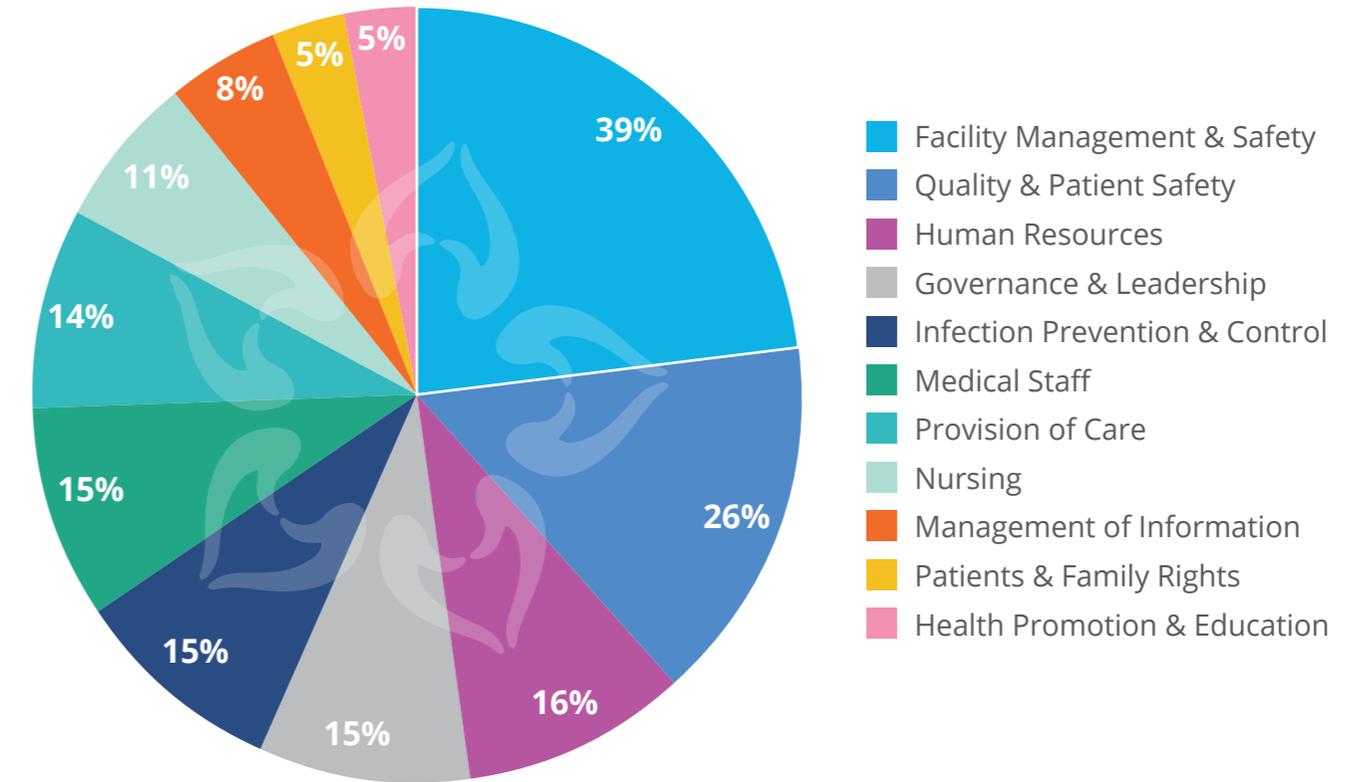




## 2021 Reports Analysis-Hospitals

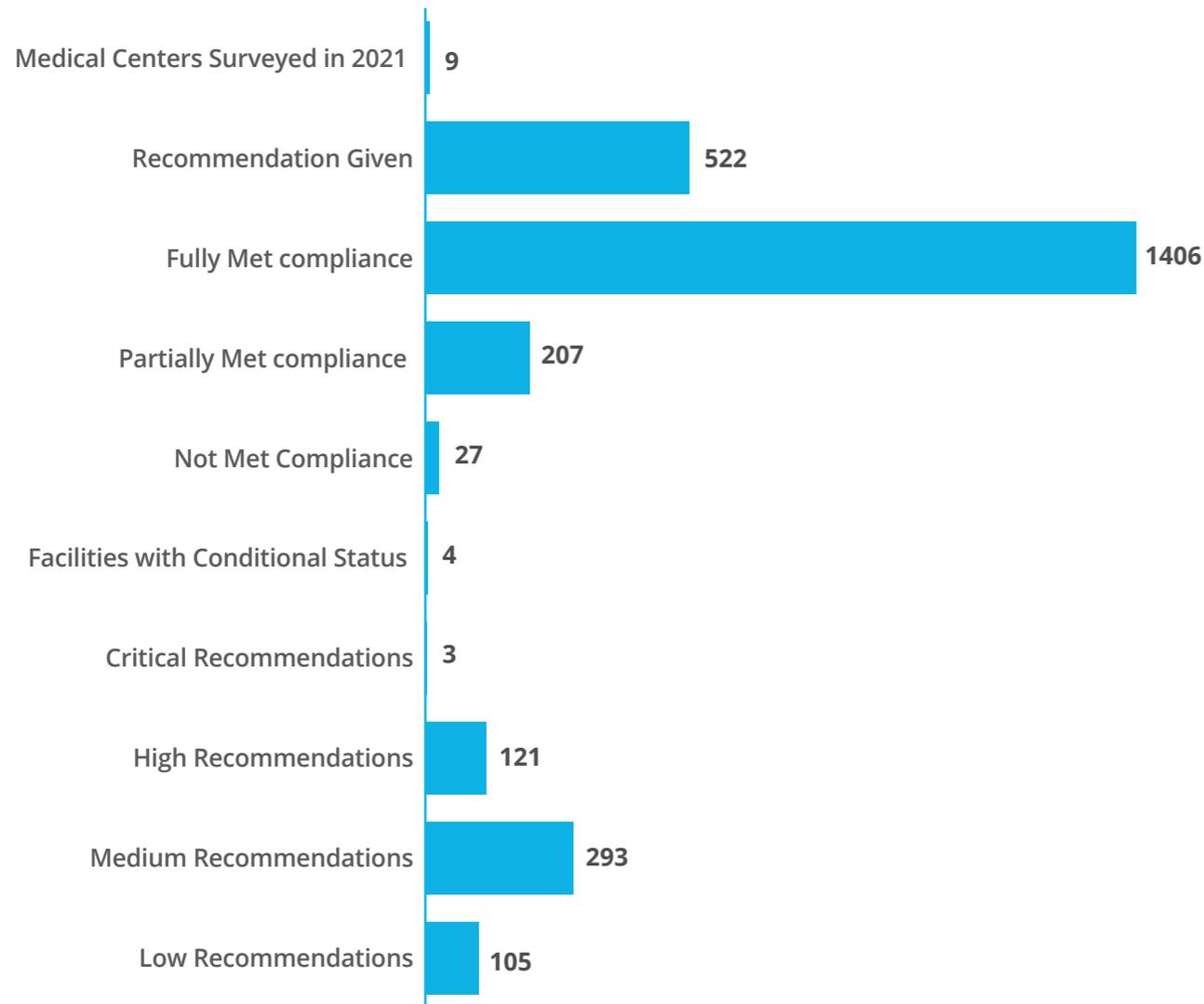


## Distribution of Non-Compliance Analysis in Core Analysis

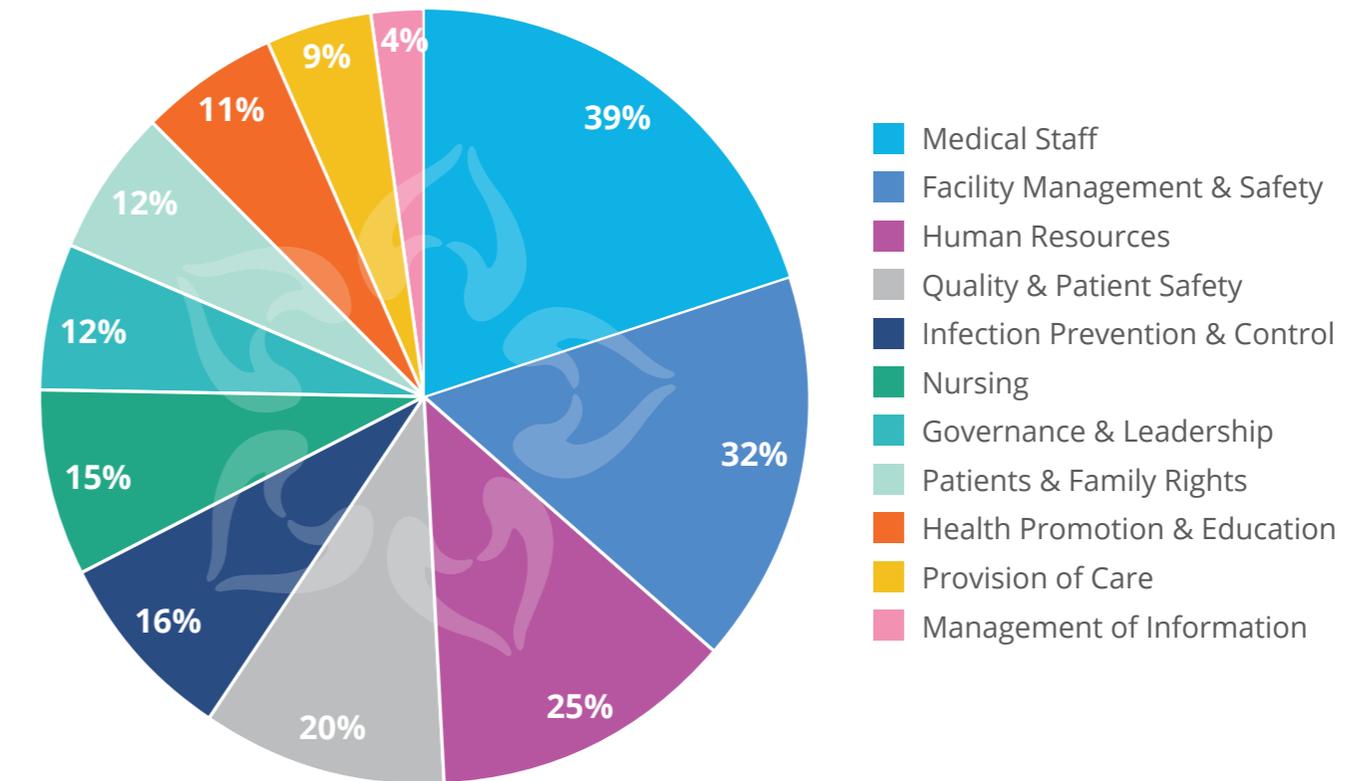




## 2021 Reports Analysis-Medical Centers



## Distribution of Non-Compliance Analysis in Core Elements





**3** total number of hospitals improvement from platinum to diamond

**1** total number of hospitals improvement from gold to platinum

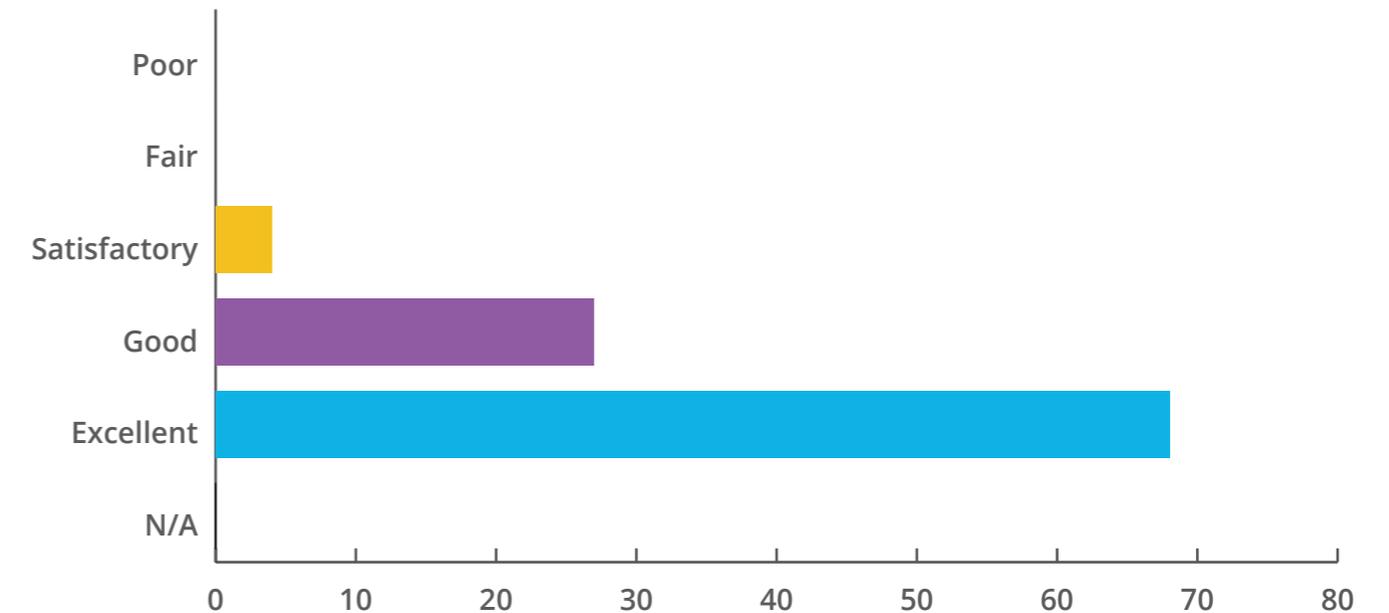
**1** total number of hospitals improvement from gold to diamond

## Annual NHRA Accreditation Feedback Survey

The Surveyors Demeanor and Attitude While Conducting the Site Visit

Answered: 22

Skipped: 0



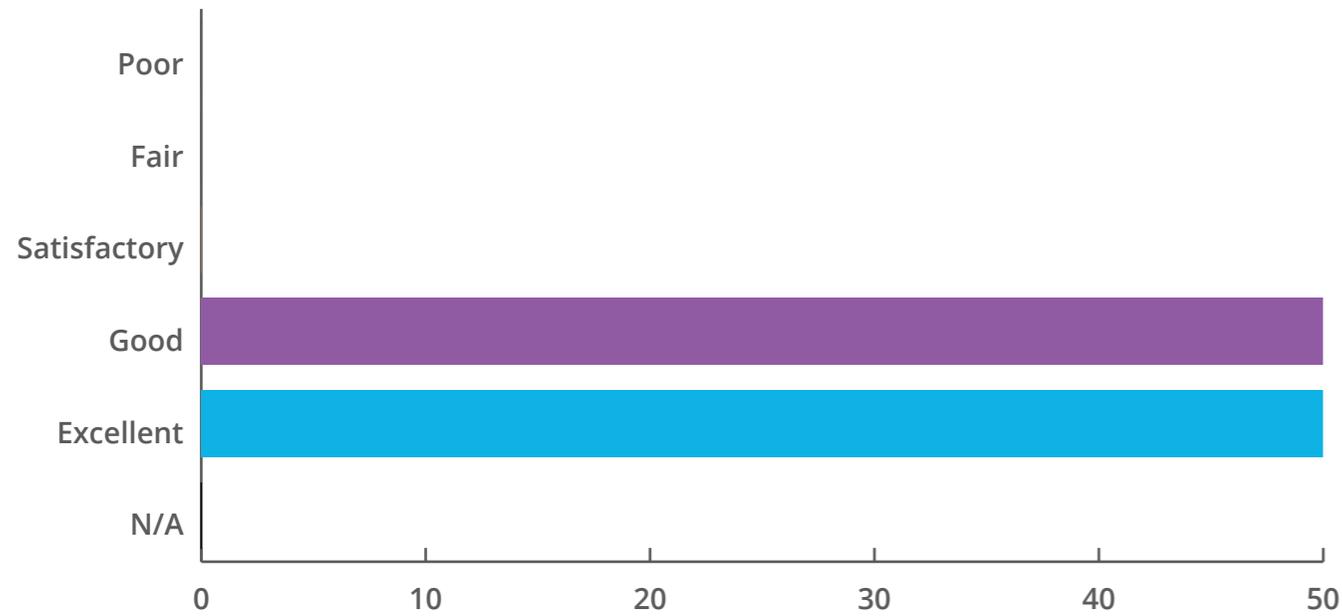


### Annual NHRA Accreditation Feedback Survey

The Surveyors Objectivity in interpreting and applying the NHRA Standards to the Program

Answered: 22

Skipped: 0

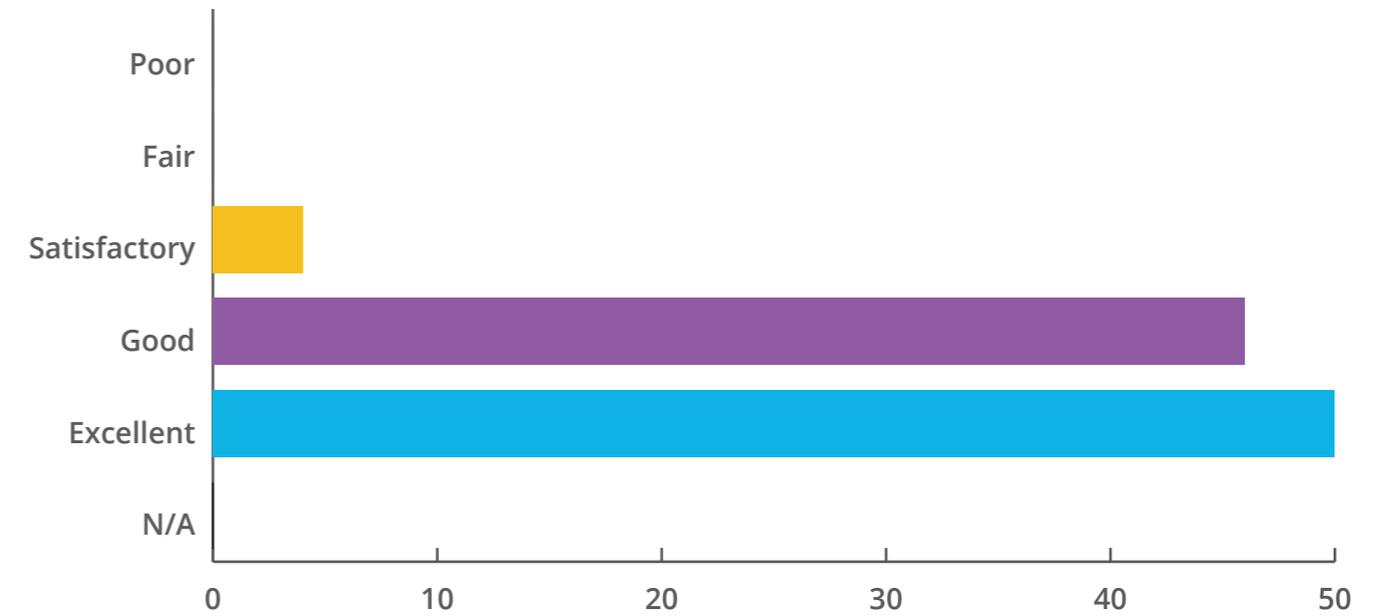


### Annual NHRA Accreditation Feedback Survey

Overall Effectiveness of the NHRA Accreditation Program

Answered: 22

Skipped: 0



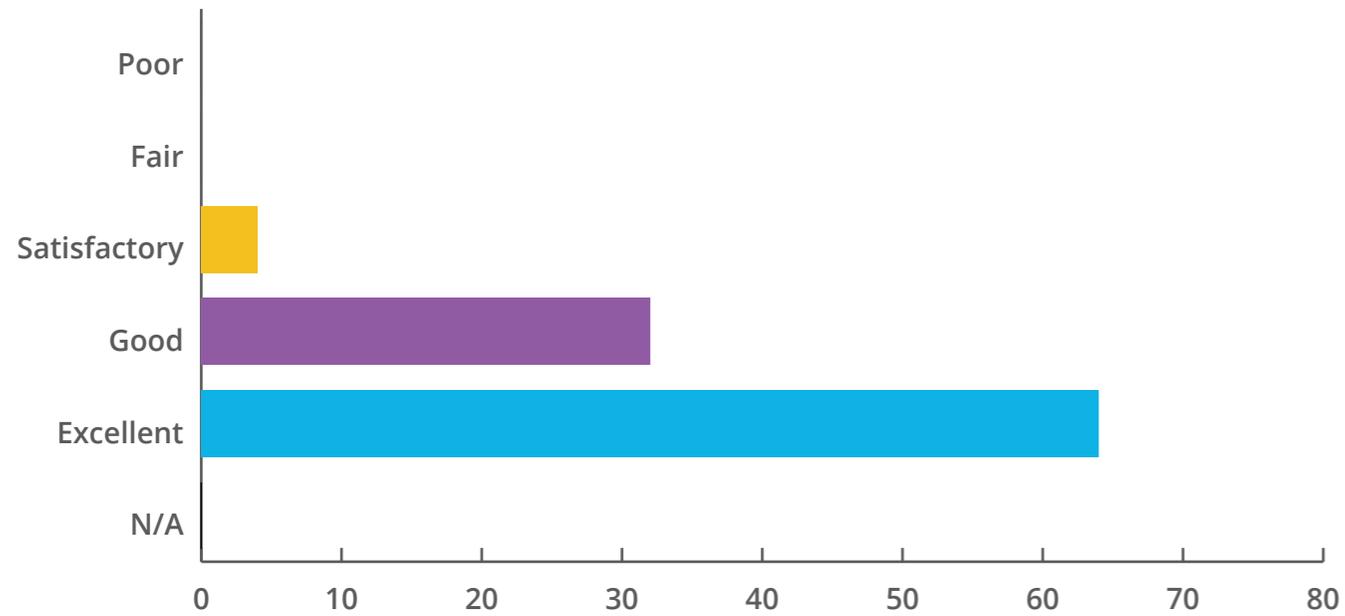


### Annual NHRA Accreditation Feedback Survey

The On Site Survey Visit

Answered: 22

Skipped: 0

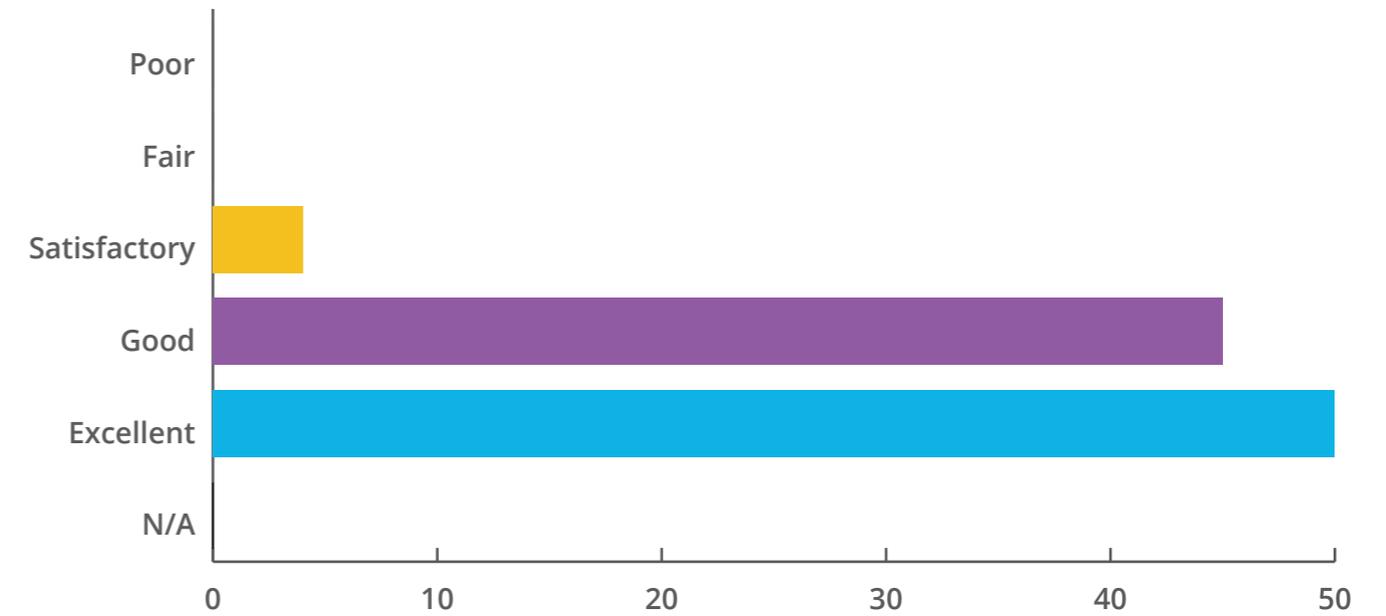


### Annual NHRA Accreditation Feedback Survey

The Surveyors Competence as Evaluators

Answered: 22

Skipped: 0





**146** total number of complaints reported from the public

**25** total number of Incidents reported by healthcare facilities

**41** total number referred by Judicial authorities for lawsuits

**213**  
total number of cases received by NHRA

In line with our goals of preserving health rights and ensuring safe health services, the complaints department continued to investigate allegations of medical errors, as the department received 213 cases for investigation in 2021. Of these, 146 were individual complaints, while 25 were reported by health care facilities, and 41 were referred by the prosecution or the courts and one case was reported by the inspection team.

The department investigated 176 cases and completed investigations in 114 of them, 44 of the cases were closed either due to irrelevance to NHRA or for lack of evidence, and the investigation is still ongoing in 18 of them.

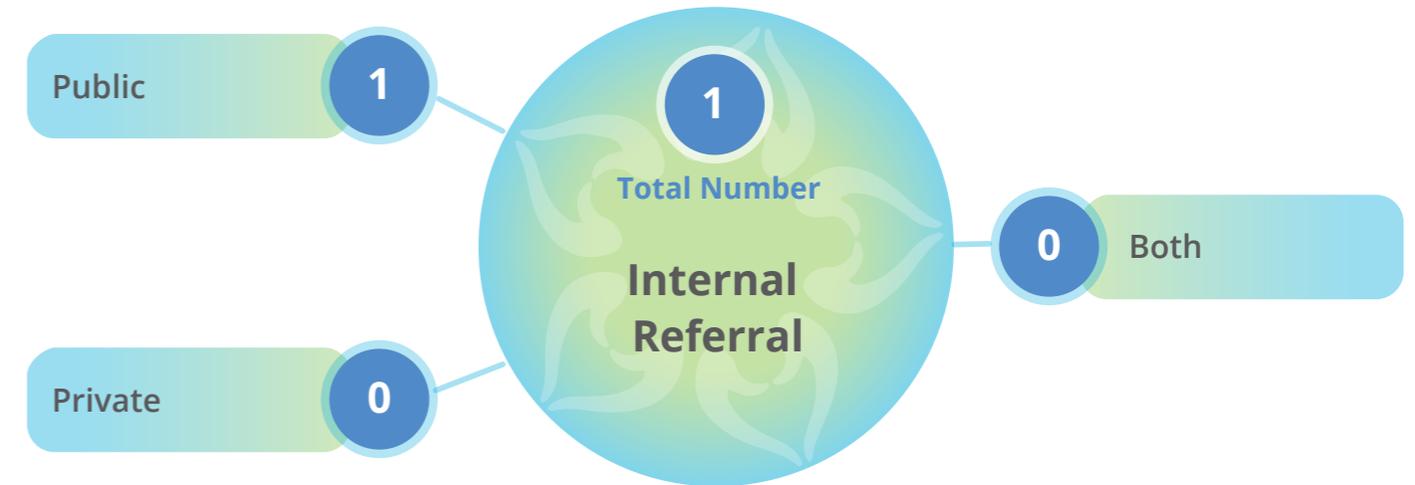


A medical error / violation of the principles, obligations, requirements, or ethics were only found in 30.7% of the investigated cases, while no medical error/violation of principles, obligations, or requirements were identified in 69.3% of them. In 42% of the cases, the treating physician was responsible for the error, while in 52% of them, the facility was responsible for the error, and in 6% of them the error was the responsibility of either the nursing, pharmacists, or other allied professions.

In the year 2021, 57 disciplinary measures were issued by the Disciplinary Committees and the Accountability Committee, including thirty (30) decisions to suspend the licenses of professionals, fifteen (15) warning notices, revocation of the licenses of four professionals, and the issuance of four (04) monetary fines, while Four (04) professionals were acquitted based on the decision of the appeal committee.



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





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

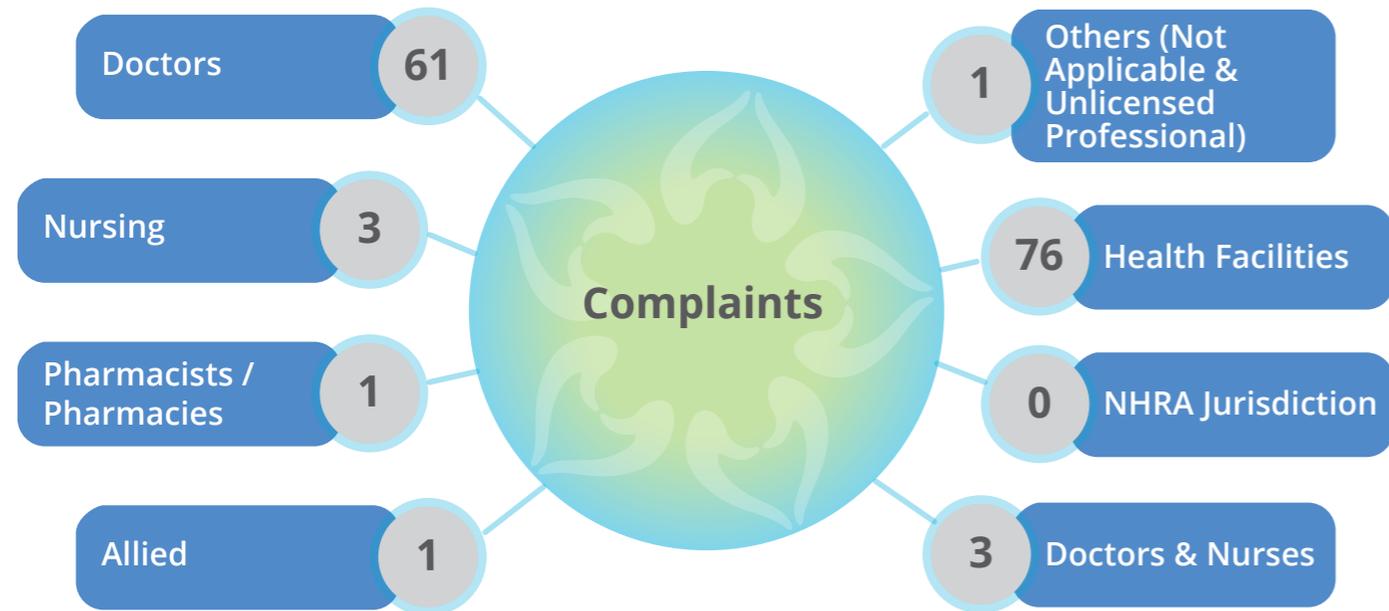


### Distribution of Complaints, Incidents and Lawsuits by Health Sector

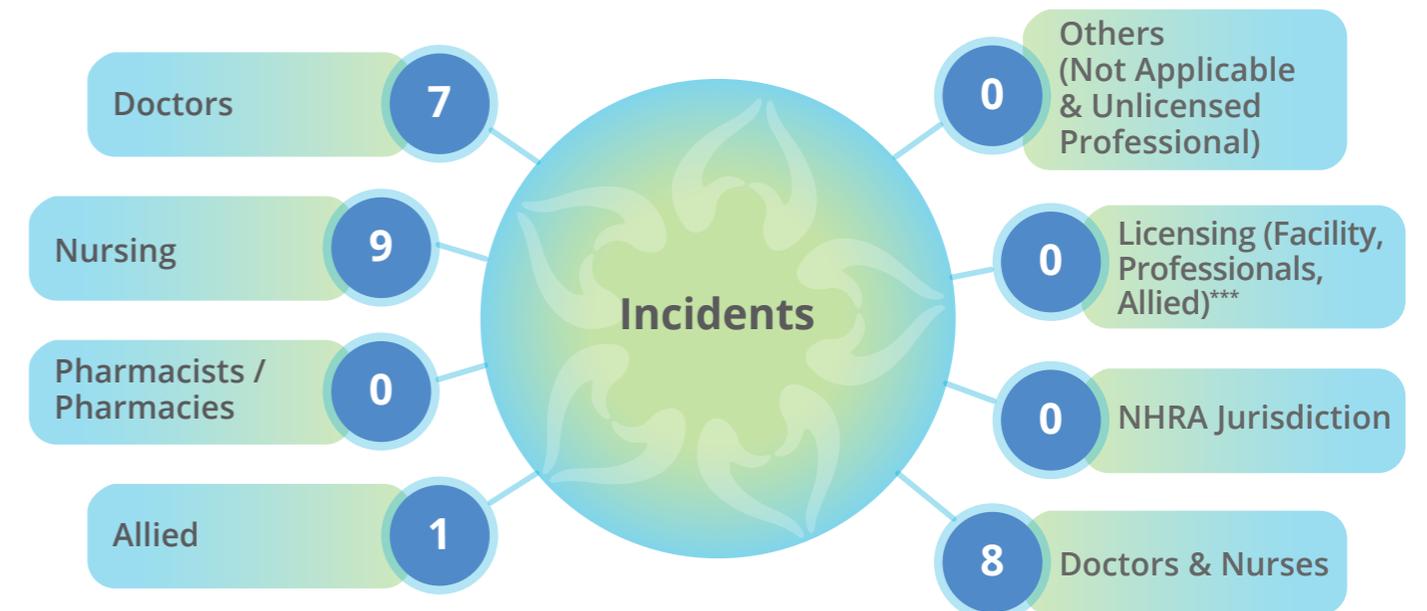




### Distribution of Complaints, Incidents and Lawsuits According to Health Profession

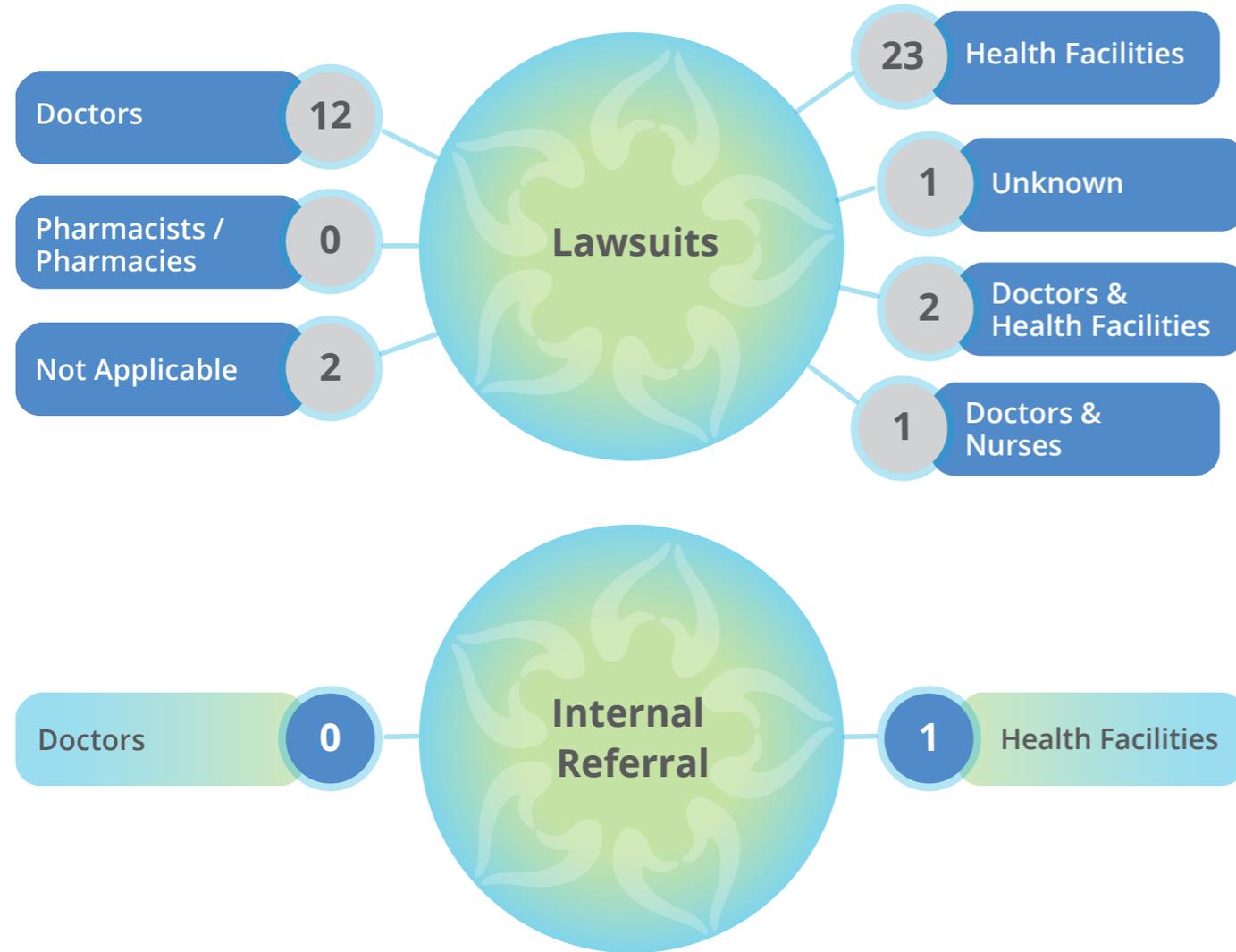


### Distribution of Complaints, Incidents and Lawsuits According to Health Profession

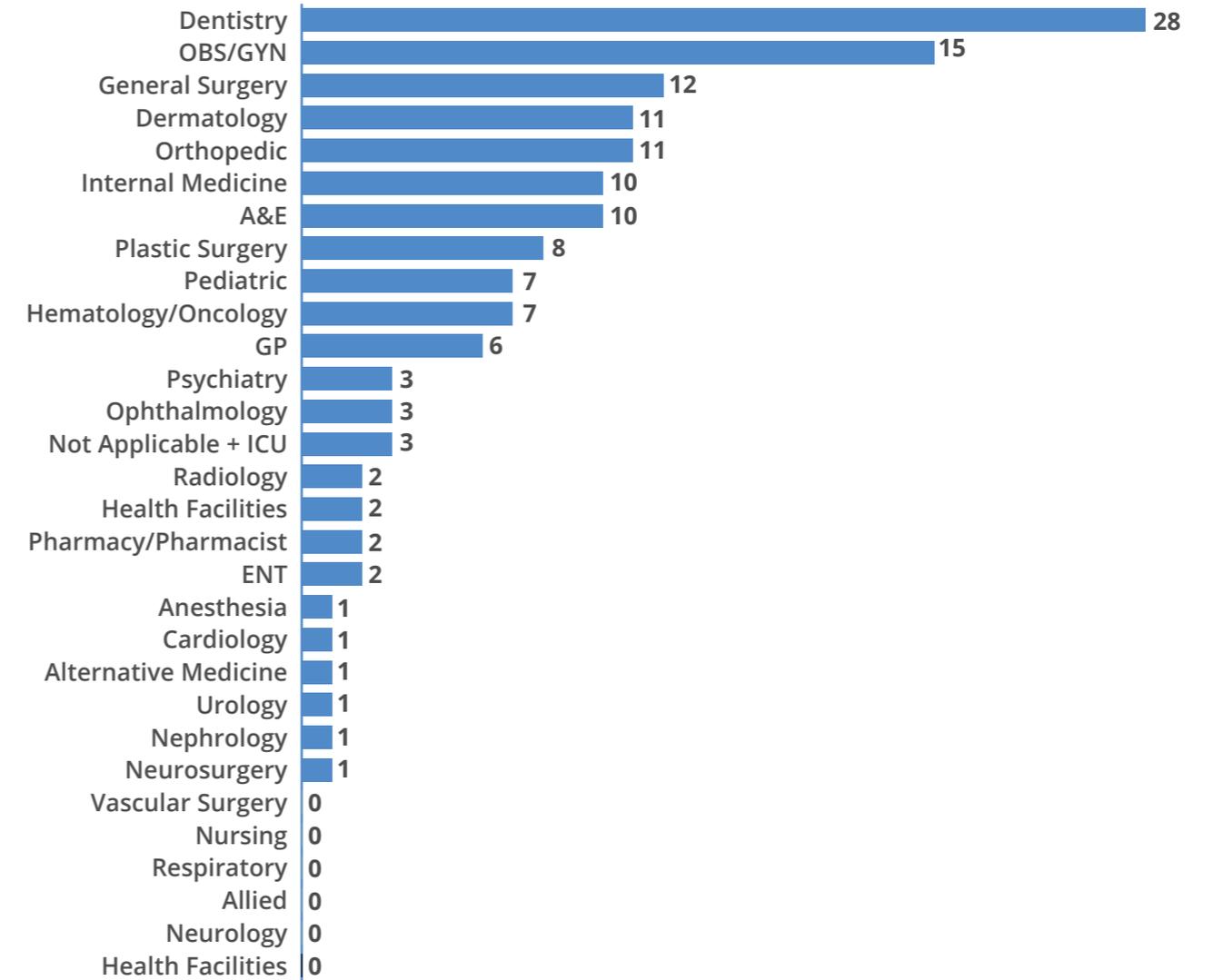




Distribution of Complaints, Incidents and Lawsuits According to Health Profession

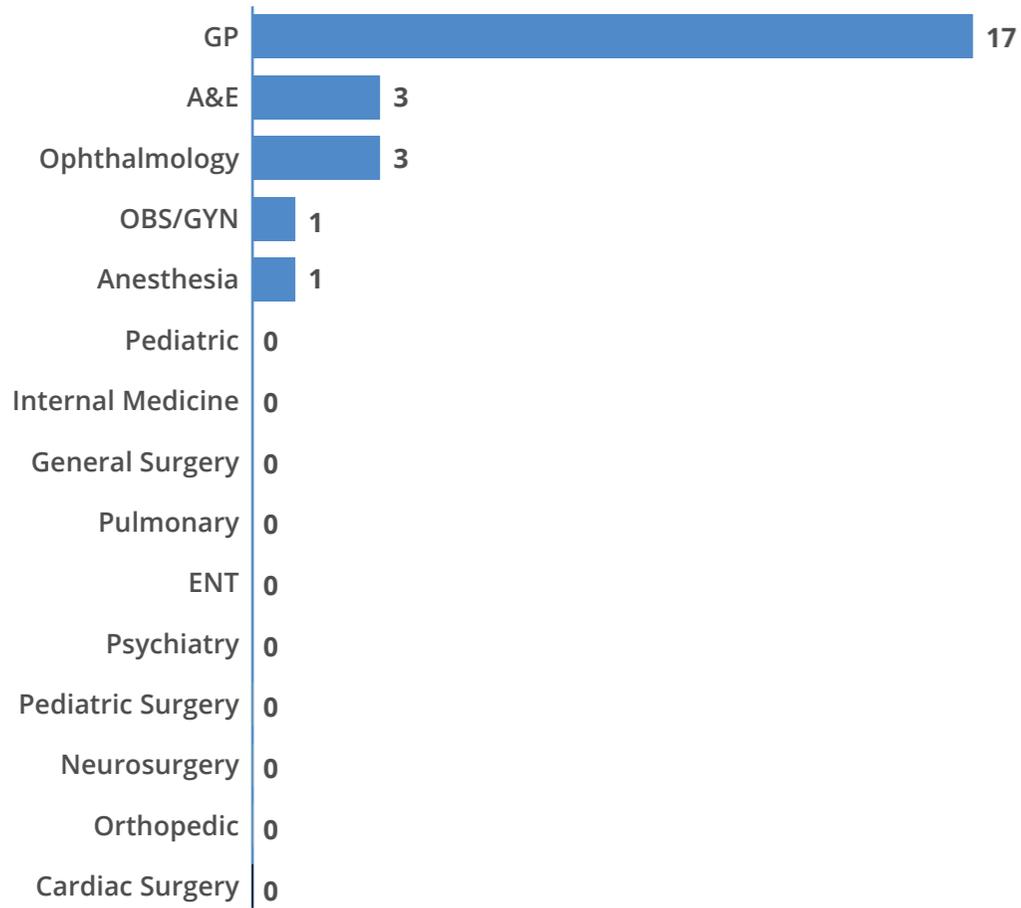


Distribution of Complaints According to the Most Frequent Speciality

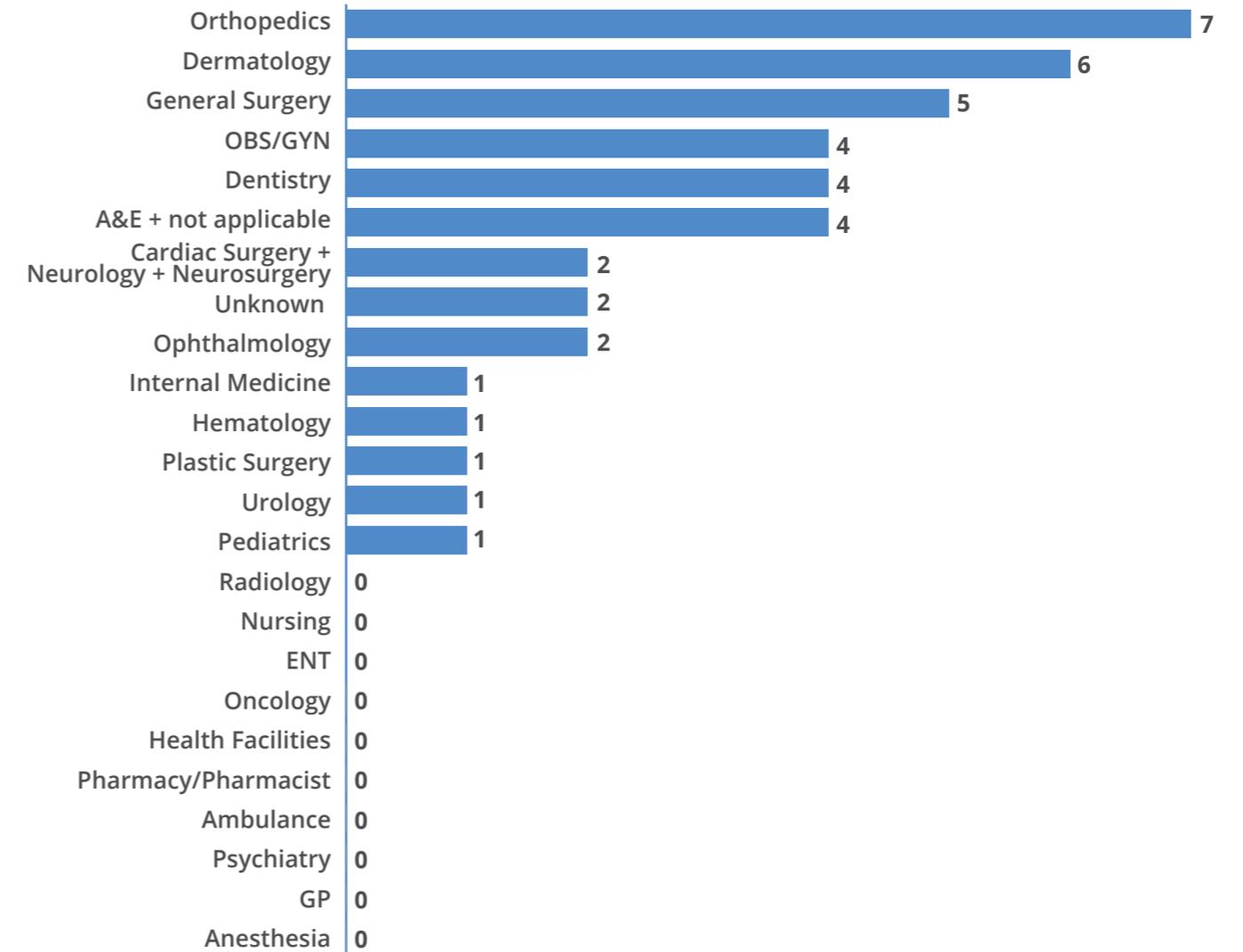




### Distribution of Incidents According to the Most Frequent Speciality



### Distribution of Lawsuits According to the Most Frequent Speciality





## Disciplinarys Decisions Issued by Disciplinary Committees at NHRA



## Total Number of Disciplinary Actions Taken Against Doctors



## Total Number of Disciplinary Actions Taken



## Total Number of Disciplinary Actions Taken Against Pharmacists/Pharmacies





## Total Number of Disciplinary Actions Taken Against Nurses



## Total Number of Disciplinary Actions Taken Against Allied Health

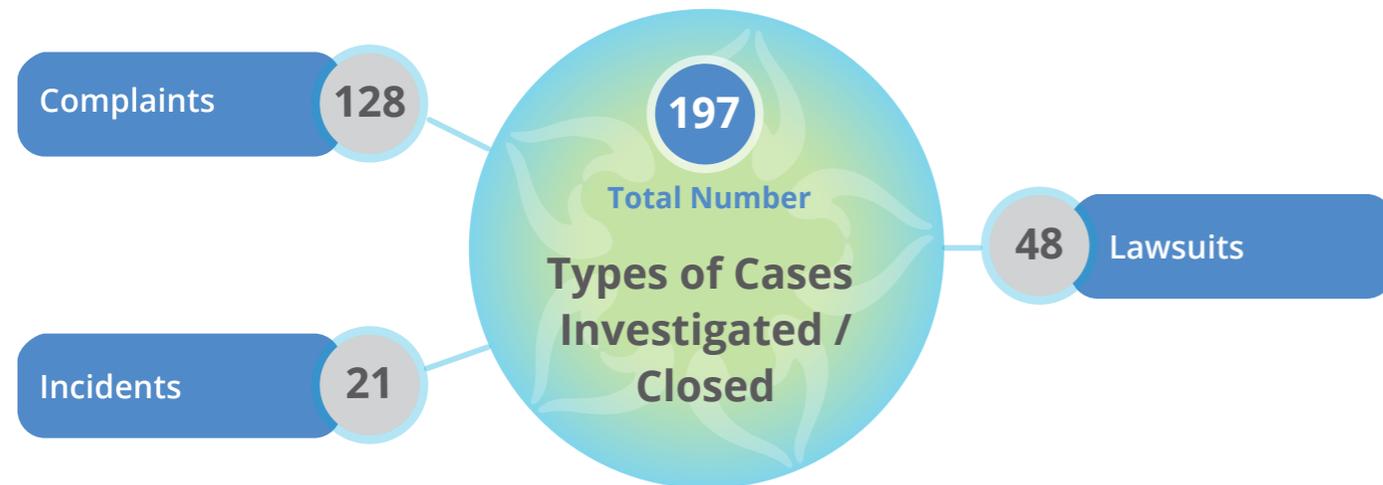


## Total Number of Disciplinary Actions Taken Against Health Facility





## Types of Cases Investigated / Closed



## Results of Investigations





### 2021 Activities of the Legal Unit

The legal unit provides legal opinion to the CEO and all NHRA departments on all issues that require a legal advisory, including Laws, resolution, Legal review of all contracts, agreements and memoranda of cooperation, follow-up, and preparation of defense memorandums, and supporting NHRA inspectors. The unit representing the authority in professional workshops to participate in legal education for health professionals.



In 2021 the legal unit prepared more than 130 resolutions that included directions to form committees, referrals for investigations, and decisions for disciplinary sanctions. The legal unit also prepared legal views in cases before the judicial authorities, where the verdict was passed in favor of the Authority in more than 20 cases so far. The unit lawyers attended all meetings of the technical and disciplinary committees for health professionals in the authority to ensure all its legal procedures and effectively represented.

The unit cooperated with other government agencies such as the Engineering Professions Council and provided them with legal expertise in the field of work, especially the laws of practicing professions and the system of work of the disciplinary committees in the authority.

The unit have also worked on developing health laws and decisions in coordination with the Legislative and Legal Opinion Authority, ministerial committees, and the Physicians Society.

The Unit prepared 35 Referral Decisions of health professionals who were charged with violations and medical errors to the Public Prosecution, to take the necessary legal measures against them.



## Legislation Activities

1. Draft law amending some provisions of the law on practicing the profession of human medicine and dentistry (under review) .
2. A draft law amending some provisions of the law on the practice of a profession of pharmacy (under review) .
3. Draft amendment to Decree-Law No. 21 of 2015 Concerning private health institutions (under review) .
4. Proposal for a law on stem cell therapy (under review) .
5. Resolution No. 48 of 2020 regarding quality control of medical devices and products (issued) .
6. Decision to amend the regulations for licensure examinations of medical professions practitioners in the authority (issued).
7. Resolution No. 32 of 2020 issuing a regulation for the registration procedures for medicines and pharmaceutical products, determining and publishing their prices (issued).
8. The decision to investigate medical errors and report accidental and serious accidents in health institutions (issued).
9. Draft decision to issue a list of requirements and procedures for licensing and regulating government health facilities (issued).
10. Resolution No. 74 of 2021 amending some provisions of Resolution No. (40) of 2016 regarding the validity period of licenses for health professions and the conditions for their renewal (issued).





In response to rising interest in investing in the Kingdom of Bahrain's emerging healthcare market, the NHRA has established an investors office to provide support and guidance to investors interested in operating a healthcare business in the country. As needed, the investors office serves as a liaison between NHRA departments and other relevant business support agencies such as the Economic Development Board, Tamkeen, and other government entities.

Since its inception, the office had received 31 inquiries from markets in the GCC, Europe, and Asia for various healthcare investments. 10% of all enquiries were regarding opening hospitals, 58% were about opening medical facilities, and 32% were about the pharmaceutical and medical device industries..

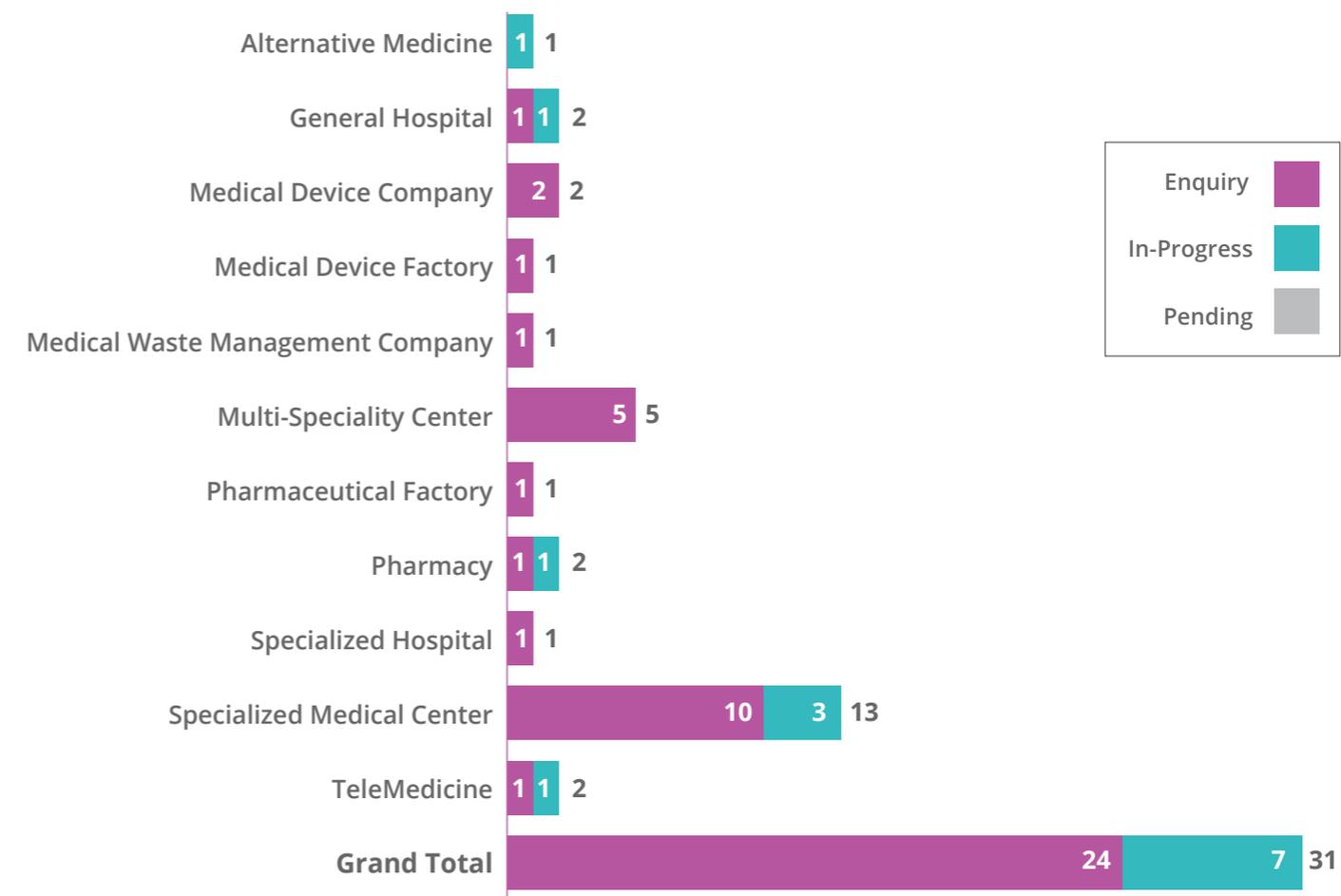
The investors office is a full-service initiative that assisted investors with everything from conceptualizing their ideas to obtaining the necessary financial permits and processes to start a healthcare business in the Kingdom.



## Total Number of Requests Received by Facility Category

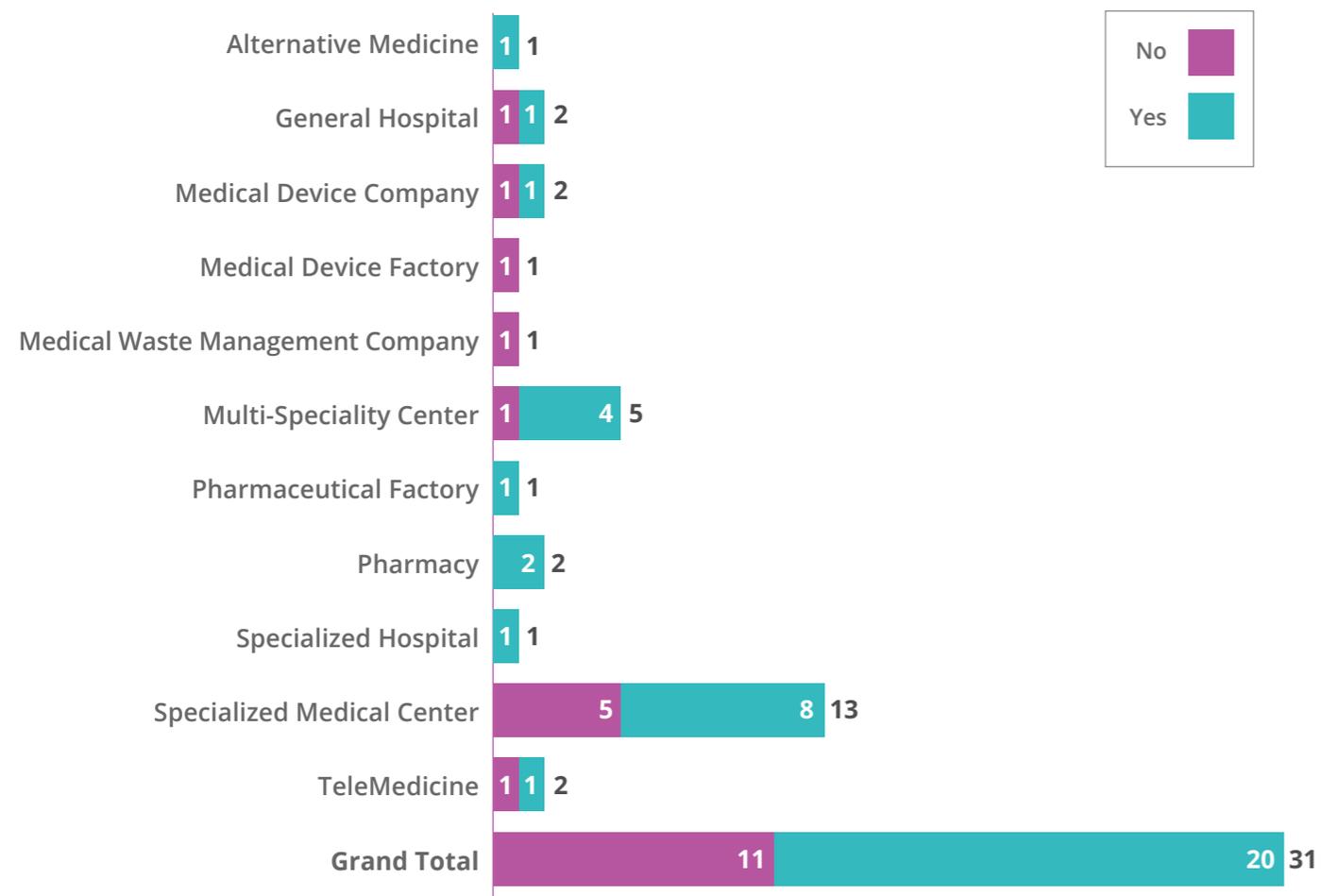


## Outcomes of Requests

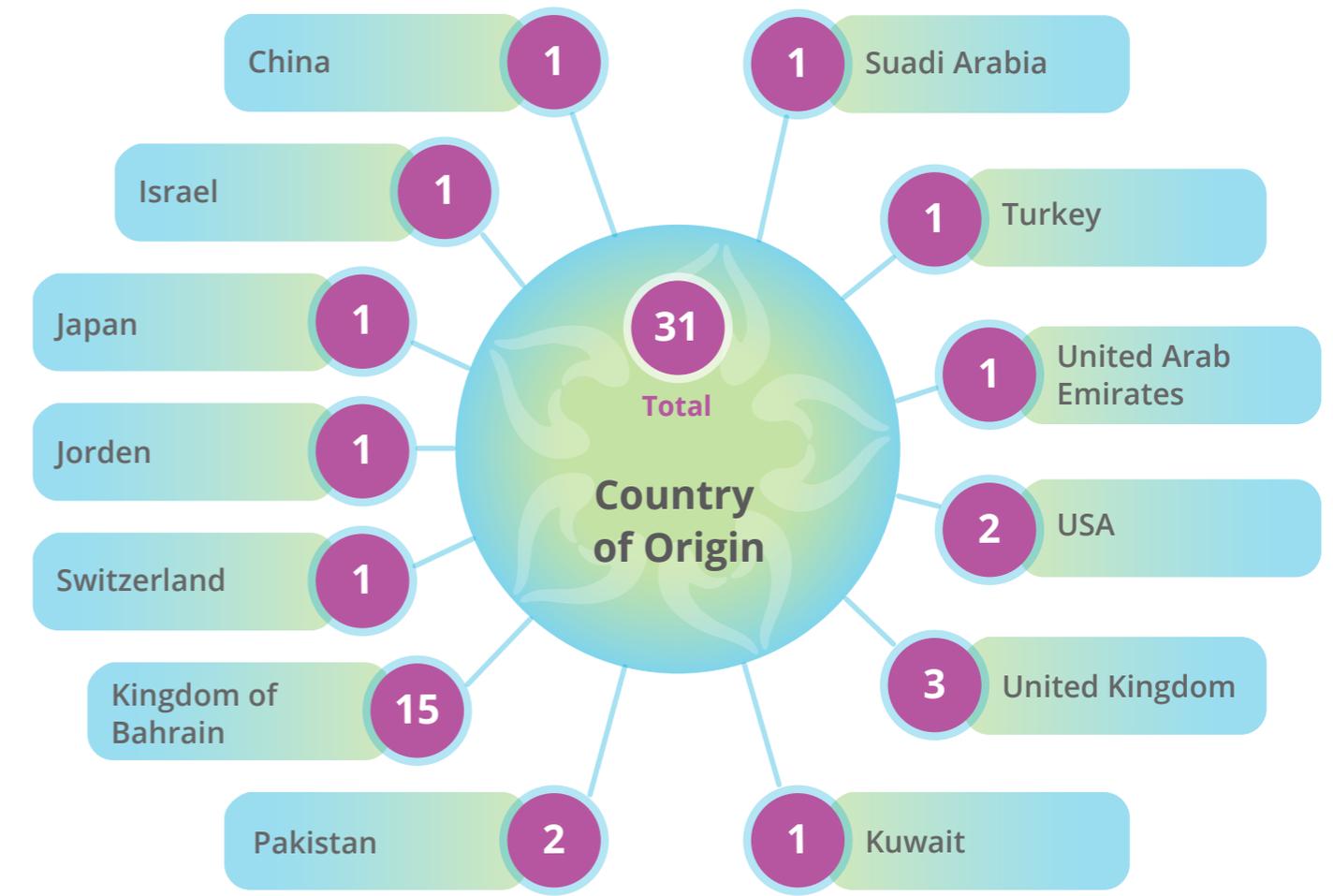




## Facility Category with Bahraini Partnerships



## Country of Origin Enquiries





**2362**  
total number of  
information requests



As part of our mission and vision to provide the best service to our Customers, we had previously implemented dedicated line of communication with NHRA through our **info@nhra.bh** email address. This has allowed customers to communicate and receive a response directly from NHRA staff within 5 working days for a general query and 48 hours for a specialized query.

The NHRA received a total of 2,362 emails in the year 2021; 2,354 of them are closed; 8 are pending more information from customers so as to resolve the query.



### Information Requests by Month



### Distribution of Inquiries by Section





## Types of Inquiries Received



## Outcome of Inquiries Received





**22** total number of employees rewarded (20.7%)

**16** total number of new employees

**24** total number of employees receiving exceptional rewarded (22.7%)

**19** total number of employees promoted (18%)

The NHRA's human and financial resources department has been actively engaged to update and develop the authority's new organizational structure, as well as redistribute 120+ employees to the right positions. The department worked extensively to implement the 2021 recruitment goals, which saw 16 new employees hired in various departments. 19 employees were promoted and 46 were given incentives and special rewards, while the training and development of all NHRA staff throughout the year. To meet the government's Fiscal Balance Program objectives, NHRA increased its revenue by 13% over the previous year and by 7% over the allocated budget in 2021, while decreasing actual recurrent non-manpower expenditure by 4% of the planned budget. Over the past five years, the NHRA financial sufficiency index has been steadily improving, rising from 45 % in 2016 to 98 % in 2021.



## The IT department achieved the following in 2021

1. Preparing and supporting 16 new employees.
2. Enhancing network performance and implementing high-level network security.
3. Providing direct support to all healthcare professions in Bahrain (more than 21,000 cases).
4. Successfully handling IT purchasing requirements with limited budget & limited human resources in the IT group.
5. Launching five new digitized systems and working as first line support for the same systems, as listed:
  - a. Mehan
  - b. Munshaat
  - c. Finance
  - d. HCP mobile App
  - e. HCF mobile App

## Human Resources Department Activities





**Digitization Initiatives of NHRA**

The IT vision of a digital NHRA has set up NHRA as the Digital Health Regulator Model in the Gulf Cooperative Council (GCC) Region. NHRA Digital Transformation Program will enable NHRA to offer end-to-end Health Regulatory eService using state-of-the-art AWS Cloud services and features.

After 11 months from January to November 2021, Phase 1 of the Program was delivered successfully. The digitization plan consists of five systems that will integrate with a number of public and private entities as follows:

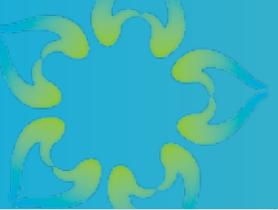
1. Healthcare Professionals (HCP) Regulation System “mehan”
2. Healthcare Facilities (HCF) Regulation System “Munshaat”
3. Accounting System
4. HCP Professional Mobile App
5. HCF Inspectors Mobile App

Integration / Interfacing with LMRA, Sijilat, iGA-CPR, NPA (e-Payment Gateway), i-Sehati/NEMR Prometric, DataFlow/Quadrabay, e-Notification system (SMS/SNS)

Phase 1 will provide many features such as being AWS Cloud-native, scalability and elasticity, self-care, services mobility and boost the Kingdom of Bahrain’s return on investment in AWS Cloud, iGA’s Cloud-first Policy compliance, and tight security.

**National Health Regulatory Authority  
Revenues and Expenditures Account  
For the period from 1 January 2021 to 31 December 2021**

Description	Budget	Actual
<b>Revenues</b>		
Taxation & Fees	2,156,000	2,242,990
Fine, Penalties & Misc	100,000	160,649
<b>Total Revenues</b>	<b>2,256,000</b>	<b>2,403,639</b>
<b>Recurrent Expenditures</b>		
Manpower	2,013,000	1,850,544
Services	714,180	692,964
Consumables	6,231	3,239
Assets	15,577	13,662
Maintenance	9,012	7,755
<b>Total Recurrent Expenditures</b>	<b>2,758,000</b>	<b>2,568,164</b>
Project Expenditures	-	-
<b>Total Expenditures</b>	<b>2,758,000</b>	<b>2,568,164</b>
<b>Surplus (Deficit)</b>	<b>502,000</b>	<b>164,525</b>



1. A committee to follow up on the implementation of the authority's electronic system project.
2. Advisory Committee for Dentistry.
3. Accountability Committee for private facilities
4. Investigation Committee
5. Disciplinary Committee for Professionals of Medicine and Dentistry
6. Technical Committee for Reporting Professional and Ethical Errors for Practitioners of Medicine
7. Technical Committee for Reporting Professional and Ethical Errors for Practitioners of Dentistry
8. Disciplinary Committee for Licensed Professionals in Pharmacy
9. Disciplinary Committee for Licensed Professionals in Nursing and Midwifery

10. Disciplinary Committee for Allied Health Professionals
11. Medical Devices Standards and Specification at NHRA Committee
12. Equal Opportunity Committee
13. Clinical Research Ethics Committee for Healthcare Facilities
14. Clinical Research Committee
15. Professionals Development and Continuous Education Program Committee
16. Advisory Committee for professional licensing
17. Occupational Health and Safety Committee
18. A Committee to Review and Adjust the Results of Evaluating the of staff performance ratio
19. The Internal Procurement and Tenders Committee
20. Appeal Committee for healthcare professionals
21. National Accreditation Committee



# Equal Opportunities Committee at NHRA



## Achievements for the year 2021:

1. The Supreme Council of Women's National Gender Balance Report 2019-2020 report and file has been completed and submitted.
2. The Supreme Council of Women has handed over an updated database of Bahraini women working in the fields of development.
3. Publication of the concept of equal opportunities for the NHRA employees.
4. Created a list of promising jobs in the medical field.
5. Remote work for employees with children in primary schools.
6. The establishment of a media committee for the Authority.
7. The establishment of a nursing mother's room for NHRA female employees.
8. The Authority's institutional performance was ranked fourth out of 45 participating government institutions, according to the results of the evaluation.





الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY

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

2021 Annual Report

Copyright © National Health Regulatory Authority