



NHRA ANNUAL REPORT 2018



صاحب السمو الملكي
الأمير خليفة بن سلمان آل خليفة
رئيس الوزراء الموقر



حضرة صاحب الجلالة
الملك حمد بن عيسى آل خليفة
ملك مملكة البحرين المفدى



صاحب السمو الملكي
الأمير سلمان بن حمد آل خليفة
ولي العهد نائب القائد الأعلى
النائب الأول لرئيس مجلس الوزراء

A word cloud centered around the words "Regulate" and "License". The word "Regulate" is the largest and most prominent, written in black. "License" is also large, written in blue. Other words in various sizes and colors (green, orange, red, yellow, light blue) include: Accreditation (green), CPD (black), Surveyors (teal), Medical Errors (orange), Legislation (blue), Clinical Trials (blue), Nurses (red), Ethics (black), CPD (black), Hospitals (red), Standards (orange), Professionals (blue), Physicians (blue), CAM (orange), Clinics (black), Centers (orange), Regulations (blue), Licensure (blue), Pharmacy (orange), Devices (orange), Medicine (red), Facilities (black), Health Products (red), Allied Health (yellow), Verifications (red), and Inspectors (yellow-green).

2018



National Health Regulatory Authority Annual Report

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Message from the CEO

It is with a lot of honor and pride to present the National Health Regulatory Authority's Annual Report for 2018. At the end of a very busy year of new work processes and technology integrations, it gives me great pleasure to look back over the accomplishments made this past year

2018 was a very productive year for the NHRA, with activity levels increasing across the spectrum, and in some cases reaching all time high including the accomplishment of 92% of our planned initiatives.

The Human Resources Section completed the recruitment of 19 new staff members and completed the upgrade of the NHRA organizational structure for the Civil Services Bureau. The Finance department has ensured a balanced budget for 2018 and the Authority's revenues this year amounted to BHD 2,237,674, an increase of 25% over the previous year, which is equivalent to 80% of the approved budget for recurring expenses for 2018.

On the legislative side, the Legal Affairs Department has reviewed and updated the proposal of new regulations, including, but not limited to, the decision to update the standards of health facilities and the decision of the standards to be met in the health facilities for the treatment of addiction, the resolution regulating pharmaceuticals and the standards of in vitro fertilization.

A total of 30,621 professionals have been registered in the Kingdom – an increase of 9% since last year. The professional's regulation department processed 2,486 new license applications, an increase of 23% from 2017.

The total number of registered health facilities in the Kingdom of Bahrain increased by 7% in 2018 reaching a total of 716 from 671 in 2017. The Kingdom's healthcare facilities include, amongst others, 21 hospitals, 95 general centers, 91 dental centers, 41 specialized centers and 132 clinics (dental and medical). NHRA inspectors conducted 697 inspection visits and corrected 1350 violations.

The Pharmaceutical Regulation department has registered 3,170 medicines and completed procedures of temporary registration of 3,391 medications. The number of licensed pharmacies in the Kingdom has reached 263, an increase of 23% over 2017.

The efforts of the medical device team has The medical device team has processed over 9 thousand requests for medical device clearances a total value of 27,573,000 Bahraini dinars. In order to register all the medical devices used in the Kingdom, which will facilitate the importation and tracking process, the Authority has established a new system for registering medical devices, with a total of 346 registered devices. 125 violations were detected to import equipment and 20 non-matching devices were withdrawn.



Dr. Mariam Al Jalahma, CEO

18 Complementary & Alternative Medicine (CAM) facilities are licensed with 10 new application processed. The CAM team achieved a milestone, which is the first of its kind in the Gulf and Arab countries, by training 25 traditional practitioners. The aim of this training was to qualify them to work within the proper framework of cupping through a cupping course in cooperation with the Sharjah International Alternative Medicine Centre. This course also trained the participants on the appropriate infection control guidelines and medical waste management.

With regards to the continuous medical education in the Kingdom, the authority has approved 19,224 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 5 clinical trials in the private and public sectors.

The Complaints Unit received 228 cases, and the technical committees completed the investigations of 116 cases. NHRA has taken a total of 64 disciplinary actions of which were 25 suspension, 14 warnings, 7 licenses were cancelled and 3 financial penalties on health care facilities.

NHRA successfully accredited 16 hospitals and 6 medical centers over a span of 2 years and this endeavor culminated in the authority winning the award of the Government Forum for Best Government Practices for the Application of the National Accreditation Program.

In light of all the successes we had this past year we also faced a few challenges – particularly in the development of the online platform to unify the authority. However we persevered and by the end of 2018 the authority accomplished two major technical objectives, the first of which was the PPR department, in collaboration with the Supreme Council of Health, was able to develop the drug utilisation repository system (DUR) which will play an integral role in the upcoming Health Insurance Fund. The second achievement was the implementation of the electronic online licensing system that was facilitated by the Information and e-Government Authority. An additional area of technical development for 2018 was the launch of our restructured NHRA website. Using feedback from our clients and staff we have adopted a more functional and user friendly website, that is much easier to navigate and help our clients find relevant information more effortlessly and quickly.

Finally, I'd would like to extend my sincere appreciation to all the staff at NHRA, the Supreme Council of Health and our other partner organisations for their continued support and cooperation this past year. I'd also like to thank all our clients and stakeholders for their unwavering commitment to ensure the provision of safe and high quality health service in the Kingdom of Bahrain. I look forward to the year ahead and the many new developments we have planned for the upcoming year!

Dr Mariam Al Jalahma
Chief Executive Officer - NHRA

NHRA OPERATIONAL PLAN 2016- 2020



In August 2016, the Supreme Council of Health endorsed the 5 year strategic plan for the National Health Regulatory Authority (NHRA). This plan was a joint collaboration between NHRA middle management, administrative staff and senior management.

The strategic plan focuses on the most important objectives to be achieved in the next five years. The strategy identifies the vision, mission and specifies the strategic directions and initiatives to achieve our goals, as well as developing key performance indicators to measure both the goals and initiatives.

All departments at NHRA are responsible to implement the initiatives/procedures in the plan in relation to its responsibilities and function, specifying the person in charge of implementation, time frame and the resources required.

The following pages summarize the operational plan for our strategy for each department. The Human and Financial resources department will implement infra-structure initiatives in order to support NHRA functions and enable it to achieve its goals.

Professionals Regulation Section

Strategy	Strategy KPI	Initiative	Initiative KPIs	Status	Comments	
Ensure the competence of health service providers	Existence of unified criteria for professional categorization	1. Establishing unified criteria of professional licensing categorization 2. Regulate Cupping practice	Produce the final document by June 2017 Develop regulations for traditional cupping practice	Completed Completed	100% 100%	
	Existence of professional code of ethics	3. Developing professional code of ethics	Produce the final document of Code of Ethics by end of Sept. 2017	Completed	100%	
	Percentage of renewed licenses linked to CPD hours of total licenses		4. Developing regulations to link renewal of licensing with CPD	Issue a resolution for professional licensing conditions by end of 2016	Completed	100%
				Develop CPD regulations by March 2017	Completed	100%
Implement a malpractice insurance system	Percentage of health care workers who are covered with malpractice insurance	Setting conditions and regulations for malpractice insurance	Develop a proposal for categories of hospitals and professionals to have mandatory malpractice insurance by mid 2018	Pending	2020	

Healthcare Facility Section



Strategy	KPI	Initiative	Initiative KPIs	Status	Comments
	Existence of regulations for the technical requirements for health facilities	Develop regulations for licensing of health care facilities	Issue a resolution for regulations for licensing of health care facilities by mid of 2017	Completed	Second version published 100%
Ensure efficient health care facilities	Existence of regulations for the establishment of pharmaceutical facilities, drug warehouses and the establishment of pharmaceutical factories	<ol style="list-style-type: none"> 1. Establish regulations for licensing pharmaceutical facilities 2. Develop regulations for the licensing of drug warehouses 3. Develop regulations for licensing pharmaceutical factories 	Issue a resolution for the following regulations: pharmaceutical facilities, factories and warehouses by the end of 2017	Completed	100%
	Establishment of regulations for the licensing of specialized health facilities	Develop regulations for specialized health facilities	Develop CAM regulations by the end of 2016	Completed	100%
			Develop Addiction management regulations by end of 2017	Completed	100%
			Develop IVF regulations by mid of 2018	Completed	100%
Ensure the quality of health services	<ol style="list-style-type: none"> 1. Implement the national accreditation program 2. Developing facility classification 	<ol style="list-style-type: none"> 1. Implementation of the national accreditation program 2. Develop facility classification 	Issue resolution regulating accreditation by end of 2016	Completed	100%
			Issue accreditation policy by January 2017	Completed	100%
			Implement accreditation by May 2017	Completed	100%

Pharmaceutical Product Regulation

Strategy	KPI	Procedures	Initiative KPIs	Status	Comments
Ensure the quality of medicines	1. Existence of regulatory standards for registration of medicines and pharmaceutical products	1. Develop regulatory standards for registration of medicines and pharmaceutical products.	Issue regulations by January 2017	Completed	100%
	2. Percentage of categorized pharmaceuticals and health products	2. Develop categorization standards for pharmaceuticals and health products	Update the old version by June 2017	Completed	100%
Ensure the quality of health services	1. Presence of pharmacovigilance system	1. Develop pharmacovigilance system	<ul style="list-style-type: none"> Develop a proposal for initiating a pharmacovigilance system by mid 2019 Implement the system by end of 2019 	Pending	2020
	2. Percentage of destroyed drugs annually from total registered	2. Establish rules for the destruction or re-export of medicines not complying with the specifications and standards	Publish rules for the destruction or re-export of medicines not complying with the specifications and standards	Completed	100%
	3. Percentage of drugs tested annually from registered	3. Subject all drugs for laboratory testing to ensure its compliance with the technical standards	All new drugs are subjected to lab testing	Completed	100%

Complaint Section

Strategy	KPI	Procedures	Initiative KPIs	Status	Comments
1. Professional accountability	1. Percentage of health facilities who received a disciplinary action	1. Initiate a Committee for Medical accountability for health care facilities	Committee established and functioning	Completed	100%
	2. Percentage of professionals who received a disciplinary action	2. Develop Disciplinary committees for different professions	Disciplinary committees established and functioning	Completed	100%
2. Surveillance of medical errors	3. Presence of an effective Surveillance system for medical error reporting	Develop a Surveillance system for reporting medical errors	Medical errors surveillance system under development	Pending	2020

Clinical Trials & CPD Section

Strategy	KPI	Procedures	Initiative KPIs	Status	Comments
1. Safe clinical trials	Presence of guidelines regulating clinical trials	1. Establish clinical trials regulations	CT Guidelines published	Completed	100%
		2. Establish ethical research committee guidelines	Committee guidelines published	Completed	100%
2. Ensure the competence of health service providers	Existence of regulation for accrediting continuous professional educational programs.	Develop a national guideline for CPD program approval process	CPD guidelines published	Completed	100%

Medical Device Licensing

Strategy	KPI	Procedures	Initiative KPIs	Status	Comments
Ensure the quality of medical supplies and devices	<ol style="list-style-type: none"> Existence of regulatory standards for registration of medical supplies and devices Percentage of registered medical devices 	<ol style="list-style-type: none"> Develop regulatory standards for registration of medical supplies and devices by 2017 Establish a comprehensive medical device national data base by end of 2018 	<p>Standard published</p> <p>Data base established</p>	<p>Completed</p> <p>In progress</p>	<p>100%</p> <p>25%</p>
Ensure the safety of medical supplies and devices	<ol style="list-style-type: none"> Percentage of medical devices recall or adverse event 	<p>Develop a Surveillance system for reporting medical devices recall, alert and adverse events by end of 2019</p>	<p>Surveillance system for reporting medical devices under development</p>	<p>Pending</p>	<p>2020</p>

Human Resources & Finance Section

Strategy	KPI	Procedures	Status	Comments
Develop human resources of NHRA	1. Internal policies developed & published.	1. Develop internal NHRA policies & procedures	Completed	100%
	2. The new organizational structure finalized and approved by CSB.	2. Update NHRA organization structure	In process	Proposal under CSB review
	3. Risk assessment plan is in place.	3. Develop a risk assessment plan	Completed	100%
	4. NHRA IT system is developed and functional.	4. Update the IT system of NHRA	In process	25%
	5. All NHRA jobs are occupied.	5. Complete the employment procedures according to budget availability	Completed	90%
	6. All NHRA staff are evaluated annually.	6. Complete performance assessment procedures.	Completed	100%
	7. Existence of an annual training plan for all NHRA staff	7. Develop training plan for all NHRA staff based on performance evaluation.	In process	50%
Develop Financial resources of NHRA	1. The financial plan is adopted and published.	1. Develop the financial policy for NHRA	Completed	100%
	2. adopted regulations for committees' payment are published.	2. Develop regulations for committees' financial payment.	Completed	100%
	3. Visiting consultants' payment scheme is adopted.	3. Develop Regulations for consultant's payment	Completed	100%



Regulating Healthcare Facilities

Clinical Trials
Professionals
Pharmacy
Verifications
Facilities
Medicine
Physicians
Standards
Centers
License
Surveyors
Clinics
Nurses
CAM
CPD
Devices
Hospitals
Inspectors
Accreditation
Ayurveda
Regulations
Health Products
Licensure
Allied Health
Legislation
Medical Errors
Pharmacies
Ethics



Healthcare Facility Section

Healthcare Facilities

The total number of registered health facilities in the Kingdom of Bahrain increased by 7% in 2018 reaching a total of 716 from 671 in 2017. The Kingdoms healthcare facilities include, amongst others, 21 hospitals, 95 public centres, 41 specialized centres and 132 clinics.

The Health Facilities Regulation inspectors conducted 697 inspection visits and made recommendations for the corrections of 1350 violations. One hundred and six appreciation letters were sent out in 2018 an increase of 88% since 2017. Appreciation letters are issued to facilities that have ensured all requirements of licensing standards are met and in cases where recommendations are fulfilled in a short amount of time.

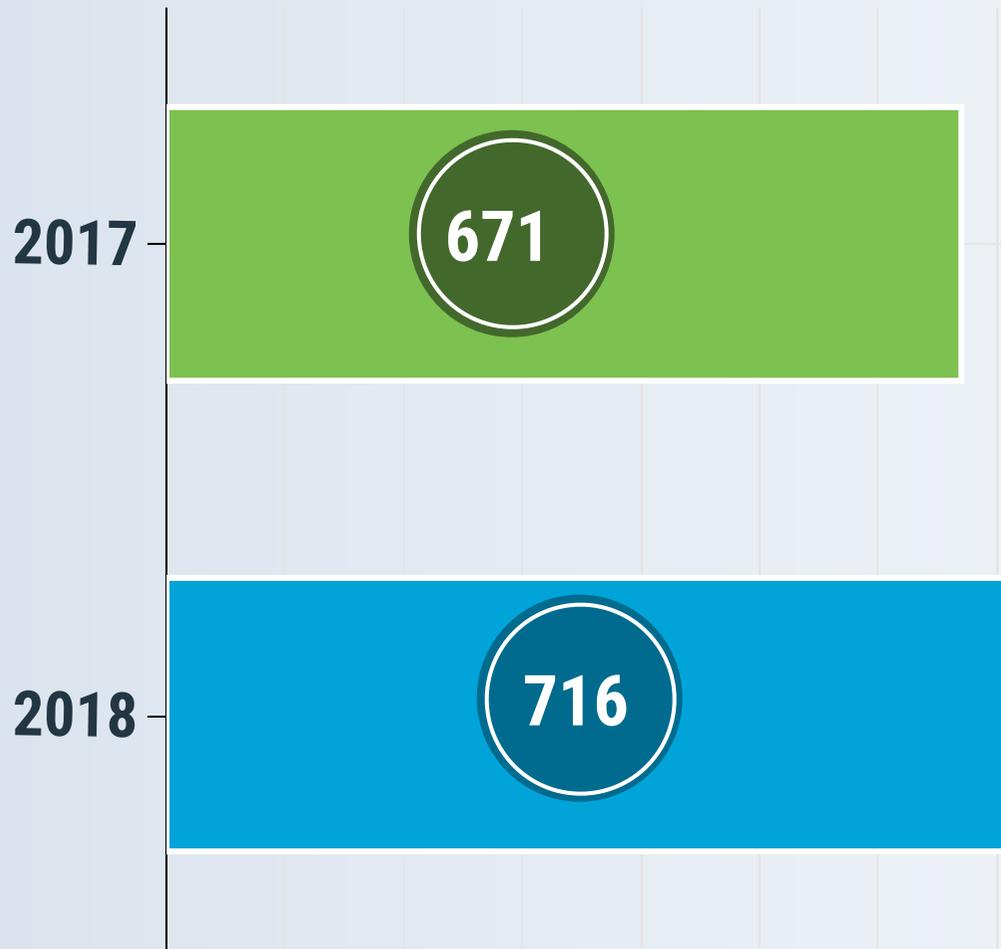
On an advisory level the department works closely with new investors to support them navigate the establishment of new facilities, which include on site consultations and advice.

The department is currently working with the Information and e-government authority to develop an online system for renewal of licences. This system will be the foundation of a national database for all licensed facilities in the Kingdom, furthermore this system will alert facilities of any pending requirements regarding their licenses so as to avoid any penalties.

Two new facility license categories have been established in order to improve healthcare services in the Kingdom:

- **Regulation of Telemedicine Services:** Has been issued a licensing code of: 30100000. The regulation outlines the rules and guidelines in providing online medical consultation.
- **Regulation of Audiology Services:** Has been issued a licensing code of: 31900000. This regulation outlines the guidelines in the provision of audiology services.

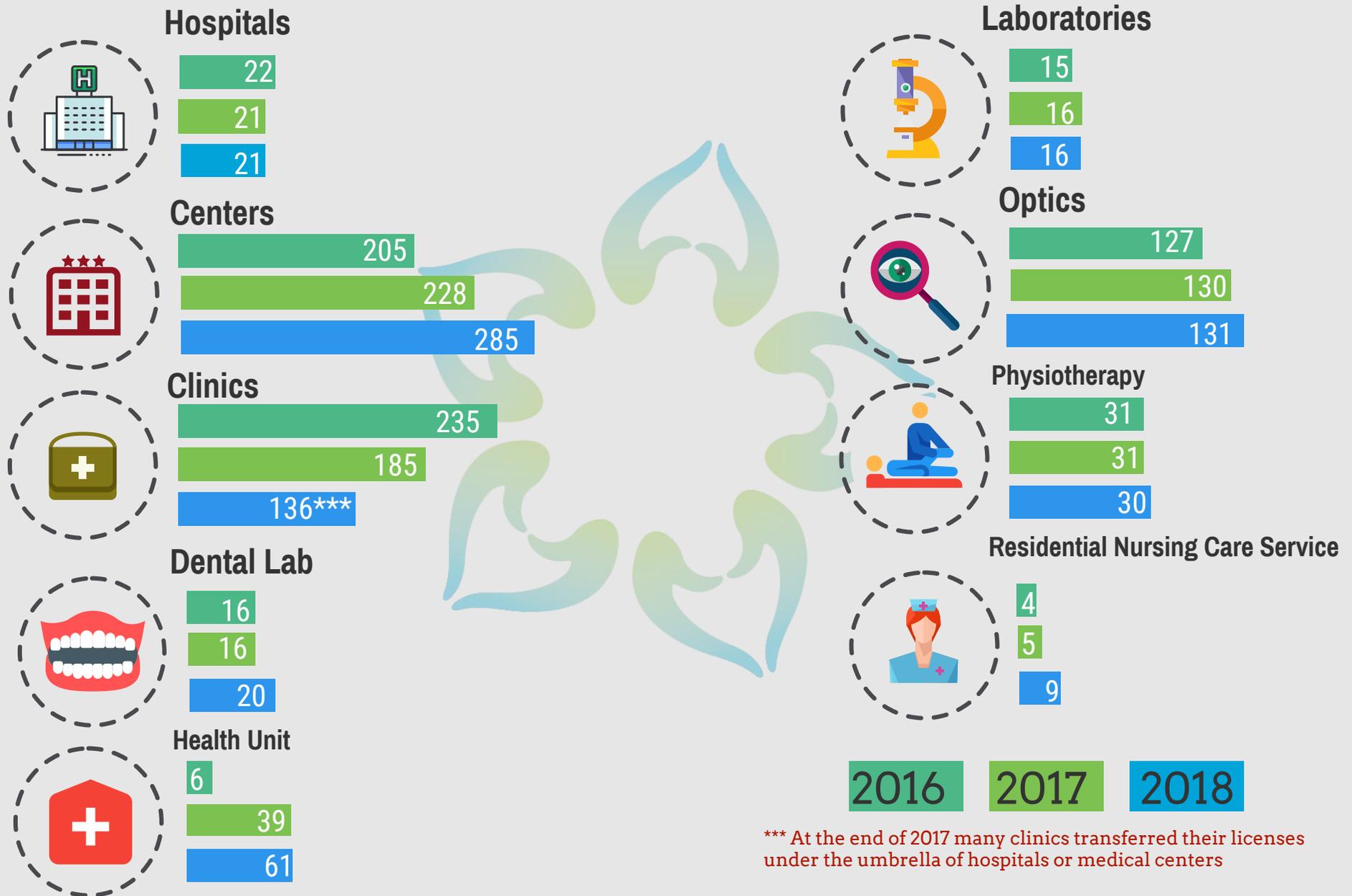
Healthcare Facilities in the Kingdom of Bahrain



Total
Number
of Licensed
Facilities
in the
Kingdom
of Bahrain

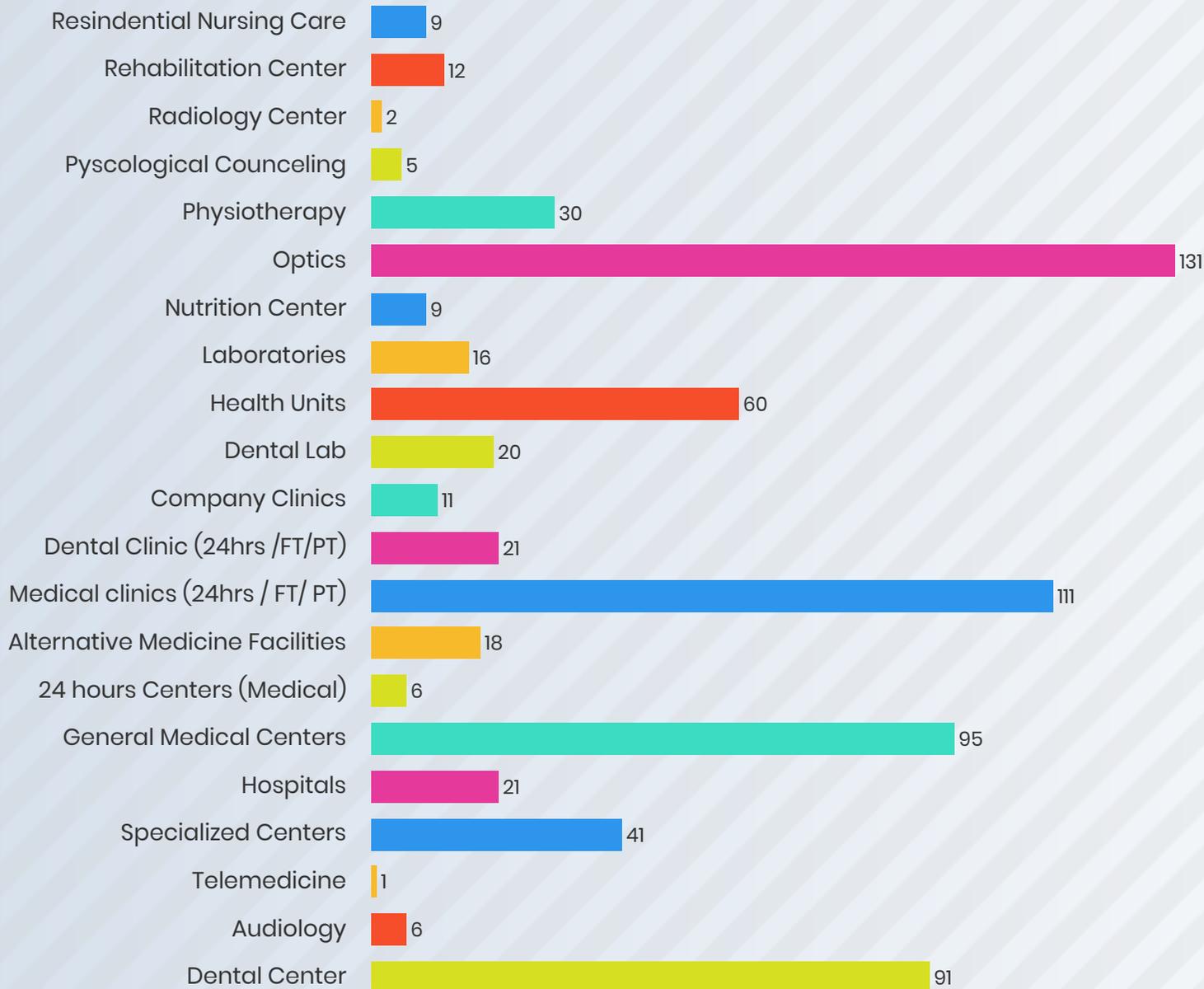
716

Licensed Healthcare Facilities 2016-2018

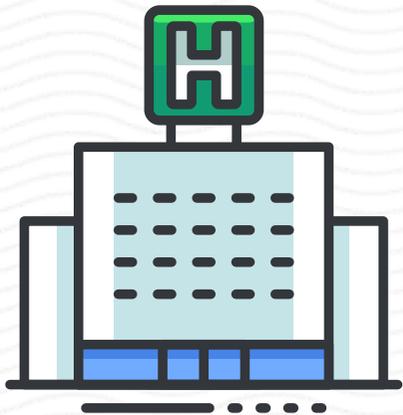
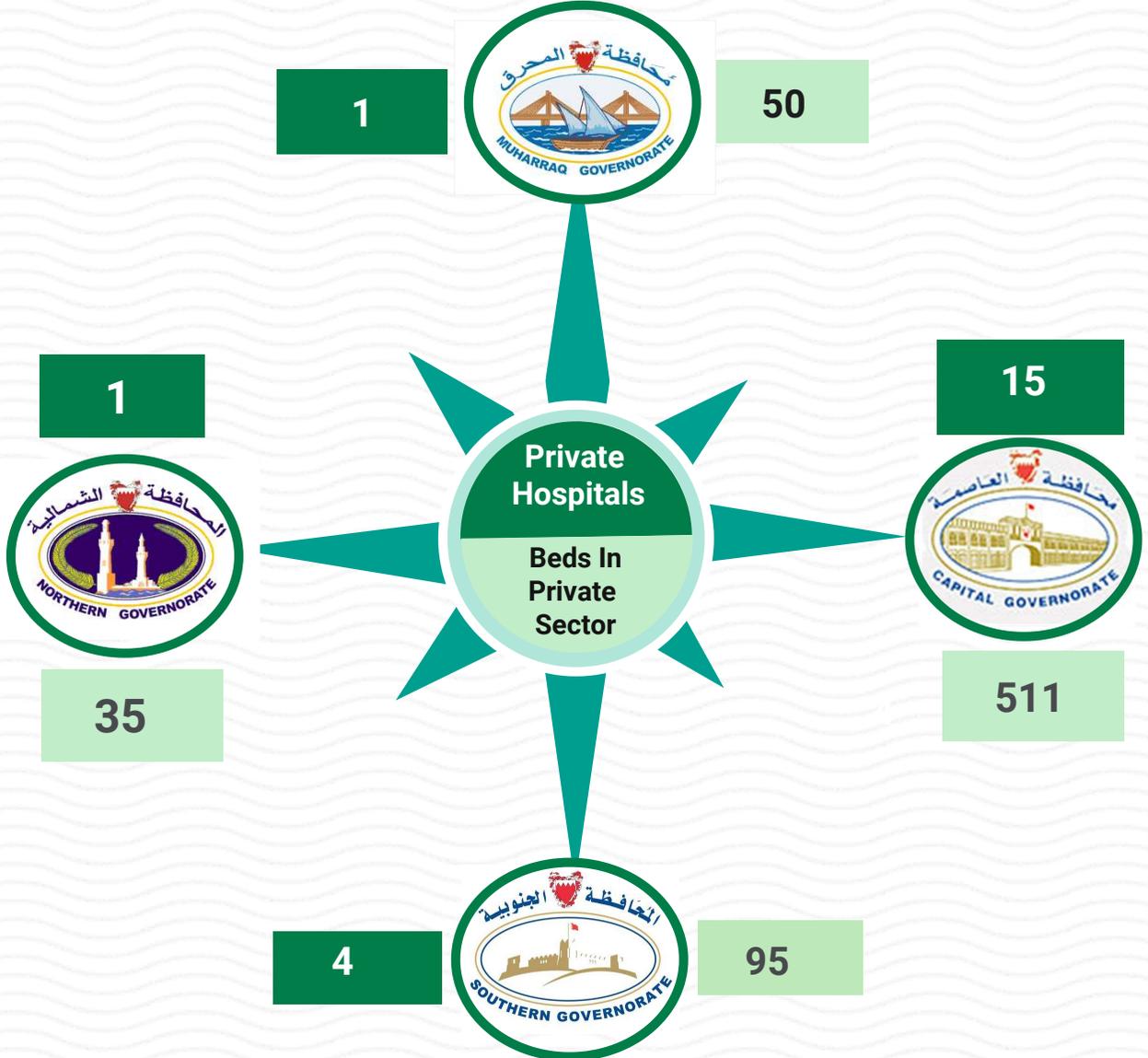


*** At the end of 2017 many clinics transferred their licenses under the umbrella of hospitals or medical centers

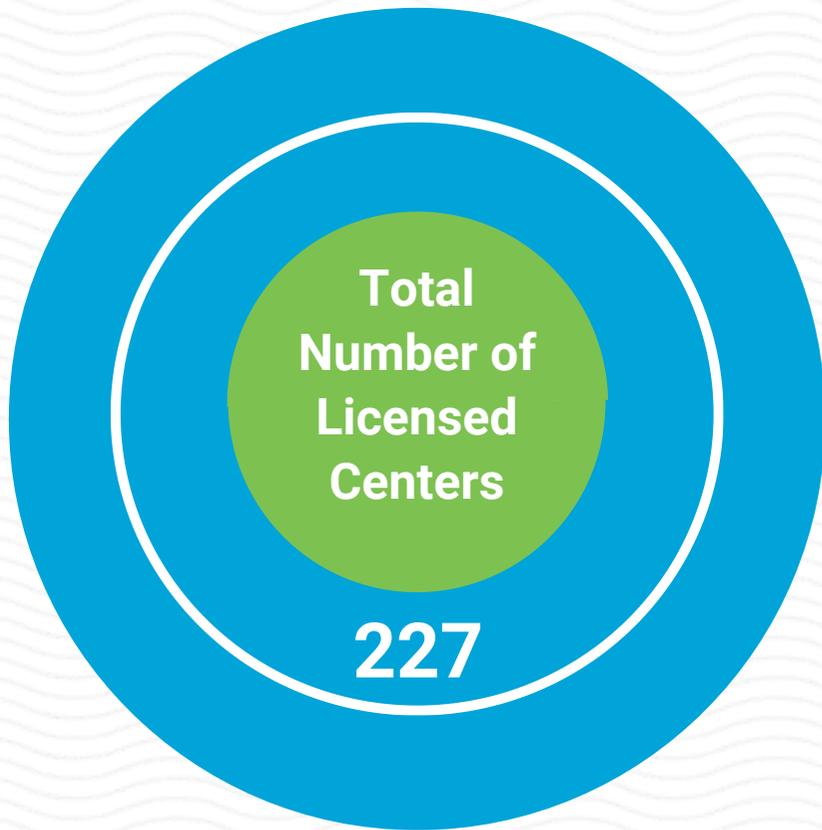
Types of Healthcare Facilities In the Kingdom



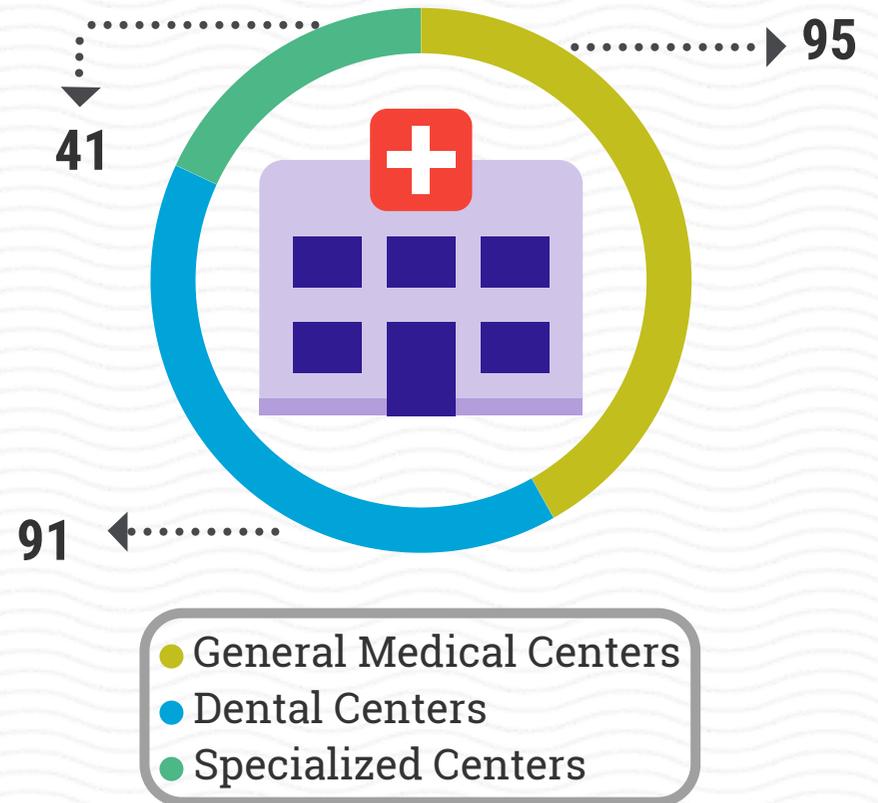
Geographic and Bed Distribution of Private Hospitals



NHRA Licensed Private Centers

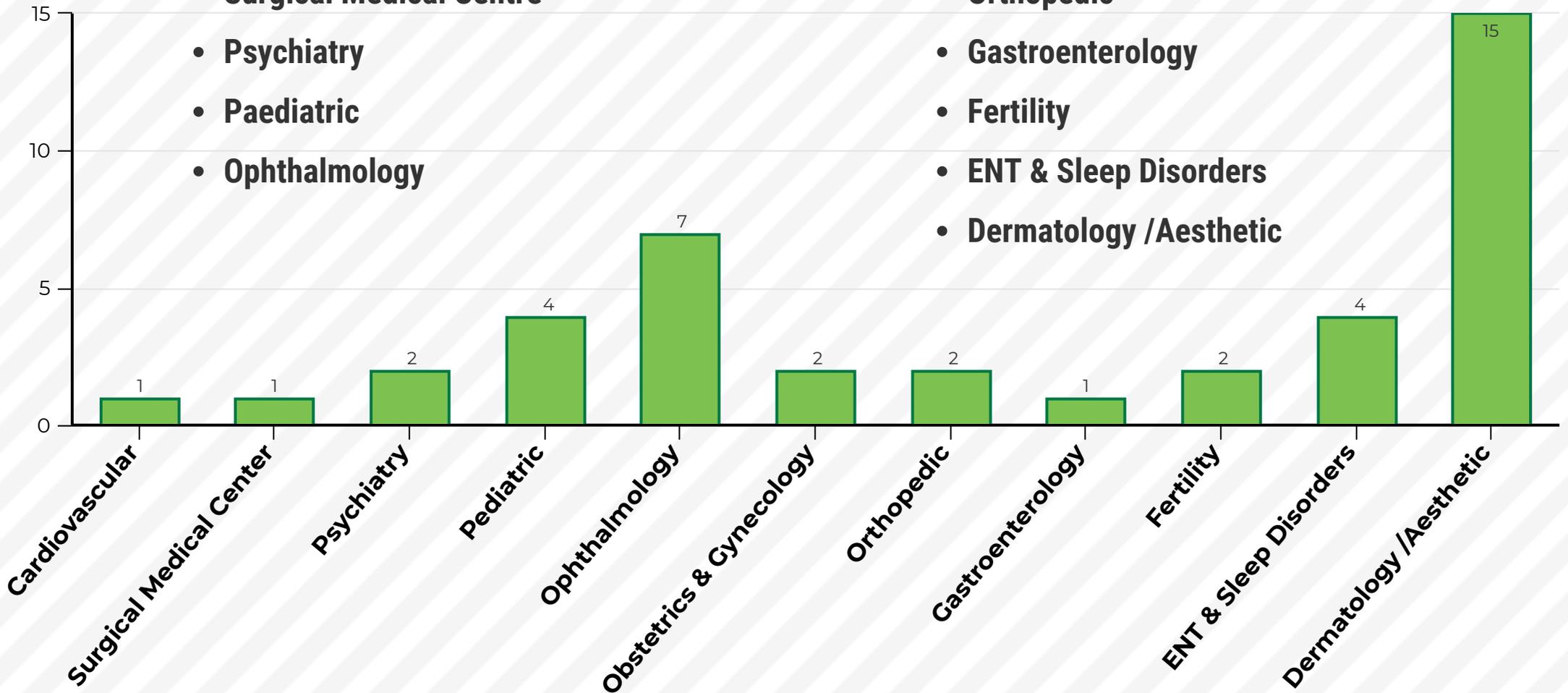


Distribution of Licensed Centers



Types of Specialized Medical Centers

- Cardiovascular
- Surgical Medical Centre
- Psychiatry
- Paediatric
- Ophthalmology
- Obstetrics & Gynecology
- Orthopedic
- Gastroenterology
- Fertility
- ENT & Sleep Disorders
- Dermatology /Aesthetic



Geographic Distribution of Centers

Capital



Muharraq



Northern

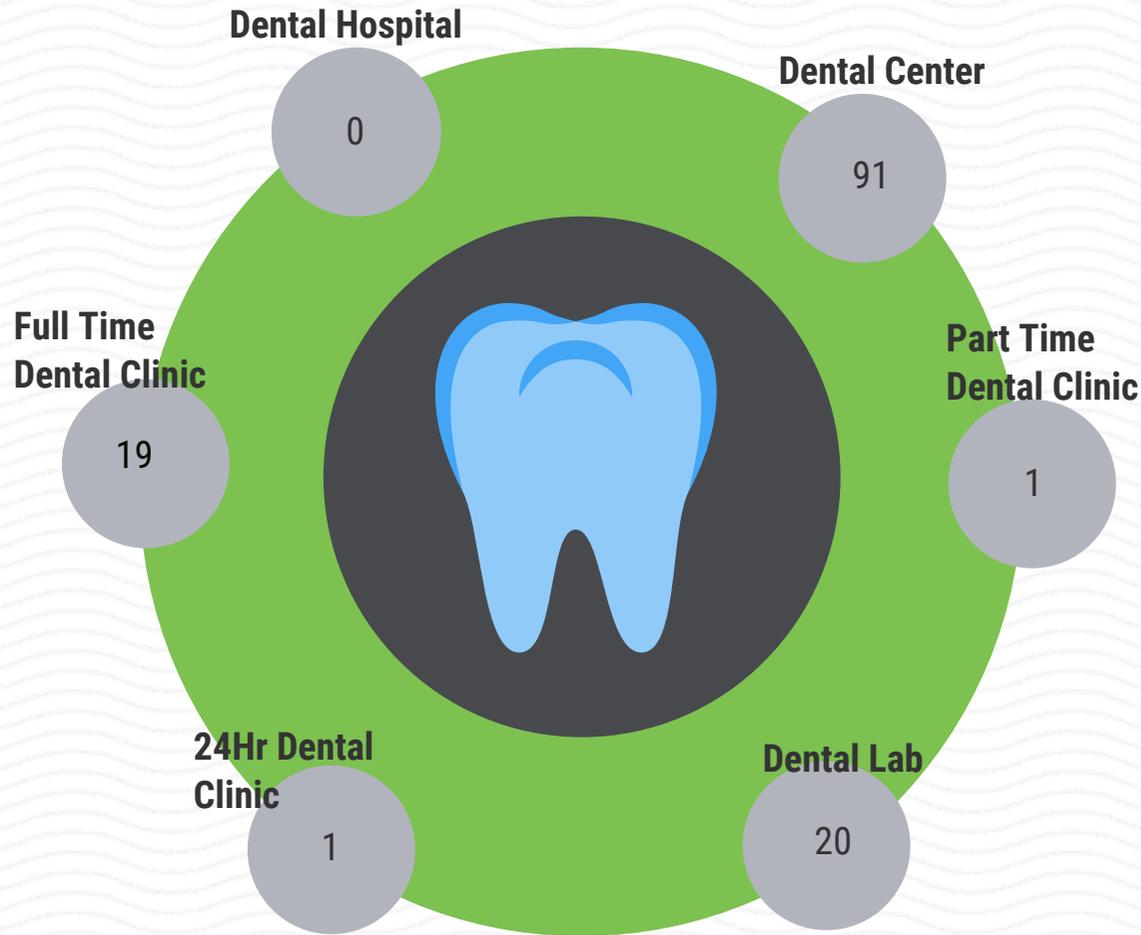


Southern

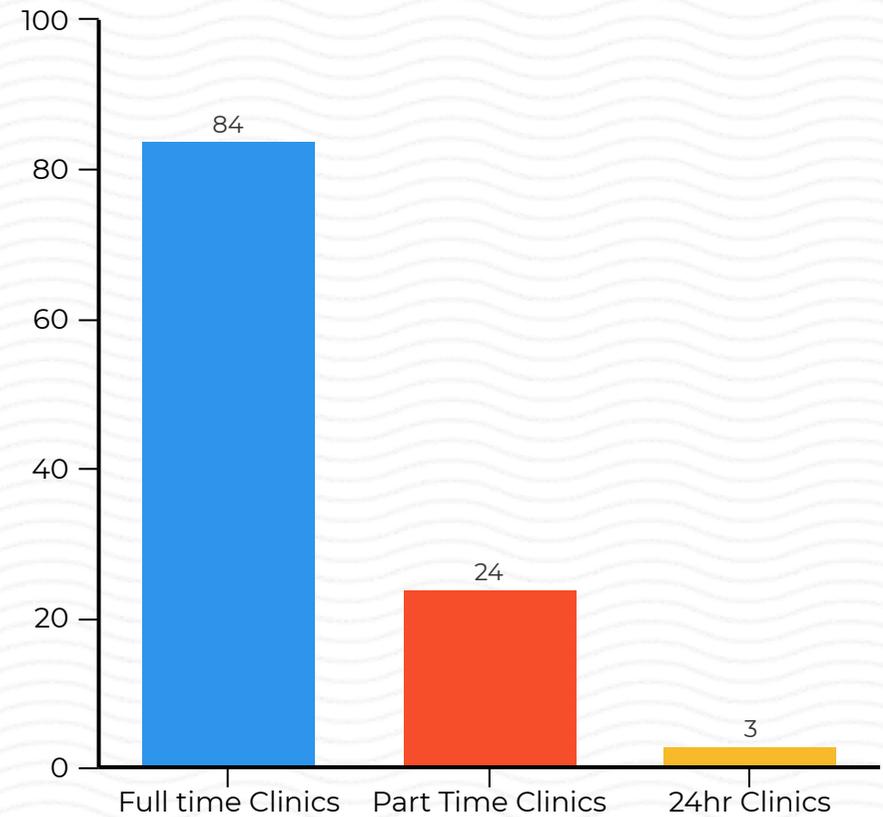


Registered Dental Facilities and Private Medical Clinics

Dental Facilities

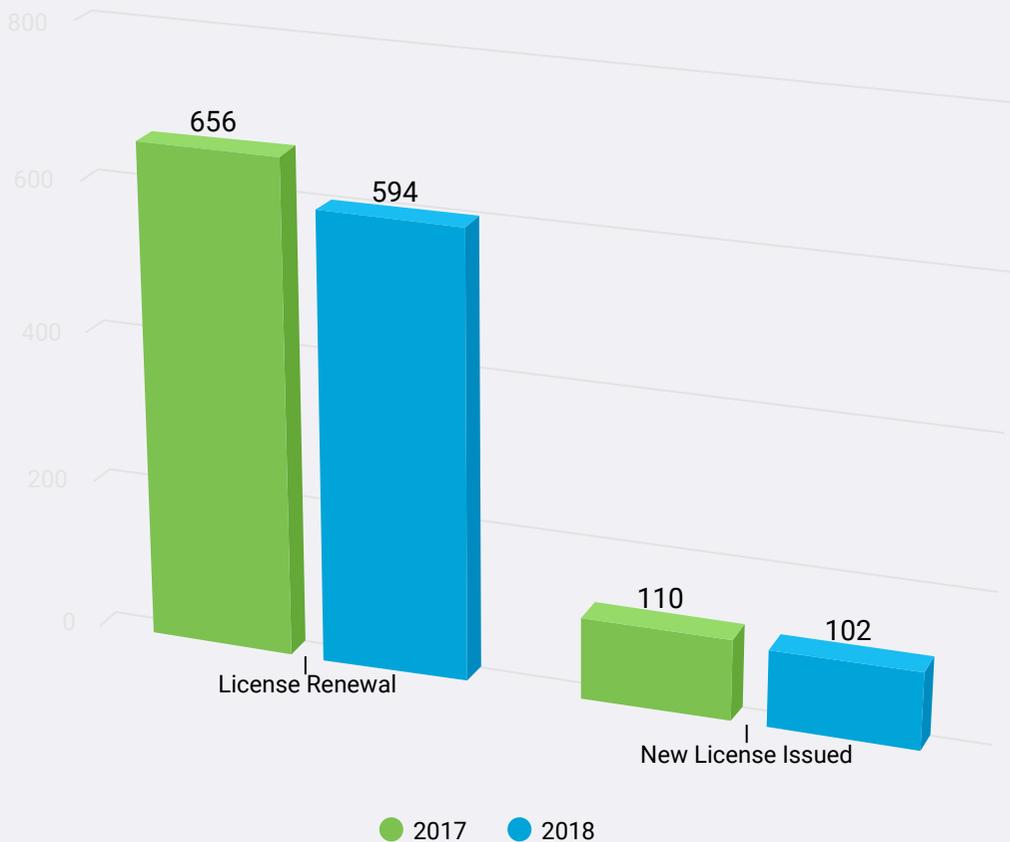


Private Medical Clinics

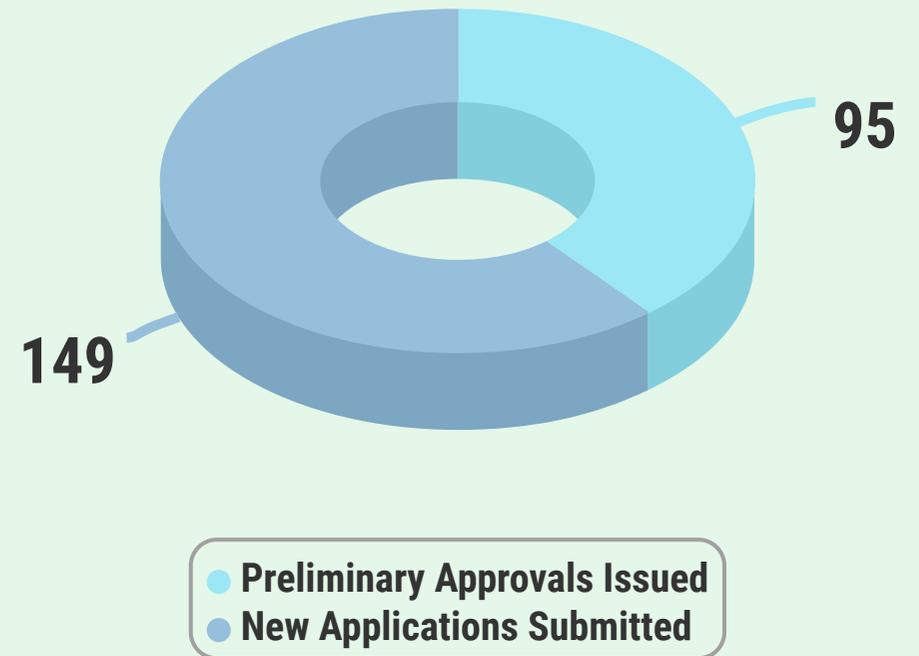


Licensing and Engineering Activities

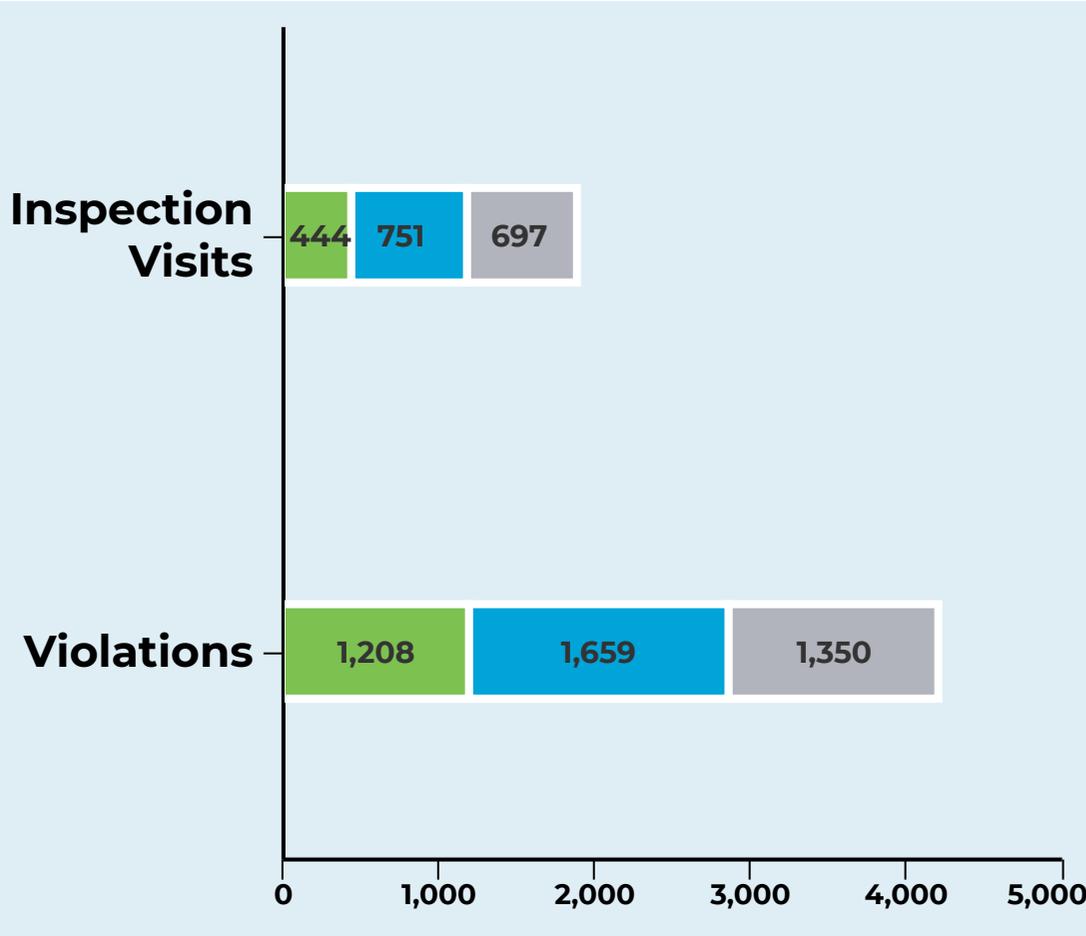
Licensing Activities



Engineering Activities

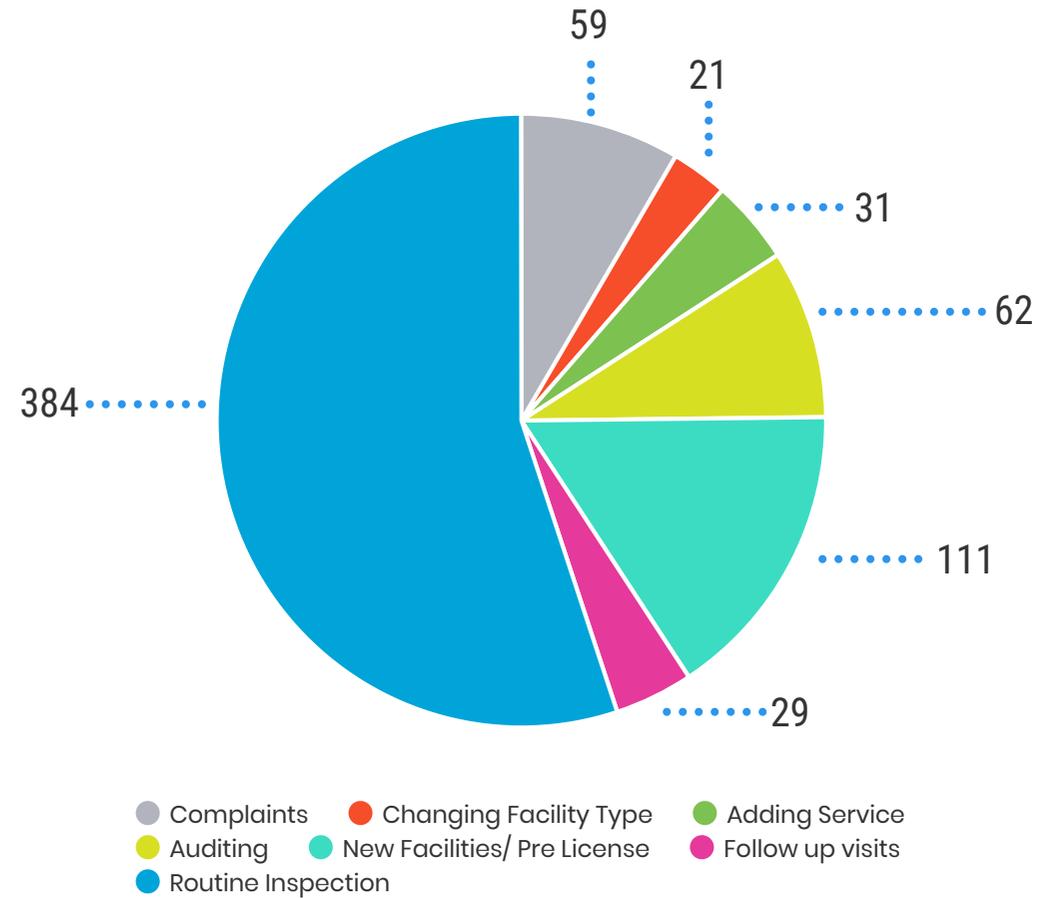


Health Care Facilities - Inspection Activities



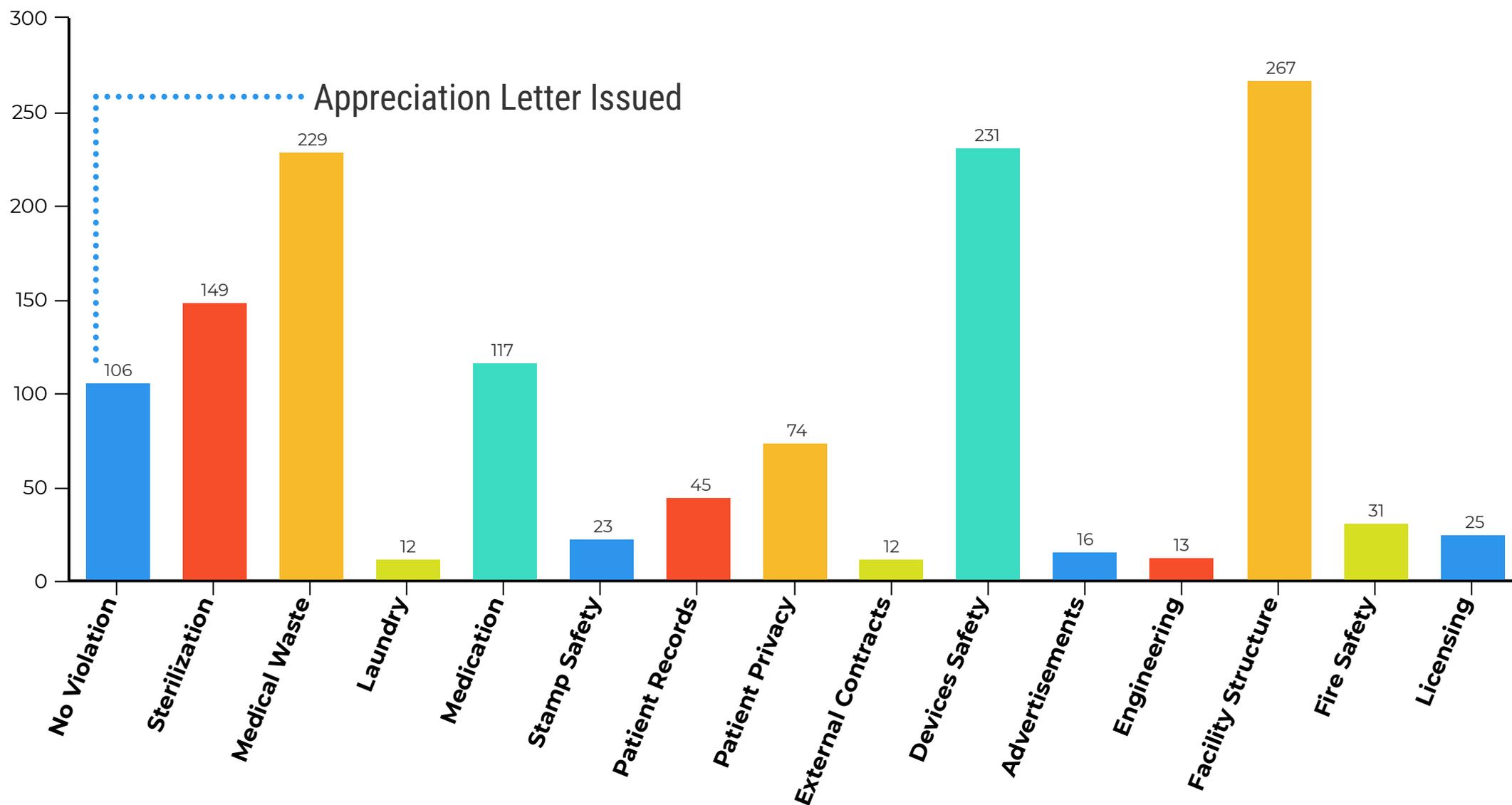
2016
 2017
 2018

Inspection Visits 2018



(Total:697)

Inspection Activities - Violation Categories



Facility Structure Sub - Violations

Facility Structure Violations



Healthcare Facilities Achievements in 2018

- Launching of two new regulations for Audiology & Telemedicine Services
- Developing facilities online database and online application system
- Developing Medical Laundry under specified guidelines and procedures
- Conducting of 62 Auditing Visits on Expatriates Pre-employment Services.
- Participating in GCC Technical Committee for Pre-employment Auditing visits in countries of origin.

Developing updated guidelines and standards for the following services:

- ▶ **Audiology Standards**
- ▶ **Bariatric Surgery Standards**
- ▶ **High Dependency Unit**
- ▶ **Telemedicine**
- ▶ **Endoscopy & Dialysis Guidelines**
- ▶ **Medical Incubator Standards**
- ▶ **Sleep Laboratories**
- ▶ **Prosthesis Center**
- ▶ **Laboratory Consultation Office**
- ▶ **Crash Cart Trolley Standards**
- ▶ **Home Health Care Services (Nursing, Physiotherapy, etc)**
- ▶ **Laser Hair Removal**
- ▶ **Audiology and Speech Centers**
- ▶ **Optical Shops**
- ▶ **Medical**
- ▶ **Medication Transportation Service**





Regulating Alternative Medicine

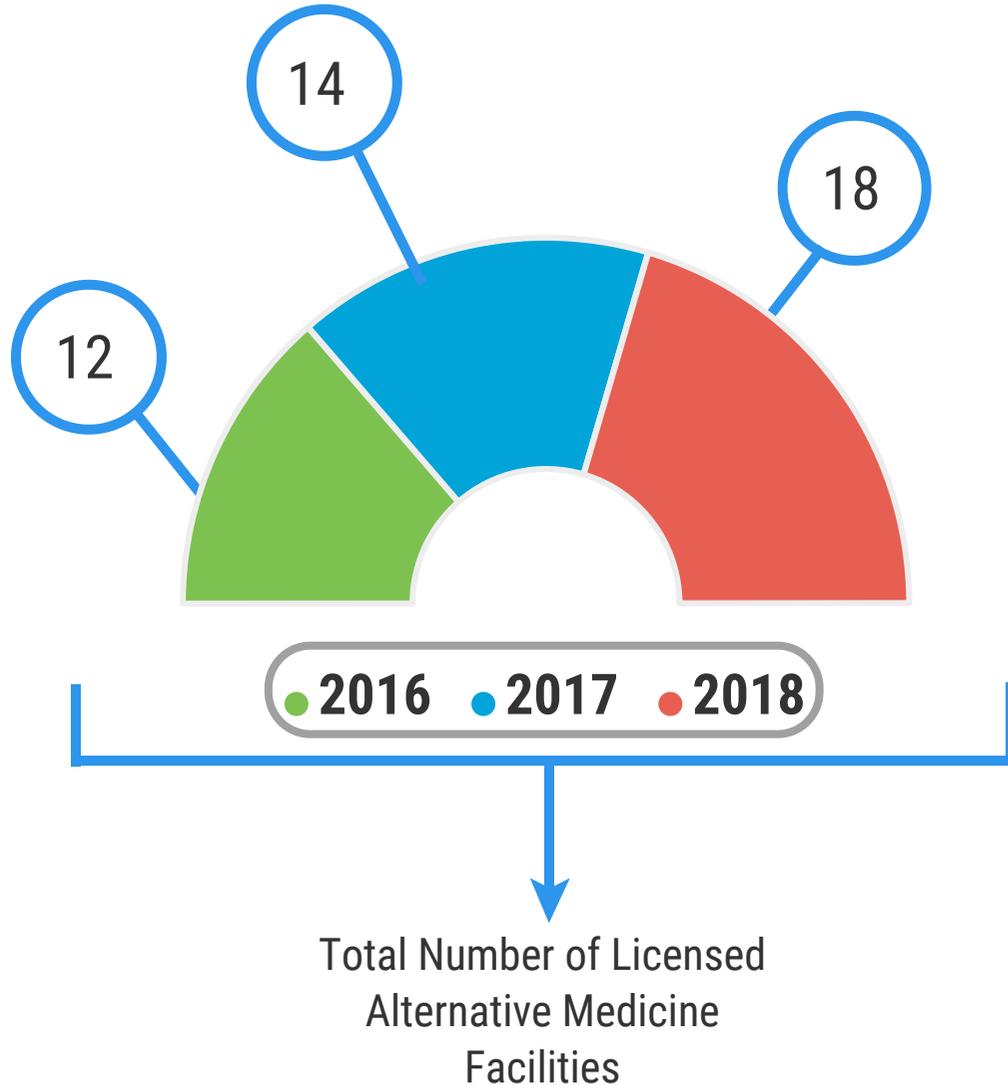
Health Products
Surveyors Accreditation Verifications
Pharmacy Devices CPD Facilities
Pharmacies Centers License Medicine
Hospitals Nurses CAM Ethics
Physicians Ayurveda Licensure Clinics
Standards Legislation Inspectors
Professionals Allied Health
Regulations Medical Errors
Clinical Trials



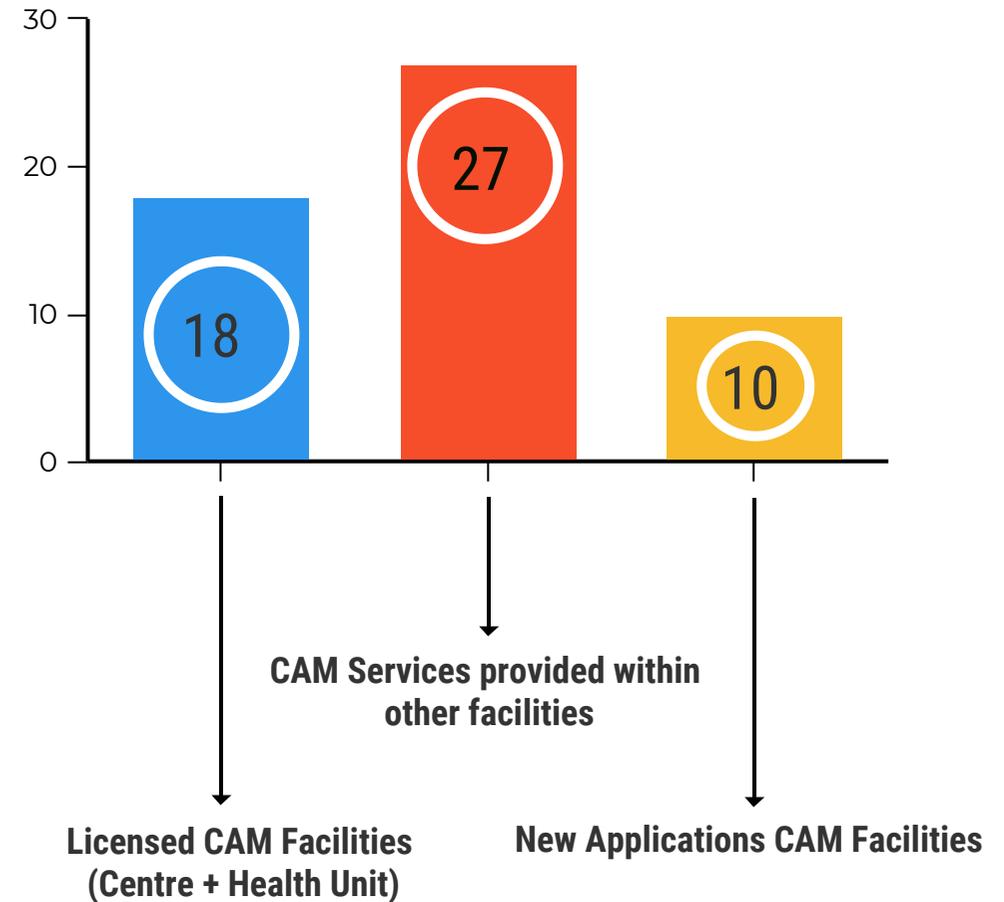
Complementary/Alternative Medicine Committee

Complementary and Alternative Medicine Licensing Activities (CAM)

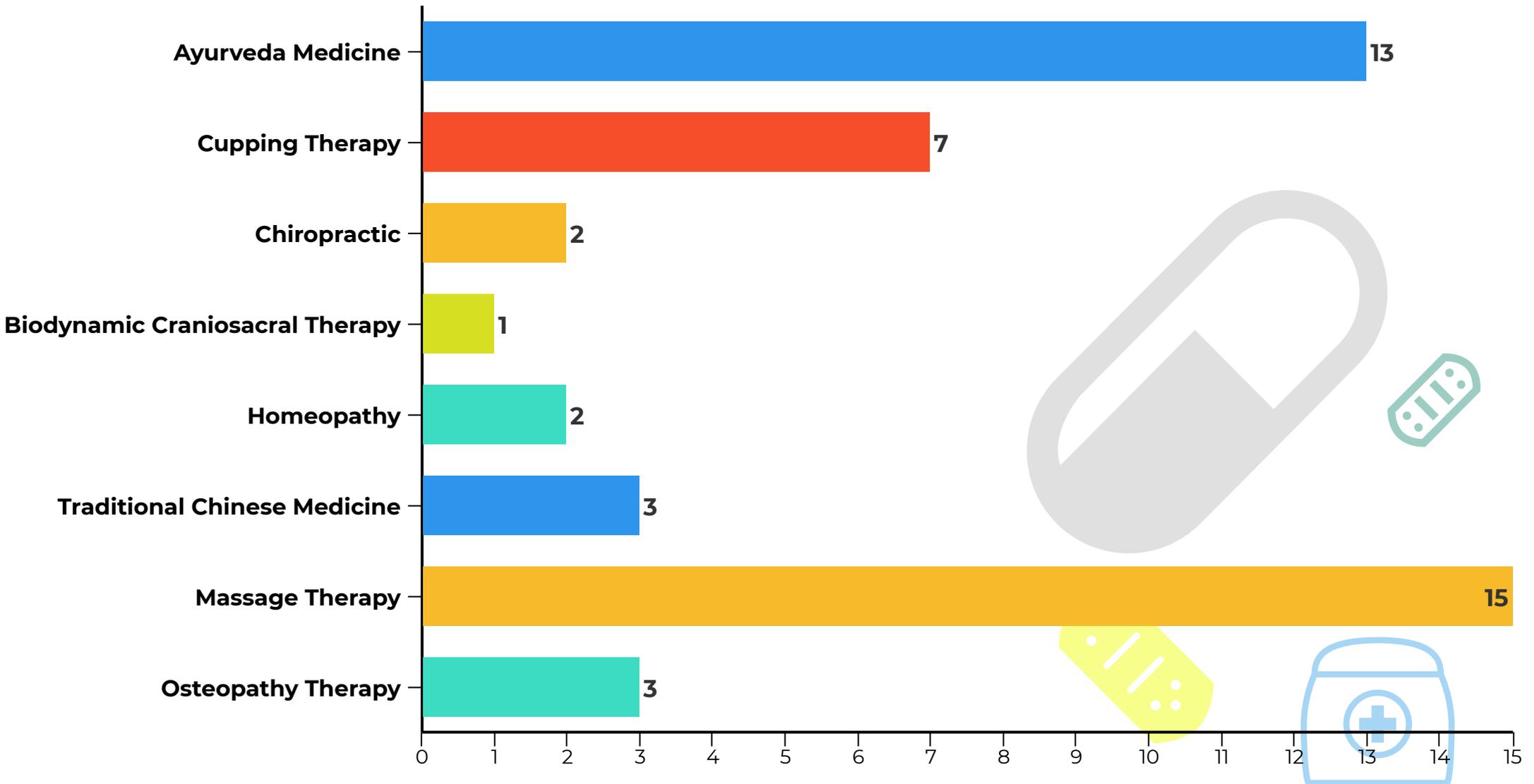
Number of CAM Facilities 2016-2018



CAM Facilities Licensed 2018

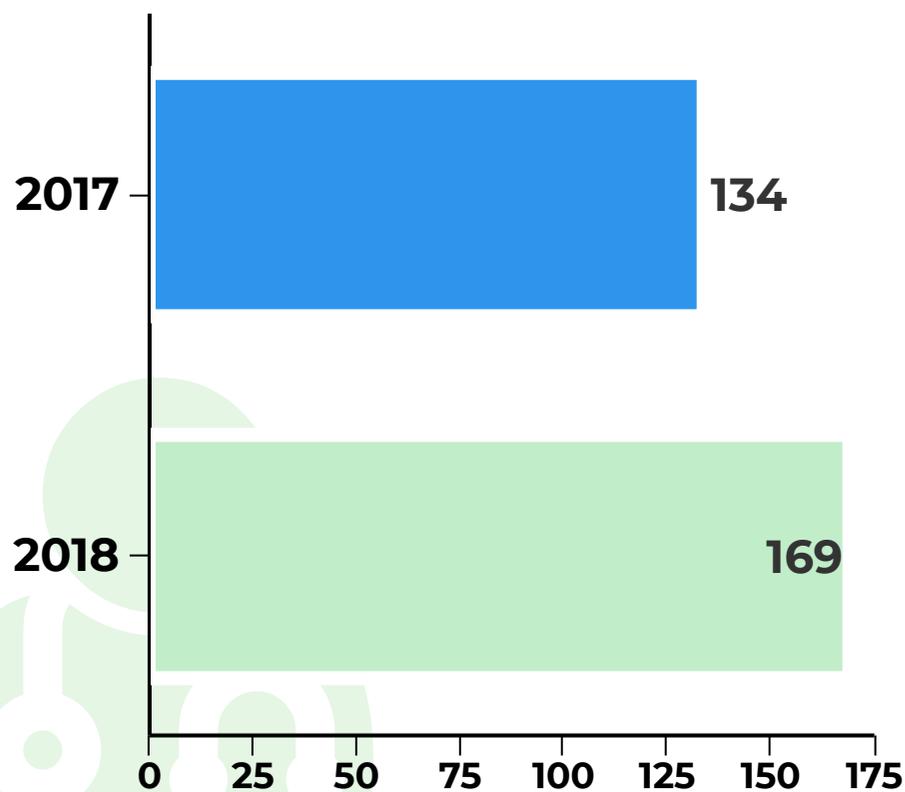


Types of Complementary and Alternative Medicine Services Available in Kingdom of Bahrain

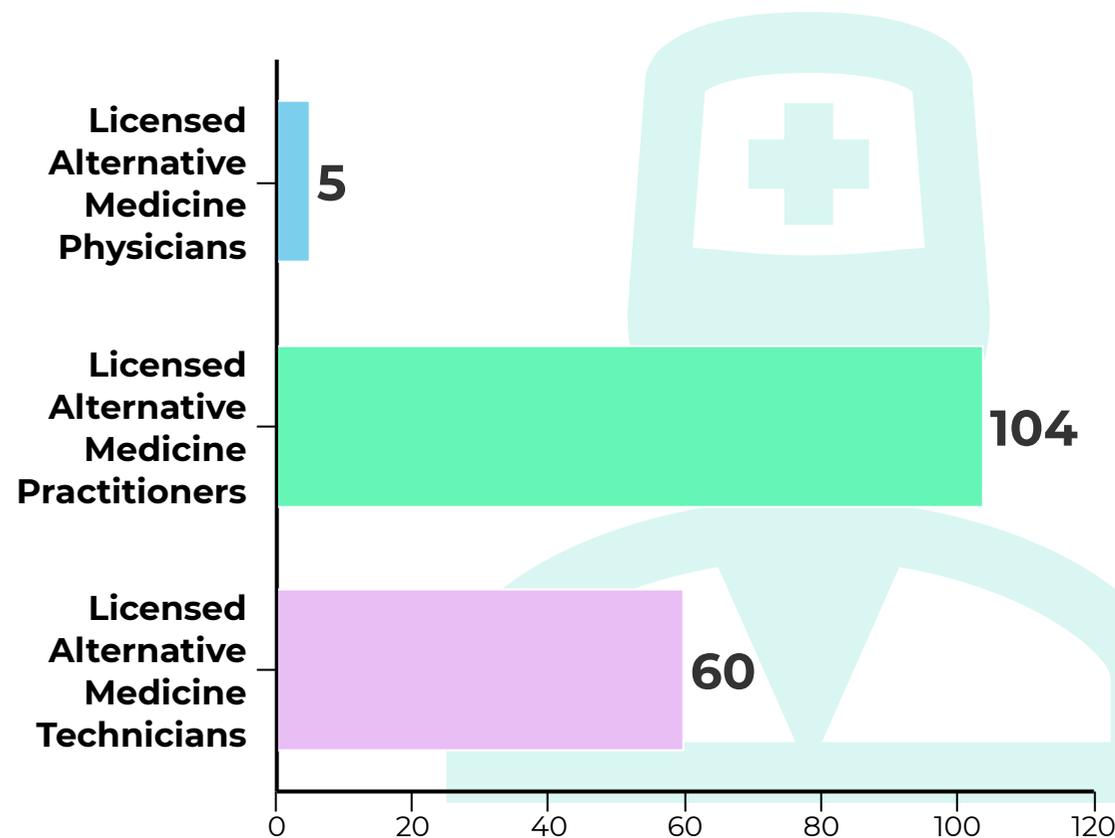


Complementary/Alternative Medicine (CAM) Professionals

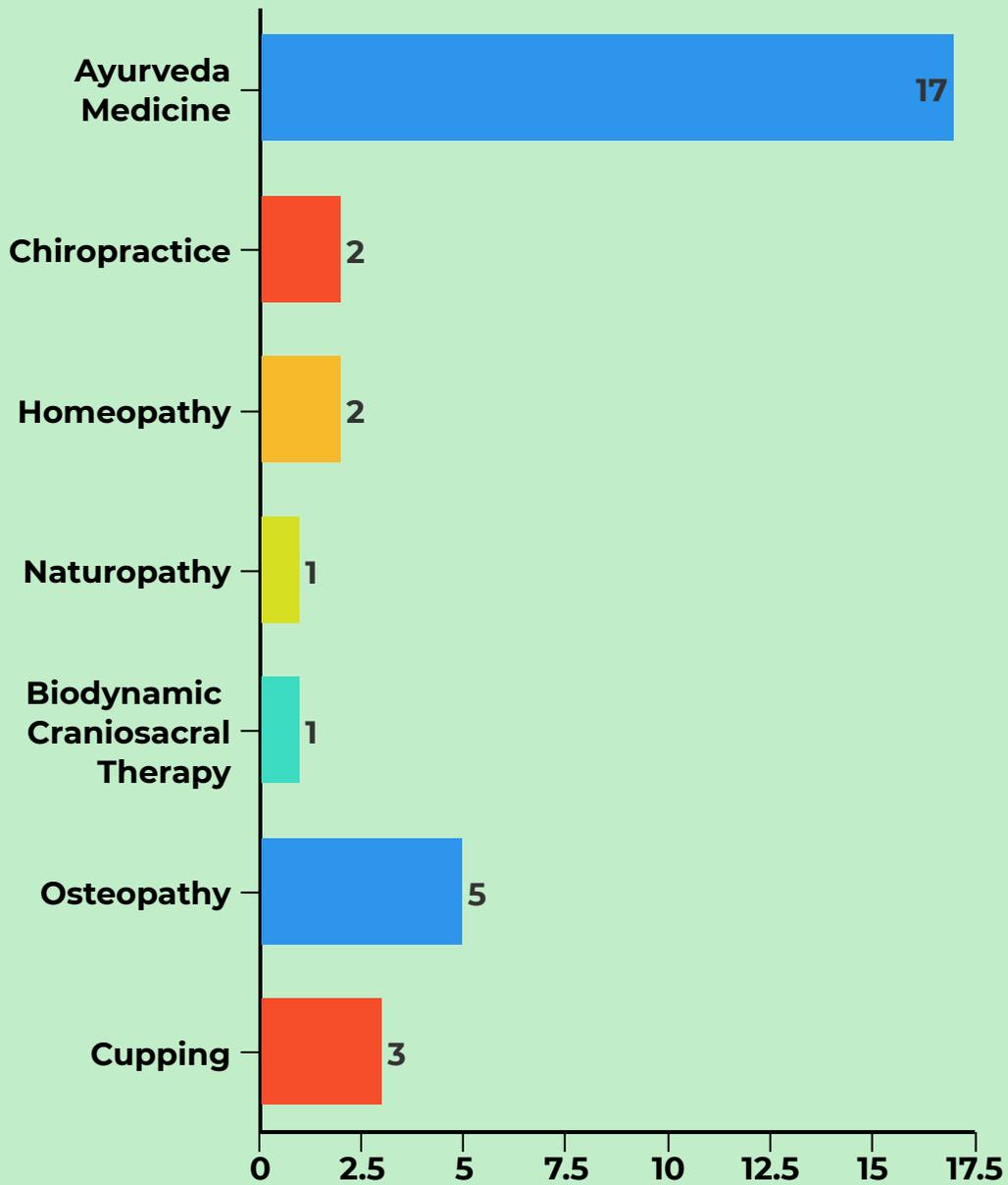
CAM Professionals in the Kingdom of Bahrain



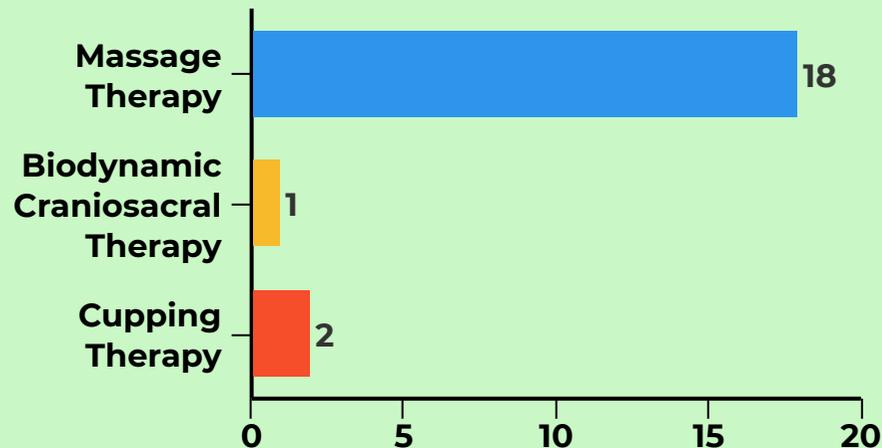
Categories of CAM Professionals



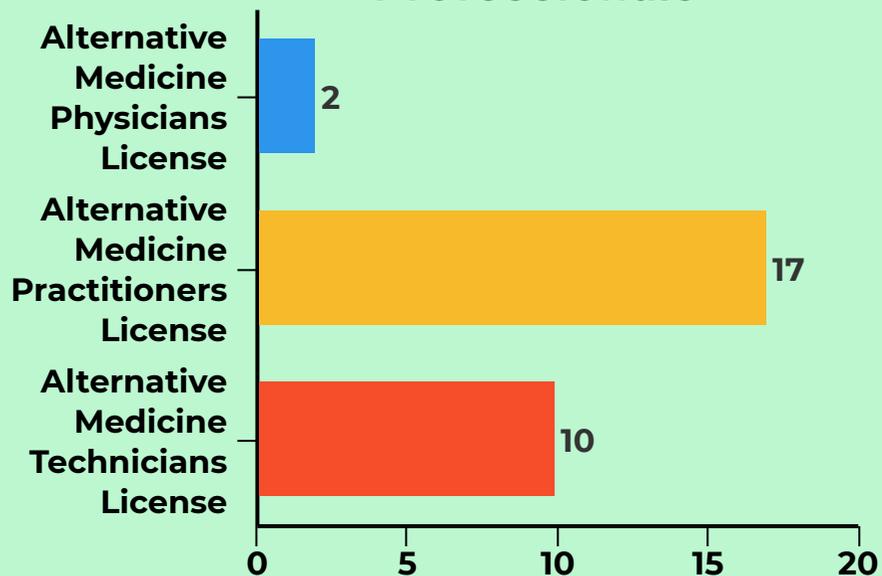
Licensed CAM Practitioners by Specialty



Licensed CAM Technicians by Services Provided



New Applications for CAM Professionals





Regulating Healthcare Professionals

Verifications
Standards
Nurses
Medical Errors
Ayurveda
Surveyors
Licensure
Legislation
Physicians
CAM
Medicine
Pharmacy
Clinical Trials
Allied Health
Health Products
CPD
Centers
License
Facilities
Clinics
Devices
Inspectors
Hospitals
Regulations
Ethics
Pharmacies



Healthcare Professionals Section

Healthcare Professionals

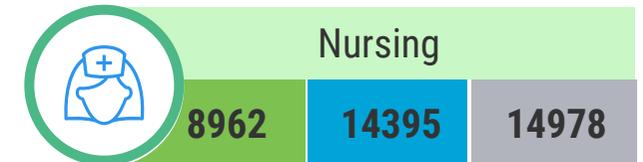
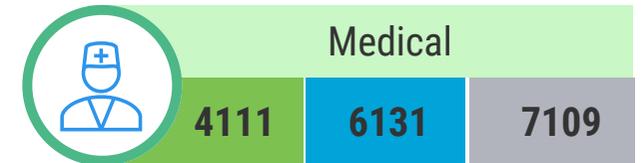
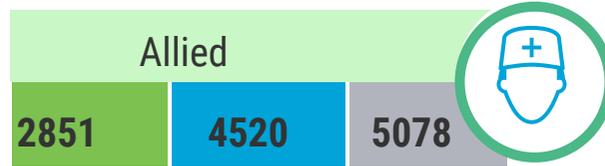
A total of 30,621 professionals have been registered in the Kingdom – an increase of 9% since last year. The professional's regulation department processed 2,486 new license applications, with an increase of 23% from 2017.

New regulations were issued for new Bahraini graduates that grants them a license upon passing the licensure exam regardless of a job offer. The regulations outline the licensees' responsibilities to maintain and update their knowledge through continuous practice and continuous professional development training that will contribute towards their CME requirements to renew their license. This new procedure aims to help new graduates cover any gap of practice.

The HCP department also implemented the online licensure examinations through its collaboration with Prometric for providing technology-enabled testing and assessments for licensure exams.

However, the greatest achievement of the department in 2018 was the development and implementation of the online licensing system enabling professionals in the Kingdom to now apply for a new license or renewal of an existing license in the convenience of their home or place of work.

Healthcare Professionals in the Kingdom of Bahrain



Distribution of Registered Professionals in the Kingdom of Bahrain



7109
Medical



2107
Pharmacists



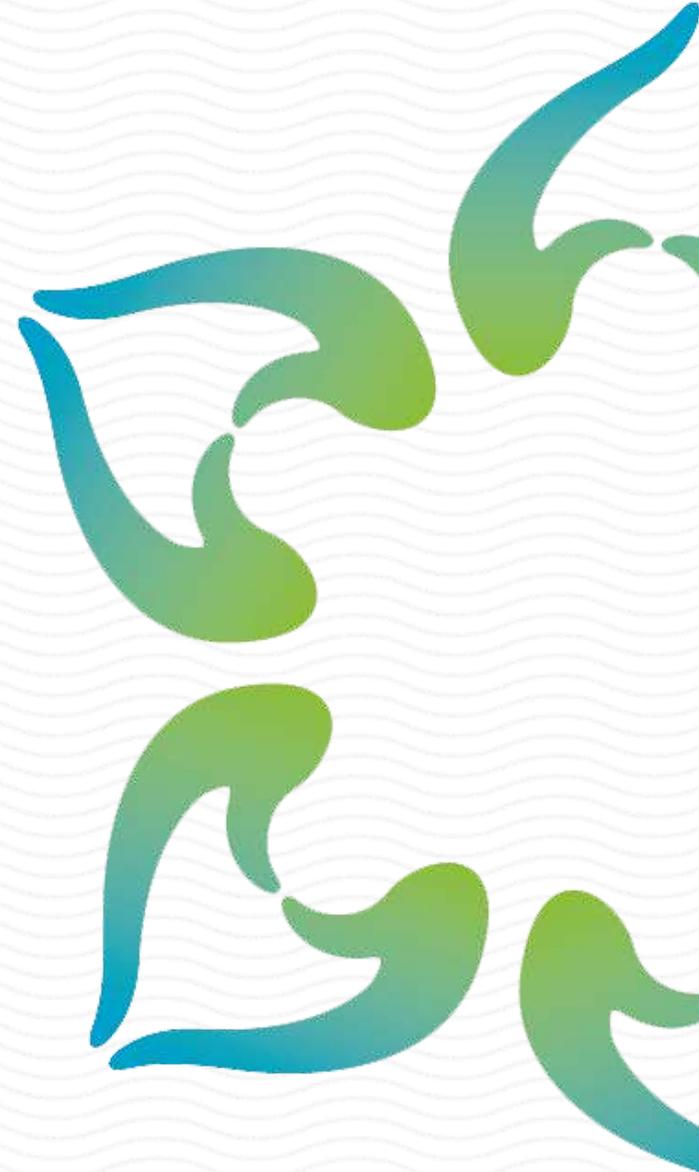
1349
Dental



5078
Allied



14978
Nursing



Categories of NHRA Registered Professionals



Physicians

Consultants	1469
Specialists	1051
General	4506
Visiting	83

Consultants	115
Specialists	247
General	976
Visiting	11



Dentists



Pharmacy Professionals

Pharmacists	1520
Technician	329
Medical Delegates	258

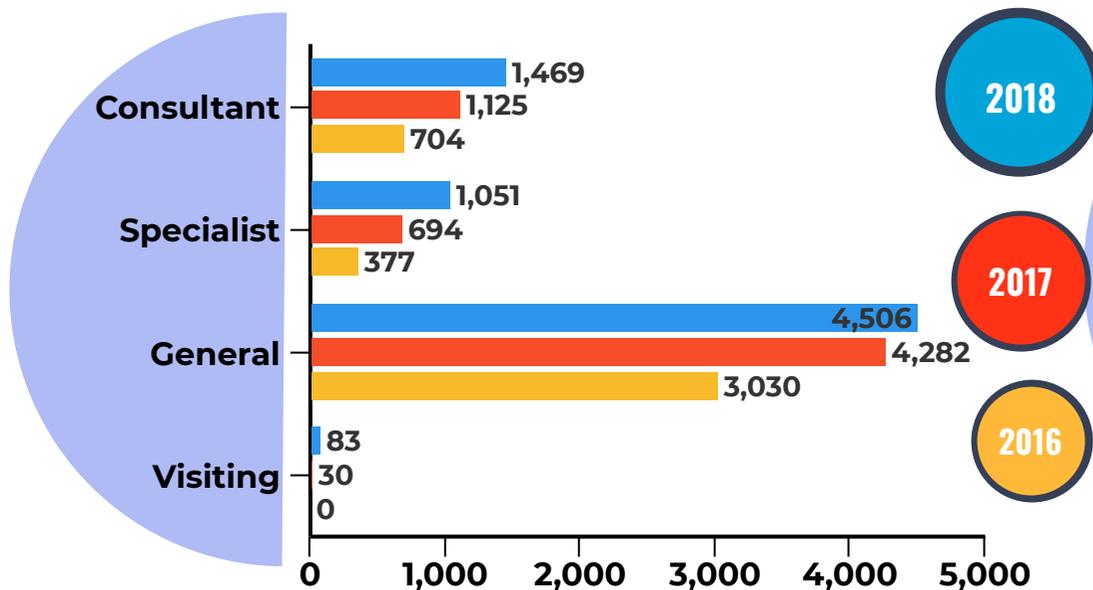
Practical	265
Midwife	335
Specialist	269
General	14108
Clinical Nurse Specialist	1



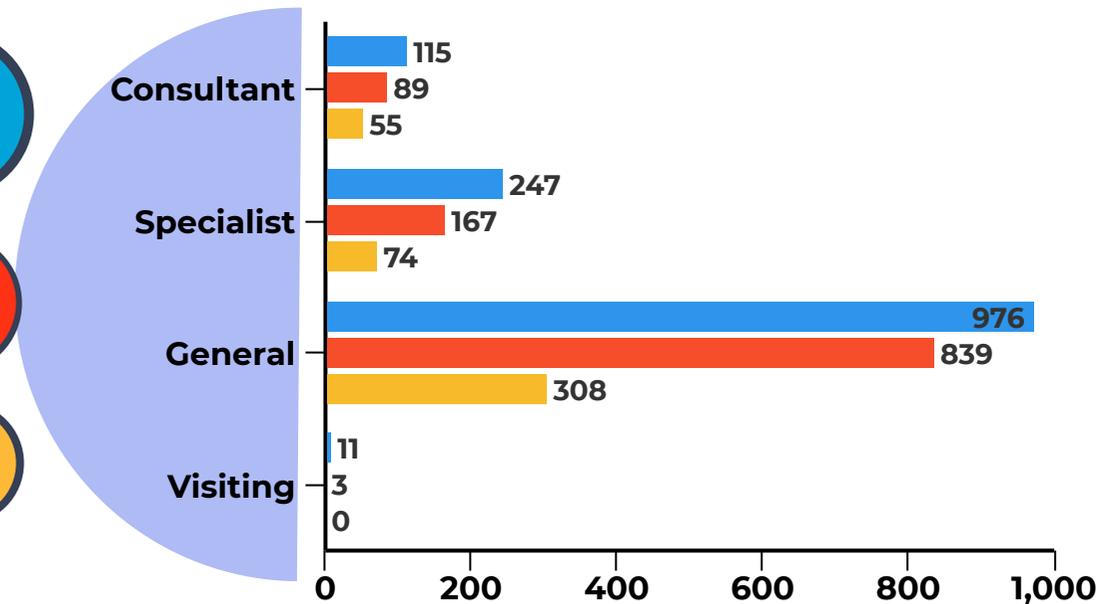
Nurses

Distribution of Professionals in the Kingdom of Bahrain

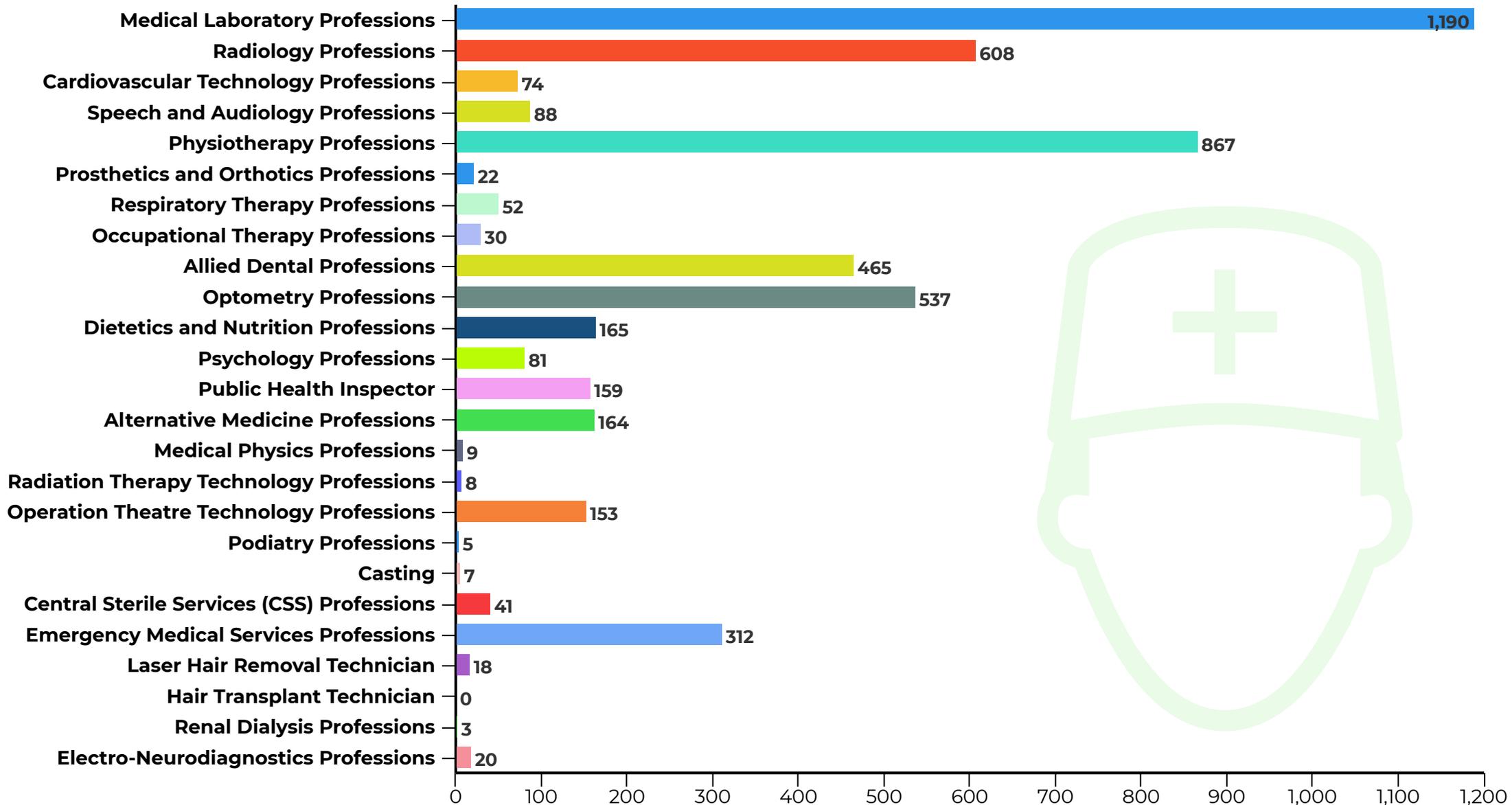
Distribution of Medical Professionals



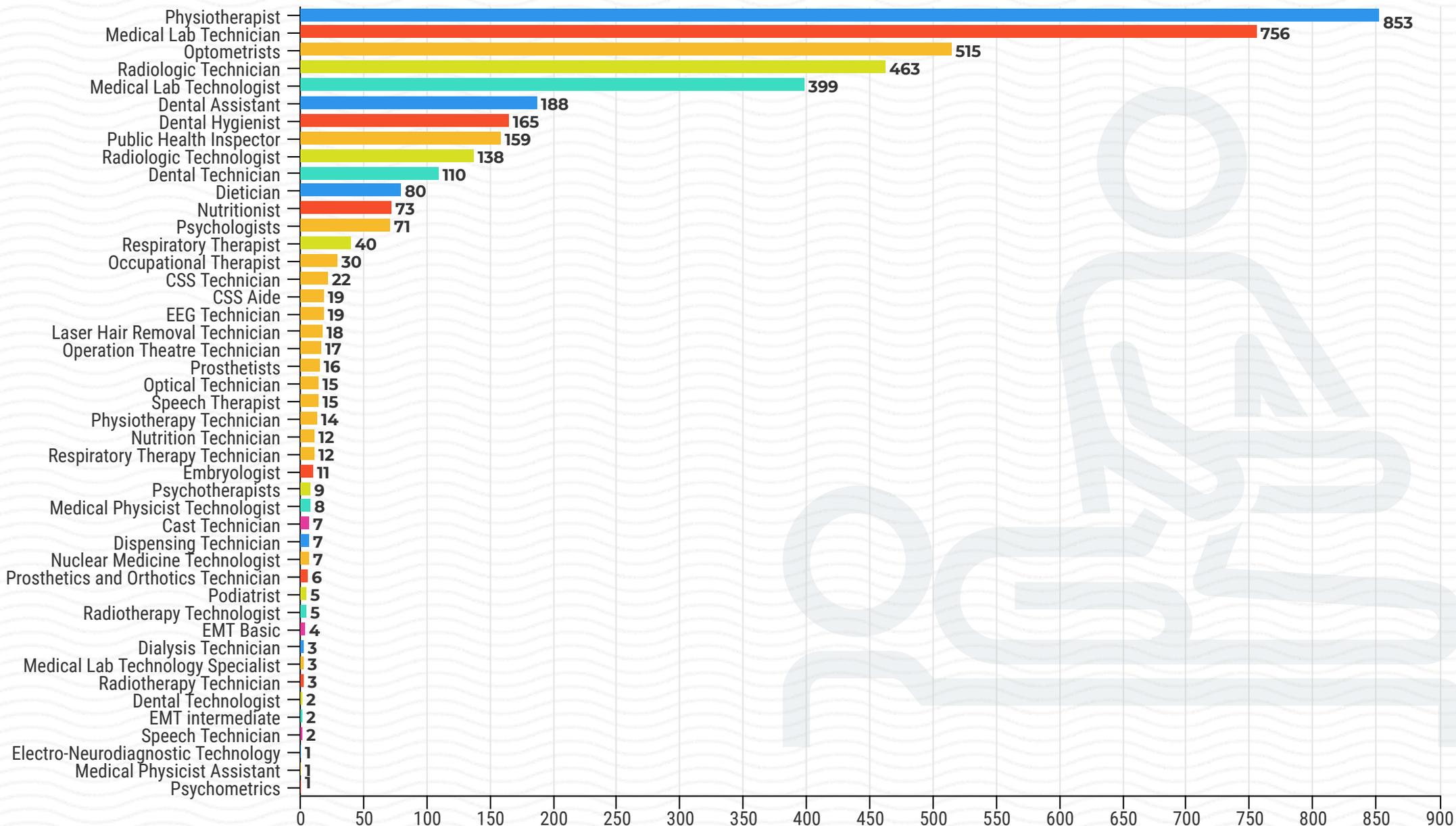
Distribution of Dental Professionals



Types of Allied Health Professionals Licensed in the Kingdom

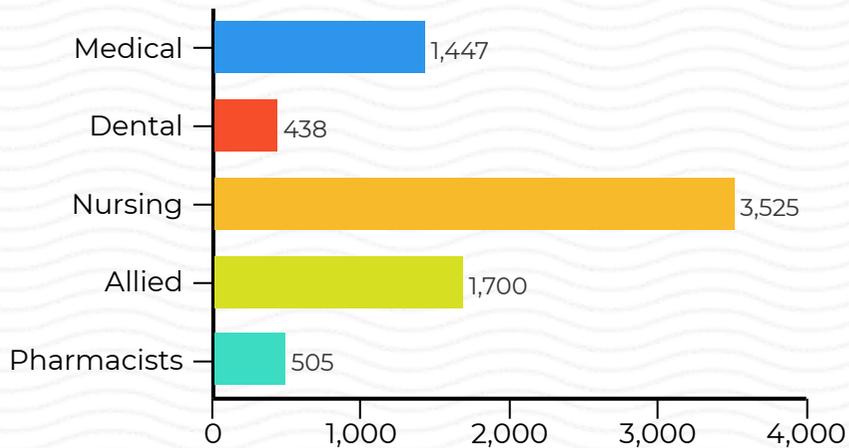


Distribution of NHRA Registered Allied Health Professionals

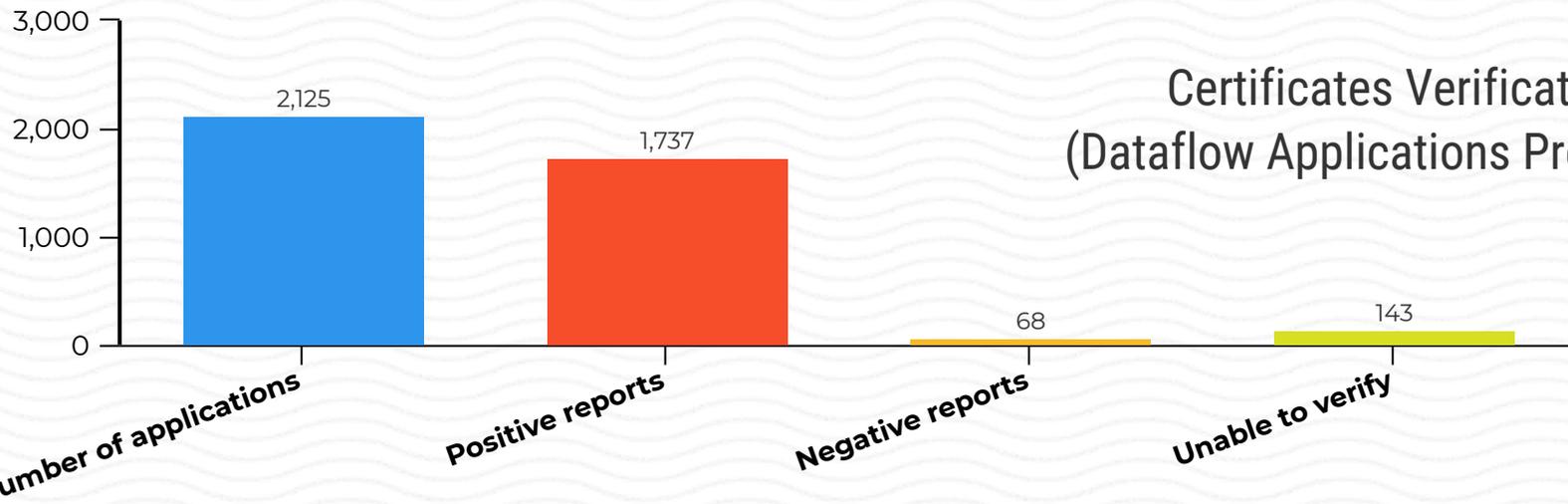
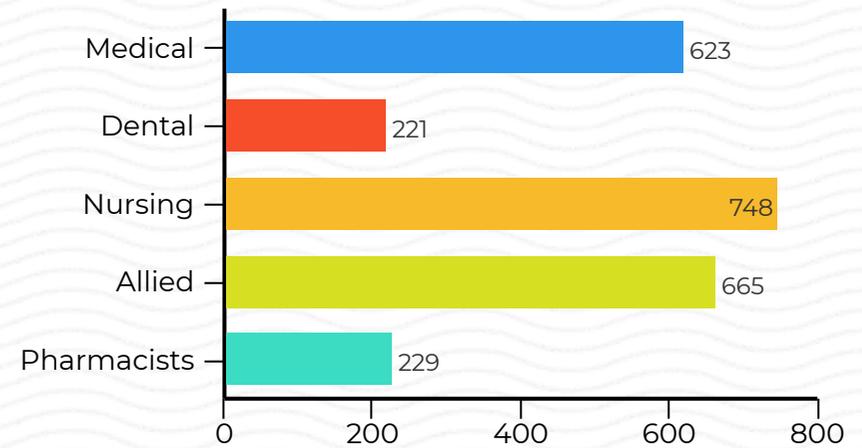


Licensing Activities

License Renewal Applications Processed

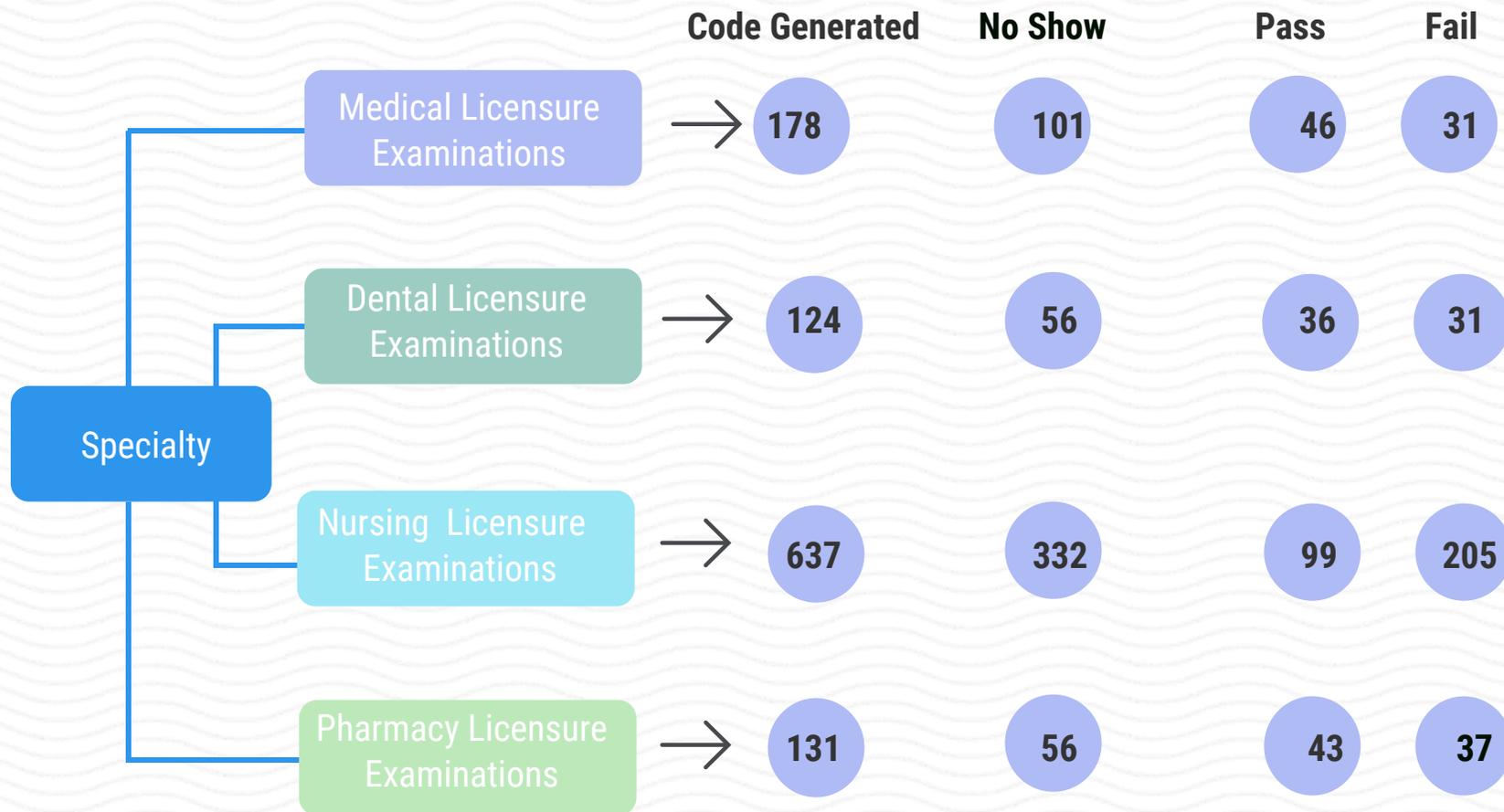


New License Applications Processed



Certificates Verification (Dataflow Applications Processed)

Licensing Exam Results 2018



Professional Regulation Department Achievements 2018

Committees Convened

1. Physicians Regulations Advisory Committee
2. Dental Advisory Committee
3. Disciplinary Committee for Physicians and Dentists



Initiatives

1. Launch of online Prometric Exams..... (May 2018)
2. Revision of Life Support Policy..... (June 2018)
3. Testing of online Licensing and Registration system....(December 2018)



Verifications Health Products
Pharmacy Medicine Centers
Devices Accreditation Licensure
Surveyors CPD License Facilities

Regulating Pharmaceutical Products

CAM Clinics Professionals Hospitals
Physicians Ayurveda Nurses Ethics
Legislation Medical Errors Standards Pharmacies
Regulations Clinical Trials Inspectors
Allied Health Regulating Healthcare Professionals



Pharmaceutical Products Section

Pharmaceutical Product Registration

The major development for department of pharmaceutical regulations in 2018, was the development and operation of the Drug Utilization Review System (DUR). The DUR system will play a key role in the National Health Insurance, allowing the Fund to track all pharmaceutical products imported and utilized in the Kingdom.

A total of 3170 medicines have been registered and a temporary registration has been granted to 3391 pharmaceutical products.

The coming year will see the development of the online Pharmaceutical Products Registration and Management system. This system together with the DUR system will allow online real time access that will help to facilitate the registry and customs release of pharmaceutical products

Pharmaceutical Products Department Activities

Registered Medication.....	3,170
Medicine Variations Approved(Assessed).....	1023
Medicines National Pricing (Assessed).....	131
New Registration.....	14
Hospital Pack Registration.....	8
License Renewal.....	359
Personal Parcels.....	1051
Pre-Approval Applications Processed.....	4389
Manual Invoices (approximately) Processed.....	12100
DUR Invoices (13 Oct - 31 Dec 2018).....	1920
Temporary Importation of Non Registered Products.....	3391
Pharmaceutical Products Classification.....	419
International Manufacturing Sites Registration	63

Alternative/Complementary Medicines

Total Number of Alternative Medicines Approved.....	45
New Alternative Medicines Applications Processed.....	48

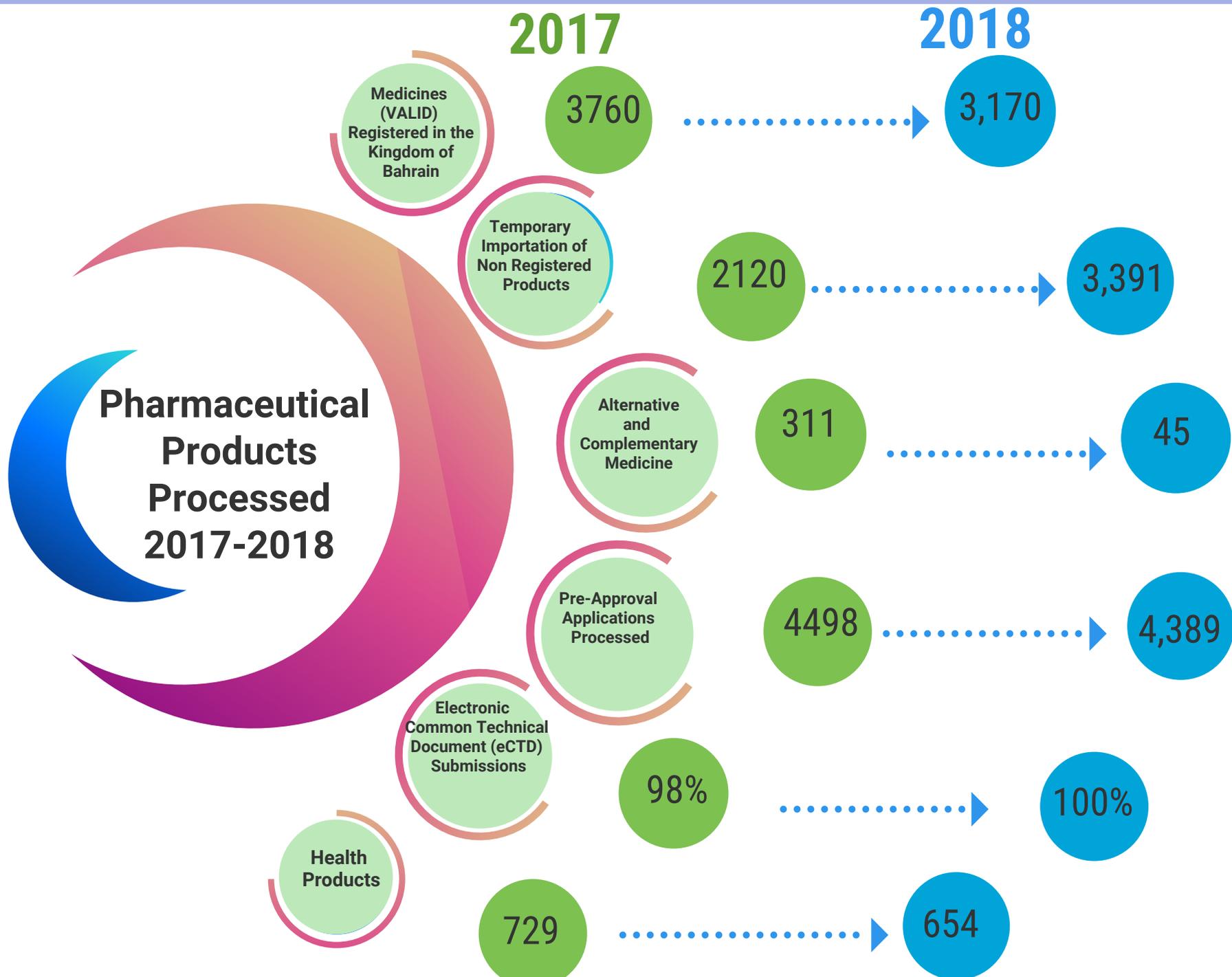
Health Products

New Registration	30
License Renewal	20

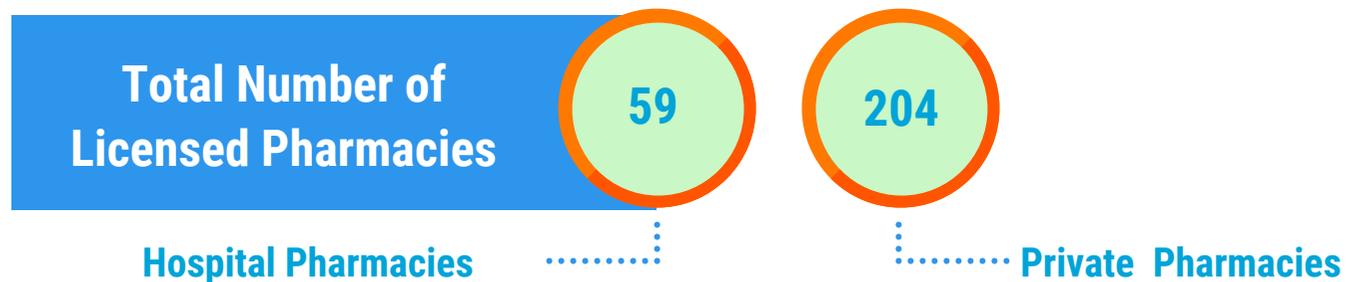
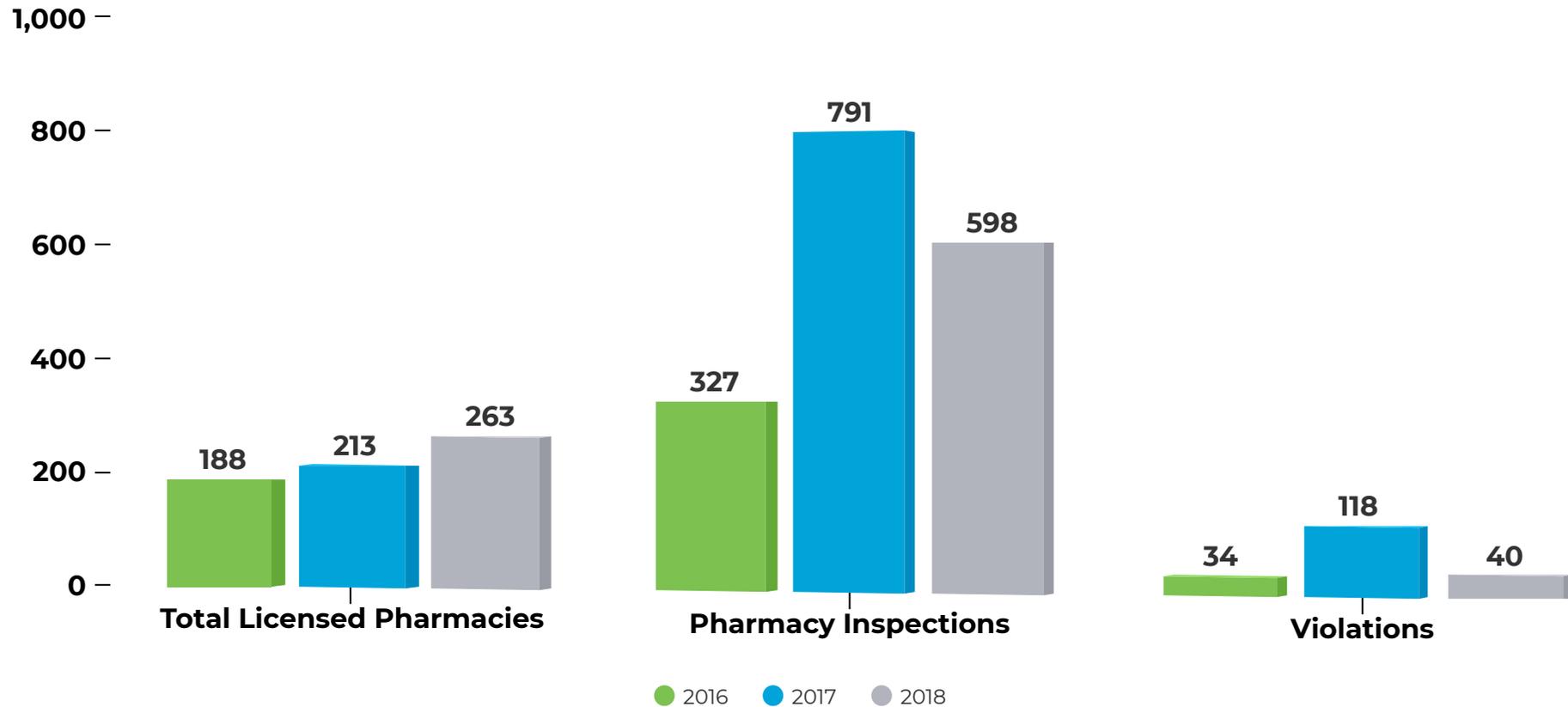
Total Number of Health Products
(VALID) Registered in the Kingdom of
Bahrain **654**

Electronic Common Technical Document (eCTD)

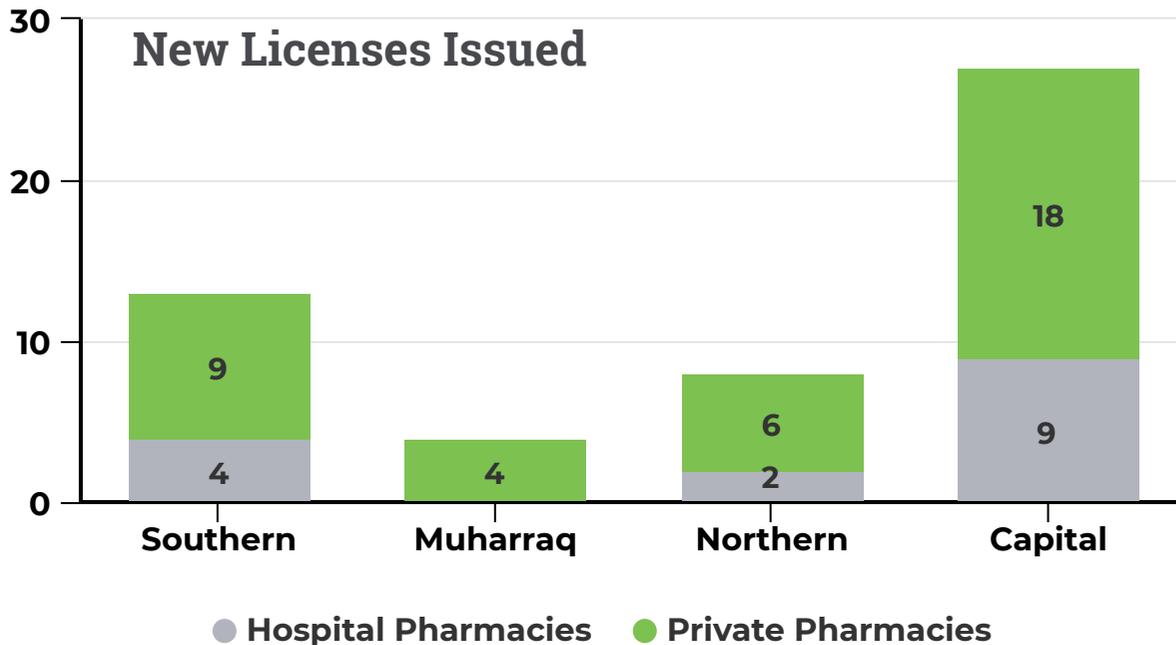
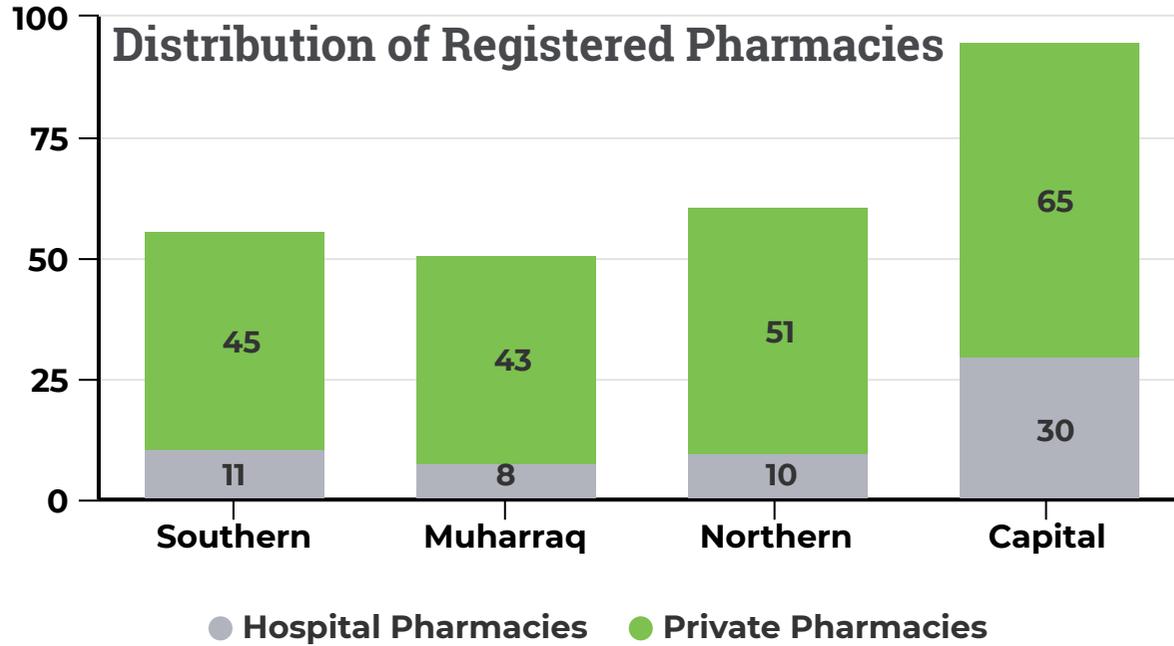
Baseline Importation Status of Applications.....**1312**



Pharmacy Regulation Activities



Pharmacy Licensing



Approvals Issued to Facilities for:

Preparation Rooms

2

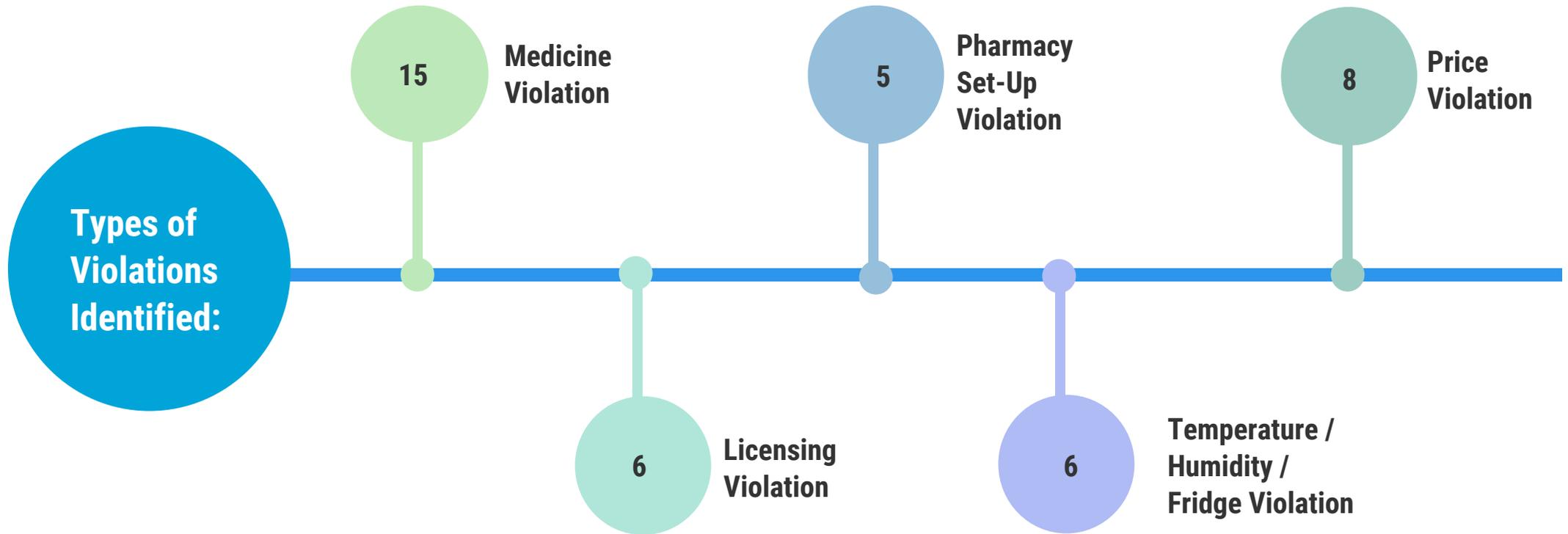
Change in Activities from Import to Retail Pharmacy

2

Inspection Activities

Total Number of Pharmacy Inspections

598



List of PPR's Guidelines, Procedures & Policies

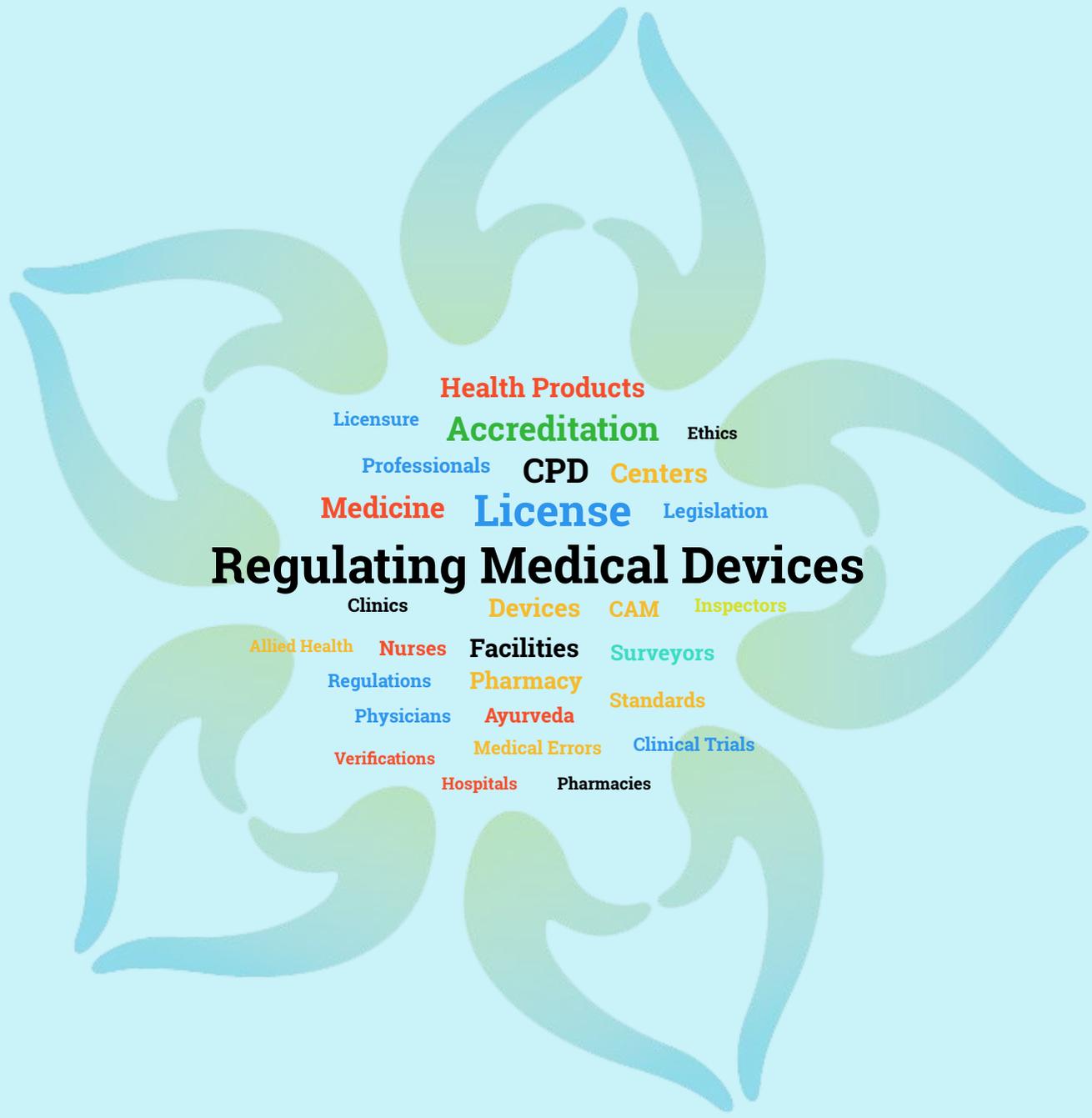
External Stakeholders Guidelines & Procedures

Guideline/Procedure Name	Version/Number	Approval Date
Pharmaceutical Products Classification Guideline.	Version 2.0	Jan - 2018
Raw Material and Manufacturer Approval Procedure	Version 1.0	May - 2018
Pharmaceutical Preparation at Healthcare Facilities Procedure	Version 1.0	Jul - 2018
Medicine Barcoding and Sterilization Guideline	Version 1.0	Aug - 2018
Invoice Clearance Procedure (Drug Utilization Review) DUR	Version 1.0	Dec - 2018

PPR Internal Policies, Procedures & SOPs

Policy/SOP Name	Version/Number	Approval Date
Laboratory Analysis Policy & Procedure.	PPR_P_002_18	Dec - 2018
Receiving of Application Policy & Procedure	PPR_P_004_18	Dec - 2018

Committees Convened : Pharmaceutical Products Licensing Committee
Disciplinary Committee - Pharmacist



Regulating Medical Devices

Health Products
Licensure Accreditation Ethics
Professionals CPD Centers
Medicine License Legislation
Clinics Devices CAM Inspectors
Allied Health Nurses Facilities Surveyors
Regulations Pharmacy Standards
Physicians Ayurveda
Verifications Medical Errors Clinical Trials
Hospitals Pharmacies



Medical Devices Team

Medical Devices

The medical device team has processed over 9 thousand requests for medical device clearances – totaling in value of 27,573,000 Bahraini dinars.

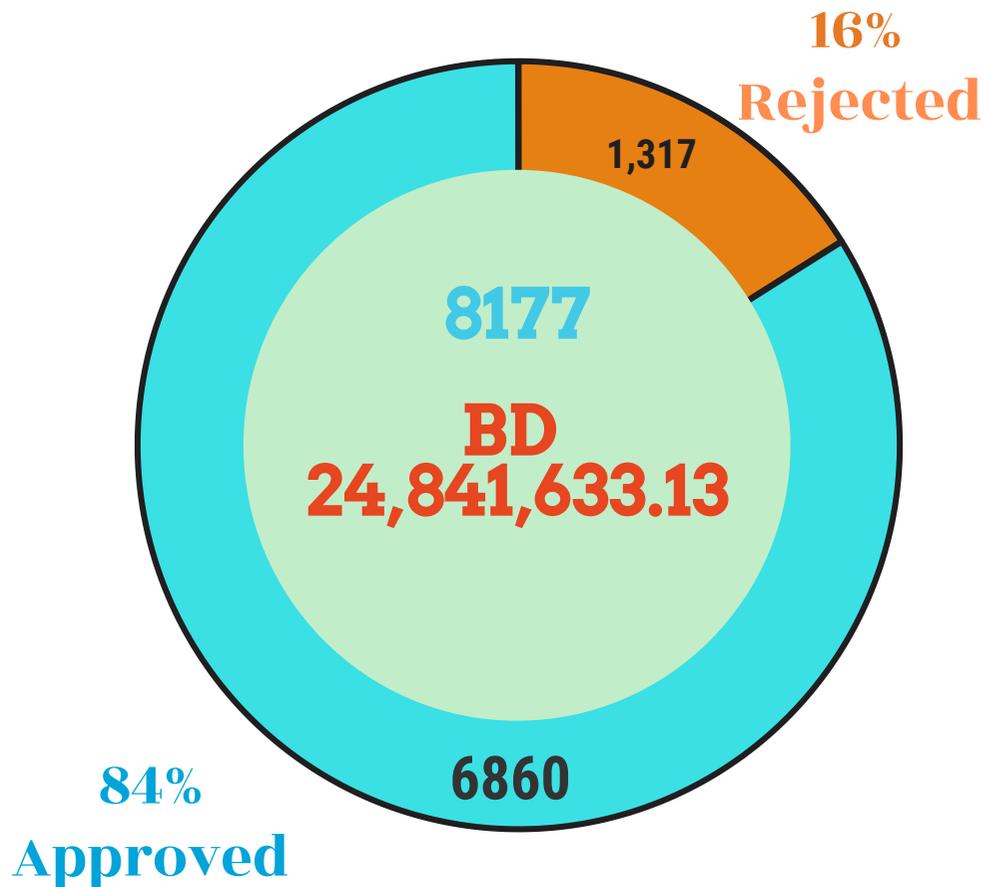
The department is committed to registering all medical devices used in the Kingdom in accordance to the law so as to facilitate the importation and tracking process. This registration process will play an integral role in the upcoming national insurance data base of medical devices for the Kingdom.

In the last quarter of 2018, the existing process of registering medical devices was updated and a total of 346 devices were registered. From the inspection standpoint 125 violations were identified in imported medical devices, one falsified medical device was withdrawn from the market and 20 recalls were made accordingly based on the information received from the manufacturers.

Medical Device Regulation

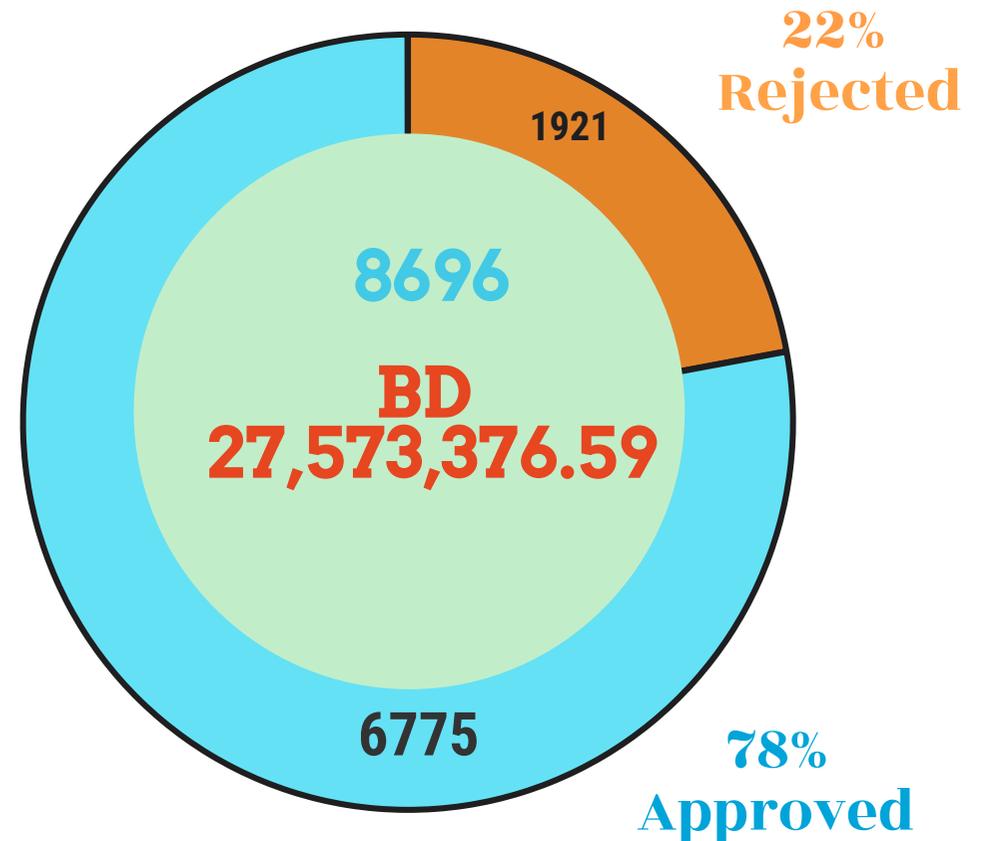
2017

Total Medical Device Applications

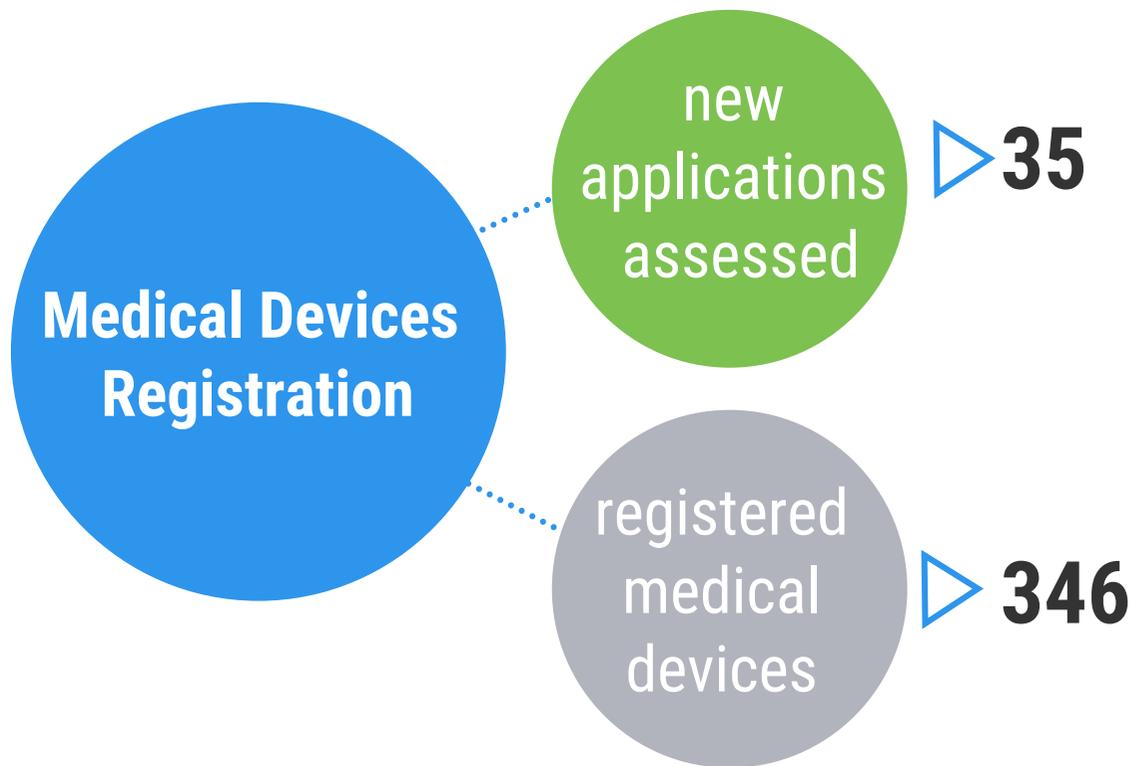


2018

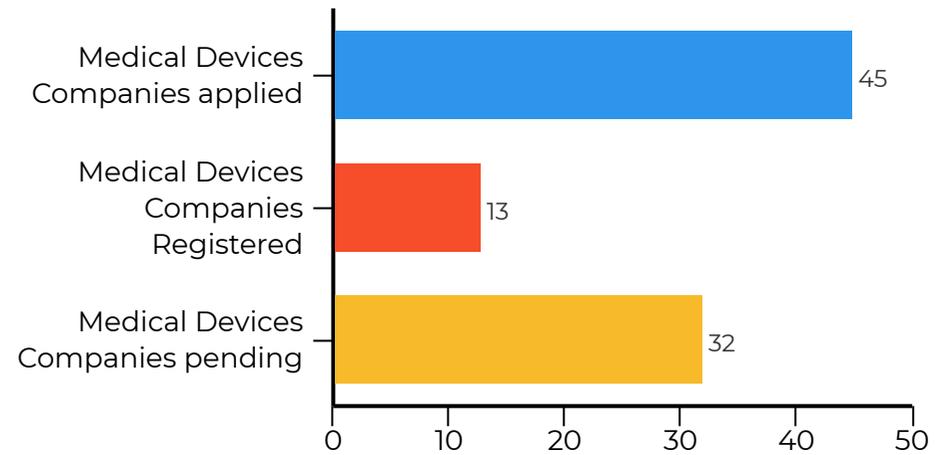
Total Medical Device Applications



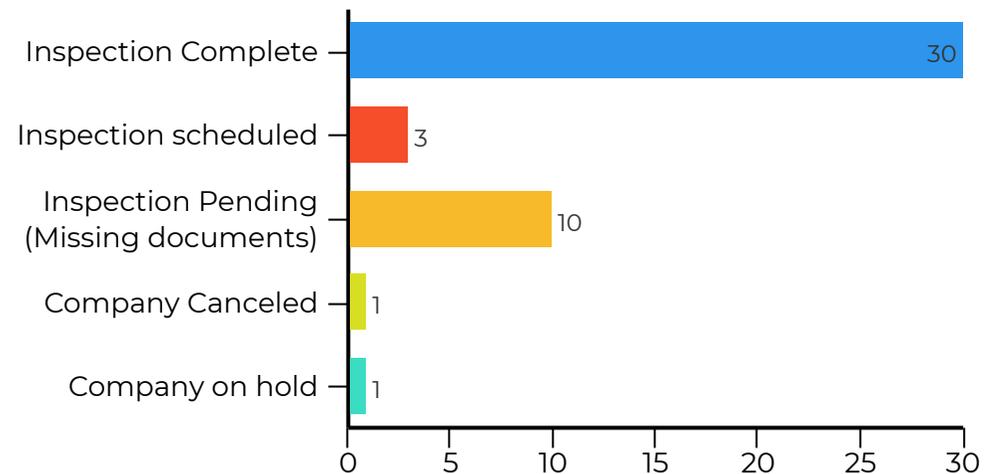
Medical Device Authorized Representative Registration



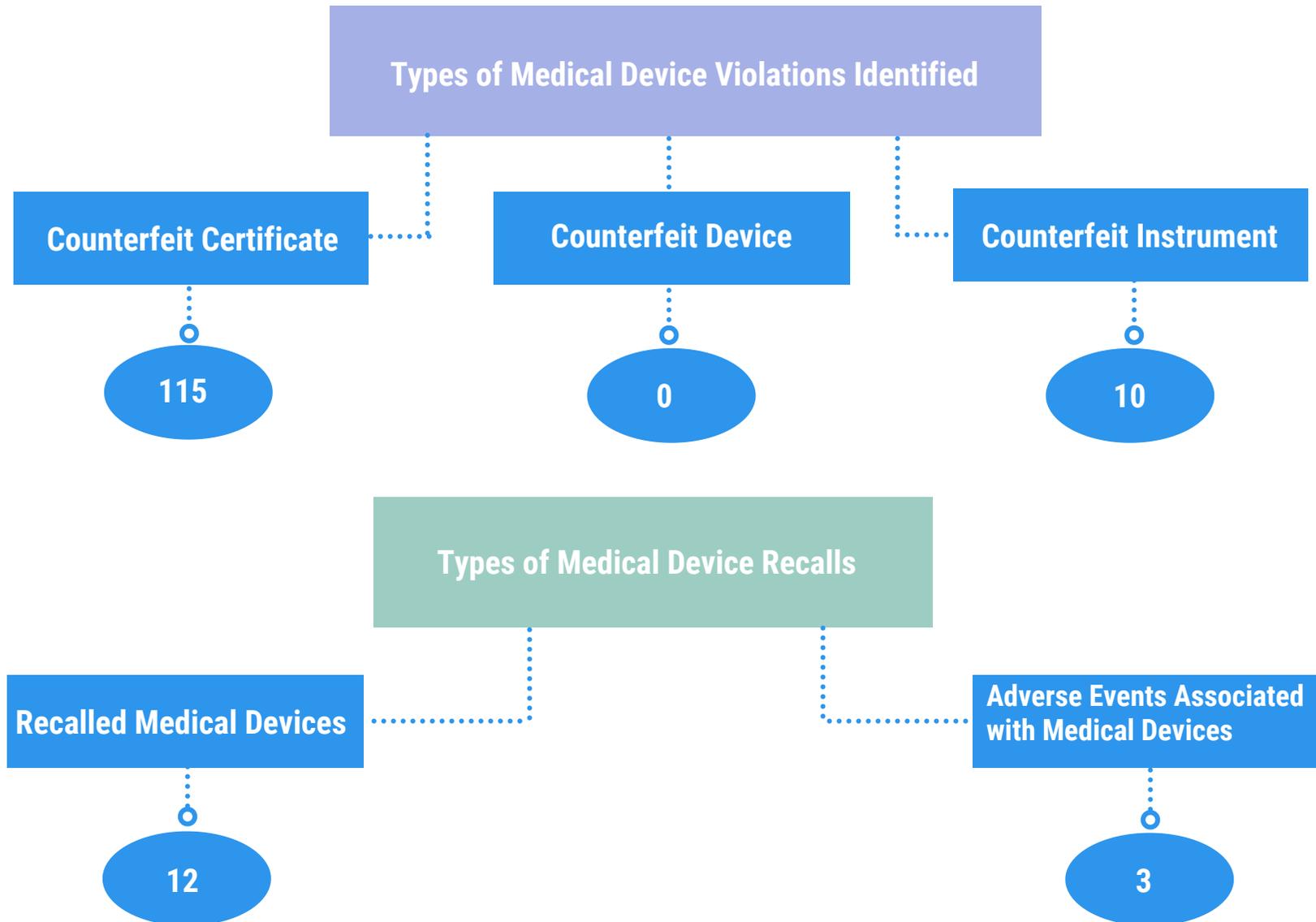
Company Registration



Company Registration Process Activities



Medical Devices Violations and Recalls



Medical Device Regulation Achievements

2018 Initiatives

Date

Incident Reporting System.....	13-06-2018
Recall & FSN Guideline.....	14-11-2018
Quality Assurance Certificates.....	14-11-2018
Medical Device Regulation Guideline.....	14-11-2018
Medical Device Company Registration Guideline.....	14-11-2018
Importation of Biological Tissues Guideline.....	14-11-2018
Combined Medical Device Importation Guideline.....	14-11-2018
Classification Guideline.....	14-11-2018
Personnel Medical Device Importation Guideline.....	12-12-2018
Medical Device Approval for Use Guideline.....	24-12-2018



Clinical Trials

CPD

Accreditation

Medicine

CME

CAM

Ethics

Facilities

Pharmacy

Devices

Regulations

Nurses

Clinics

Verifications

Licensure

Allied Health

Standards

Centers

Surveyors

Health Products

Ayurveda

Hospitals

Legislation

Inspection

Physicians

Professionals

Inspectors

Medical Errors

Pharmacies

Pharmacists

Pharmaceuticals

Pharmaceuticals



Clinical Trials and CPD Committee

Clinical Trials and Continuing Professional Development Regulations

The Clinical Trials and Continuing Professional Development Regulations Unit (CT & CPD) has approved 19,224 continuous medical education programs. The CPD committee ensured that all the conducted programs are in line with NHRA requirements and that both the speaker and the organizer are qualified to hold such activities.

For 2019 the CPD Committee has developed the second edition of CPD regulations, to ensure amongst other things, that professionals will engage in CPD activities relevant to their practice.

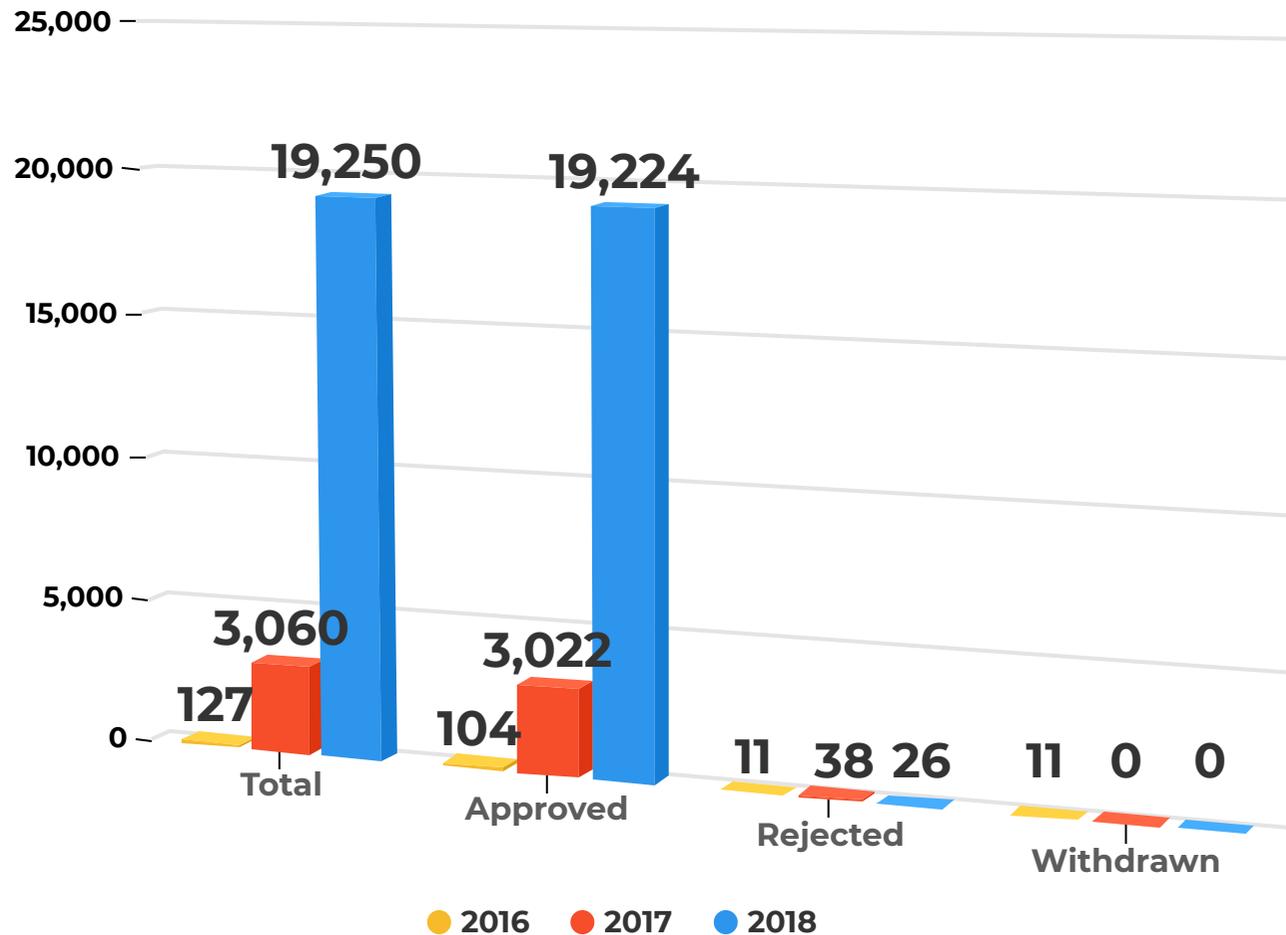
The department was also involved in the Joint Health Care Professional Training Programs Committee that permits the license of Health Care Training Centers. The committee was in collaboration with the Ministry of Labor & Social Development, Ministry of Health, Ministry of Education and Quality Assurance Authority for Education & Training.

In the Clinical Trials front, 4 clinical trials were reviewed by Clinical Trial Committee (CTC), one trial has been completed, one trial is ongoing from 2017 and two were rejected.

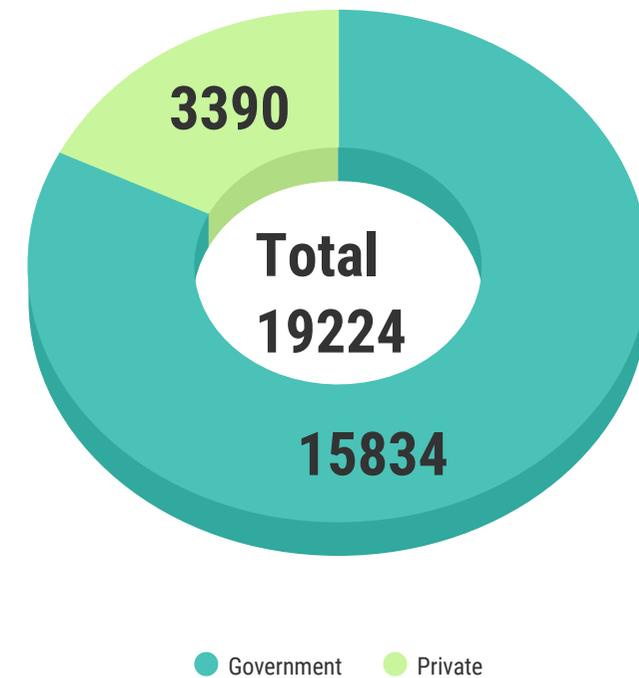
In 2018 the regulations for the use of stem cells in clinical trials was established in collaboration with the Supreme Council of Health so as to ensure the safety of individuals participating in such trails and enabling a roadmap for potential researchers in this field. The NHRA in collaboration with the Arabian Gulf University held the 1st Stem Cells Regulation Conference in the Kingdom in December 2018 and the department participated in multiple forums, working group meetings and conferences around the GCC.

Continuous Professional Development (CPD) Unit Activities

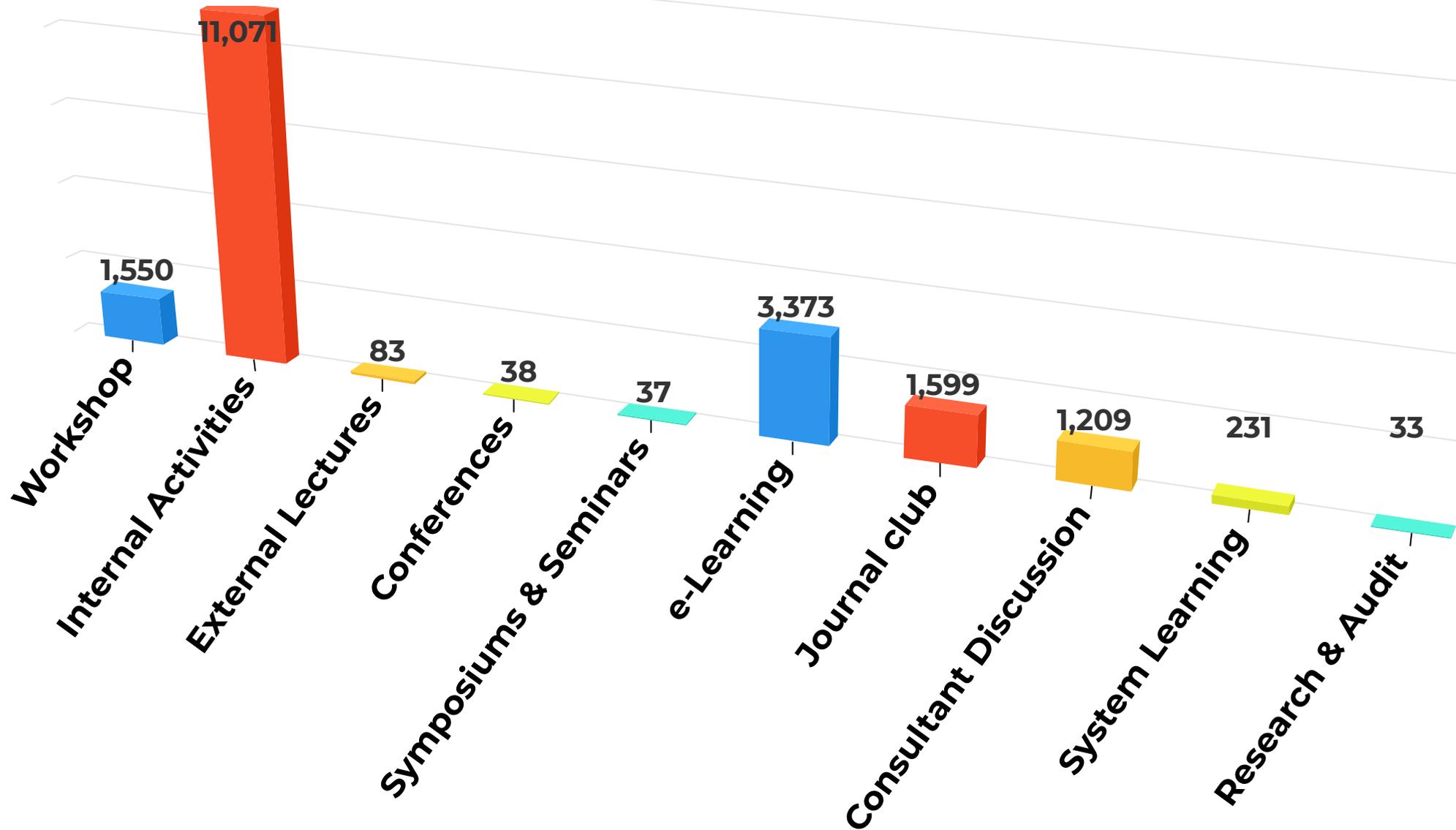
Total CPD Activities



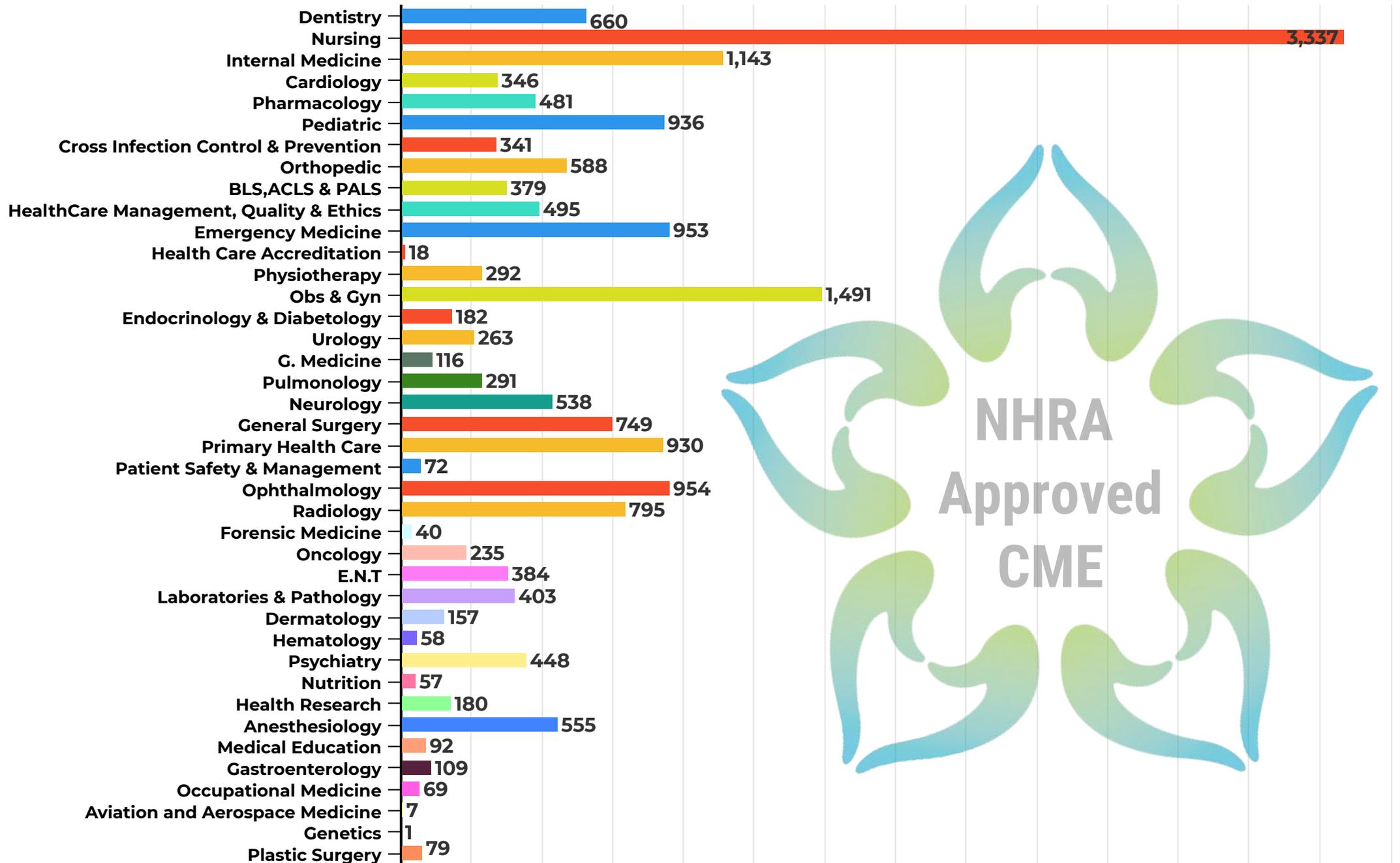
Public / Private Sector Distribution of CPD Activities



Types of CPD Activities Approved



Distribution of Approved CPD Activities by Specialty



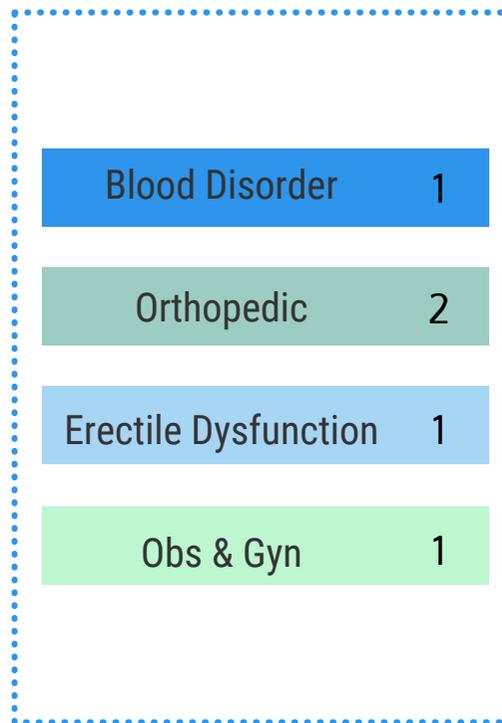
Clinical Trials Regulation

Outcomes of Clinical Trial Applications Submitted to NHRA

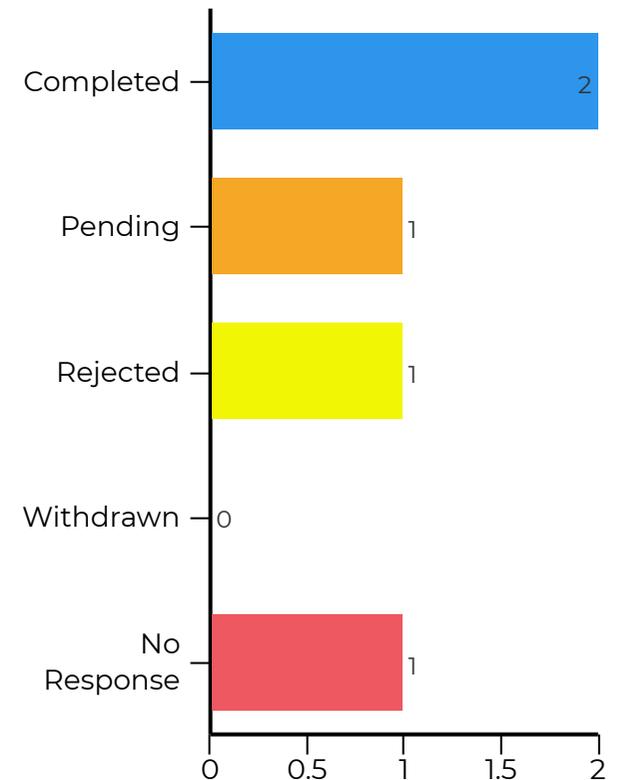
Clinical Trials
Submitted Private
Sector

5

Distribution of Clinical Trials Applications by Specialty



Outcomes of Clinical Trials Applications



Department Achievements

Accomplishments-2018

CPD	Joint Committee (NHRA-MoL&SD) for Health Care Professional Training Program	Jan -18
CPD	Update CPD Application Approval Form	Jan -18
CT	Stem Cells Regulations Conference	May -18
CT	Visit of Expert General Director of stem cells at the University of Jordan- Hashemite Kingdom of Jordan in Stem Cells to NHRA	Sep -18
CPD	UAE-Regulations Conference / Medical Education Attendance	Oct -18
CPD	2nd Edition CPD Regulations Charter	Dec -18
CPD	Continuing Professional Development Application-Online Activities	Dec -18
CPD	Continuing Professional Development Application-External Activity	Dec -18
CPD	Continuing Professional Development Application-Internal Activities	Dec -18
CT	New Clinical Trial Application -Phase II&III	Dec -18
CT	New Clinical Trial Application -Phase IV	Dec -18
CT	Substantial/Minor Amendments Application for an Approved Clinical Trial	Dec -18
CT	Conflict of Interest in Clinical Trial Committee-NHRA	Dec -18
CT	Clinical Trails by Using Stem Cells Regulations & Standers	Dec -18
CT	2nd GCC Clinical Trial Conference Participation	Dec -18

07 CT Meeting	Jan-Dec 2018
25 CPD Committee Meetings	Jan-Dec 2018
11 Monitoring CPD visits	Jan-Dec 2018

The committees convened:

1. Continues Professional Development Committee
2. Clinical Trial Committee
3. Stem Cells Regulation Working Group
4. NHRA- Ethical Committee for Private Hospital
5. Technical Committee for Investigating Professional & Ethical errors for Medical Practitioners.
6. GCC Clinical Trials Committee



Hospitals Regulations
Standards Legislation Allied Health
Physicians **Health Products** Ethics
Facilities **Medicine** Nurses
Verifications
Accreditation
Surveyors License Devices Clinics
Licensure
Pharmacies CAM Centers CPD Clinical Trials
Inspectors Pharmacy Ayurveda
Professionals Medical Errors



Accreditation Team

Accreditation

The National Accreditation Program for health facilities comes within the framework of the Kingdom's keenness to strengthen the system of supervision of health facilities in accordance with the highest international quality standards.

Over the past two years, the NHRA accreditation team has accredited 16 hospitals and 6 medical centers in the Kingdom of Bahrain. A fundamental component of the accreditation processes were the recommendations provided to health facilities by the expert surveyors. The total number of recommendations submitted to all hospitals was 1,238 recommendations for all accredited standards, and the recommendations related to the core standards amounted to 822. The survey process and analysis of the results (of elements that were consistently Not Met or Partially met) highlighted amongst other things also the specific details of areas that were challenging for facilities to comply with and the areas of high risk that healthcare facilities face in the Kingdom today. The overarching goals of the recommendations were to always keep patient safety as a high priority.

The Authority's efforts in the implementation of the National Accreditation Program culminated in the winning of the Government Best Practices Award at the 2018 Government Forum held under the patronage of His Royal Highness Prince Khalifa bin Salman Al Khalifa, Prime Minister and His Highness Prince Salman bin Hamad Al Khalifa, Crown Prince and Deputy Supreme Commander, First Deputy Prime Minister. This award embodies a level of distinction attained by the department and confers great honor and pride for NHRA as an organization.

Accredited Facilities 2017 - 2018

Hospitals



16



0

Hospital Affiliated Medical Centre



6



6

General Medical Centre

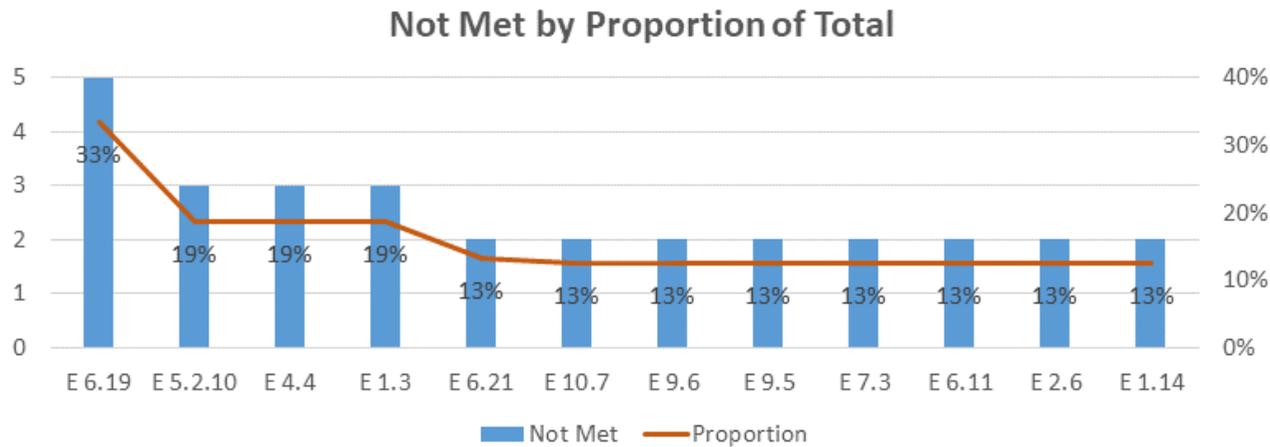


1



10

Accreditation Analysis of Standards - Not Met



Element 6.19, a standard set to ensure that all CSSD staff have adequate knowledge and training is Not Met by 5 of 15 (not a requirement for one hospital) hospitals, this comprise about 33% of all hospitals.



Other elements that need attention which were Not Met by 19% of the hospitals are:

Element 5.2.10 – Review of medical records for compliance



Element 4.4 – Analysis of potential risk processes and implement



Of the 149 elements considered in evaluating the standards of the hospitals, over 50% of the NOT met criteria could be resolved by regulating the standards of the 12 elements shown above.

First 5 elements comprise 28% of the standards



Core Standards Evaluation

OF THE 149 MAIN CORE CRITERIA EVALUATED IN 16 HOSPITALS (A TOTAL OF 2365 ELEMENTS).

FULLY MET CORE STANDARDS

85% OF FULLY MET COMPLIANCE WAS ACHIEVED IN 16 HOSPITALS.



NOT MET STANDARDS

2% OF THOSE ELEMENTS RECEIVED A NOT MET



50% OF THE NOT MET STANDARDS COULD BE RESOLVED BY REGULATING THE ELEMENTS OF THE FOLLOWING STANDARDS:

1. Infection Control
2. Governance & leadership
3. HR
4. Quality Management
5. Medical information & records
6. Facilities management & safety
7. Provision of health care
8. Medical Staff

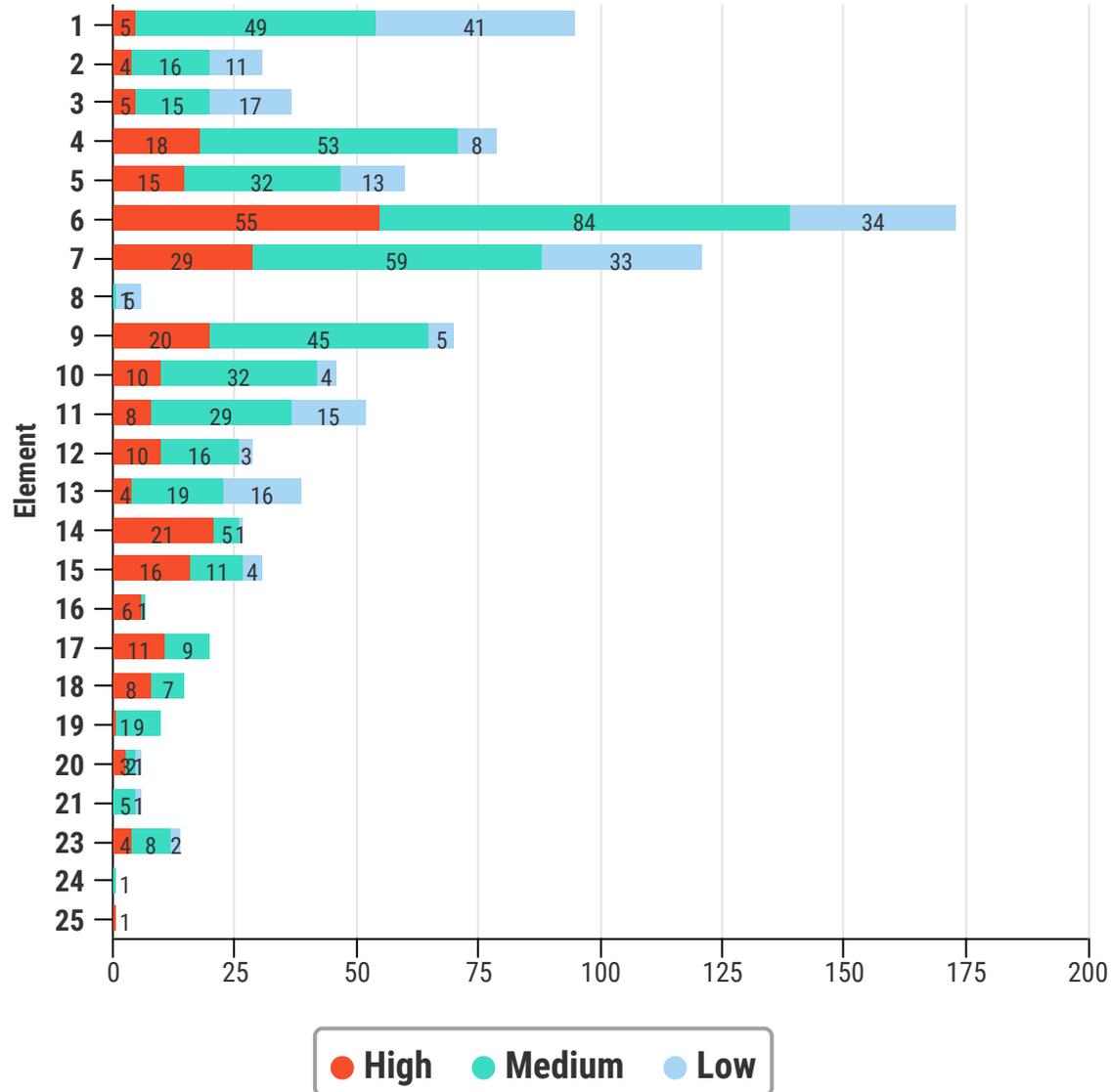


PARTIALLY MET

12% WERE PARTIALLY MET



Distribution of Priorities by Element



Core Standards

Governance, Management and Leadership

Human Resources

Patient and Family Education and Rights

Quality Management & Patient Safety

Management of Information and Medical Records

Infection Prevention and Control (including CSSD)

Facility Management & Safety

Health Promotion and Education

Provision of Care/Patient Journey

Medical Staff

Nursing Staff

High	✓
Medium	✓
Low	✓

Facility Specific Elements

Emergency Room

Operating Room/Theatre and Surgery Provision

Anaesthesia and Sedation

Intensive Care Unit

Labor and Delivery

Out Patients

Clinical Support Services:

Fertility

Dental

Optometry

Haemodialysis

Burns care

Psychiatry

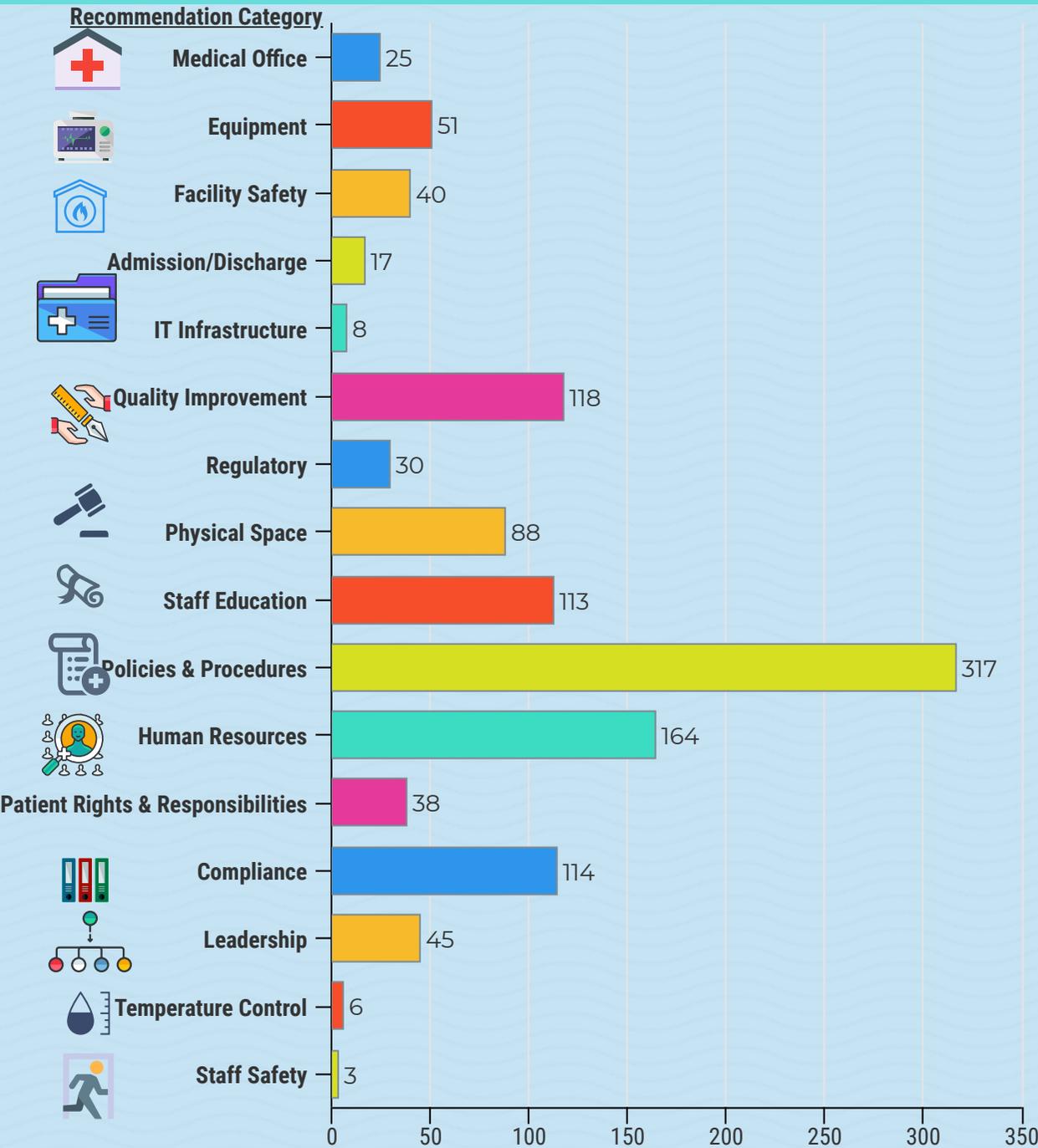
Support Standards

Radiology Services

Laboratory Services

Pharmacy

Distribution of Recommendation Categories



More than
50%

Of the accredited hospitals were given a recommendation to ensure a formal and periodic assessment of the performance of the Board of Directors and Executive Management.

More than
50%

Of the accredited hospitals were recommended to implement an effective evaluation of health professionals' performance, that include recommendations on their performance and their training needs.

31%

Of hospitals were recommended to ensure that the facility has an enforceable and evidence-based mechanism that all laboratory results are signed by the physician prior to their placement in patient records

More than
50%

Of the accredited hospitals have been recommended to raise awareness among staff about the management of medical waste and the management of textiles related to infection control

More than
80%

Of the accredited hospitals were required to ensure evidence-based clinical practice guidelines, which are reviewed at least every two years or when needed, and that professionals follow those guidelines

Areas of Deficiencies - Achieving best practices and standardized care delivery

Elements that were **Consistently Not Met** or **Partially Met** highlighted the specific details of areas that were challenging for facilities to comply with:

1. Creation and implementation of clinical practice guidelines.

2. Detailed policies and procedures on waste management that includes the implementation of safe waste collection, storage and disposal, using the required resources in a way that protect patients, staff and the environment.

3. Evidence of approved strategic and management plans and periodic evaluation of the governing body effectiveness.

4. Transfer agreements with a predetermined hospitals (Tertiary Care hospitals).

5. Annual performance evaluation for medical staff.

6. Complying with the NHRA minimum design standards and the Kingdom of Bahrain laws & regulations for the building.

7. Deficiencies in risk management.

8. Medical Record audits

9. Medication Management

10. Appropriate staff in the Emergency rooms

11. Deficiencies in the services provided in the intensive care units.



RECOMMENDATIONS GIVEN TO REDUCE RISKS IN PROVIDING CARE

NHRA prioritized risk mitigation areas:

More than a third of the facilities were given a recommendation to enhance their systems for reporting incidents and near misses and have a policy for handling incidents, near misses and sentinel events which required further investigation.



More than a third of the facilities were given a recommendation to implement a formalized risk management program whereby the leaders use a planned approach to identify, analyse potential risk processes and implement interventions to eliminate or minimize risk.



More than 50% of the facilities had been recommended to ensure that the physical structure/building and its services comply with the NHRA rules and guidance on minimum design standards, and adhere to the Kingdom of Bahrain laws & regulations which also include the implementation and monitoring of fire drills and emergency response systems.



More than 40% of the facilities had been recommended to ensure the availability and monitoring of the process that identifies patients in need for emergent or urgent care and that this care is provided in a timely way.



Improving staffing and licensing procedures:

- 88% in recruiting an appropriate head of ED
- 42% in recruiting an appropriate head of ICU
- 33% in recruiting appropriate staff for the CSSD
- 18% in recruiting an appropriate head of Dental



More than 50% of the facilities were given the recommendation to implement and monitor infection control policies and waste management.



NEXT STEPS TO STRENGTHEN THE ACCREDITATION PROGRAM IN THE KINGDOM



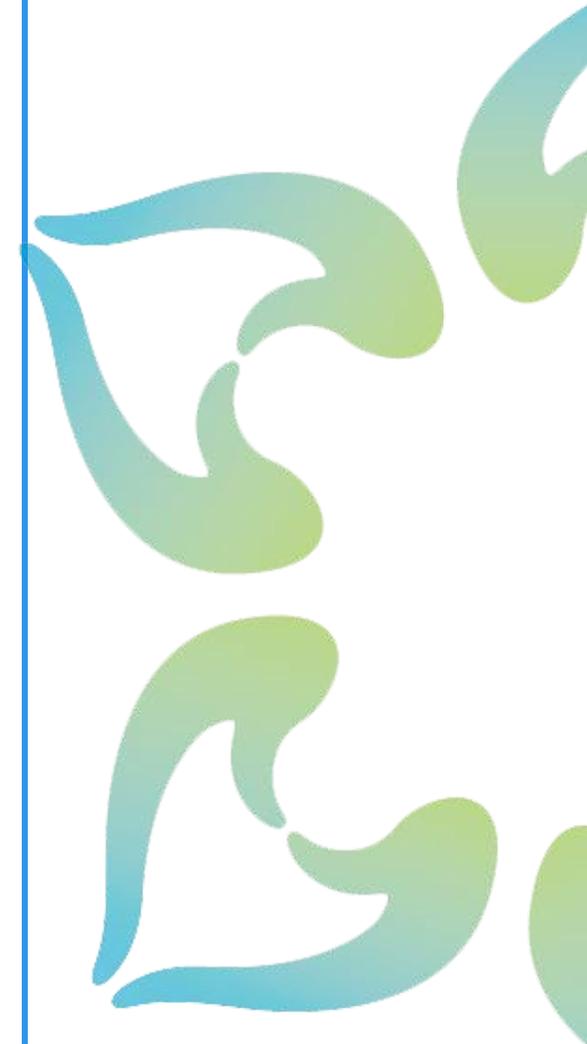
Strengthen cooperation between secondary and tertiary care hospitals in the Kingdom of Bahrain through a formal agreement for the transfer of patients with difficult or critical conditions between hospitals to ensure that there are clear and continuous channels of communication in the provision of appropriate care.



Encouraging and attracting professional from specialized fields such as an emergency medical consultant or specialized sterilization staff through speeding up the procedures for licensing the profession of the high need



Identify future training areas for hospitals and conduct workshops with subject matter experts in the deficient areas





Medical Errors Professionals
Physicians Pharmacy Pharmacies
Surveyors Devices Nurses
CAM Accreditation
Licensure **Complaints** Hospitals Clinics
Medicine CPD Centers Ethics
Regulations **Health Products** Standards
Clinical Trials Facilities Legislation
Allied Health Ayurveda Inspectors
Verifications



Medical Complaints Unit

Medical Complaints

The authority's processes for complaints against medical professionals and healthcare facilities are designed to safeguard members of the public, and focus on investigating complaints in an impartial and fair manner.

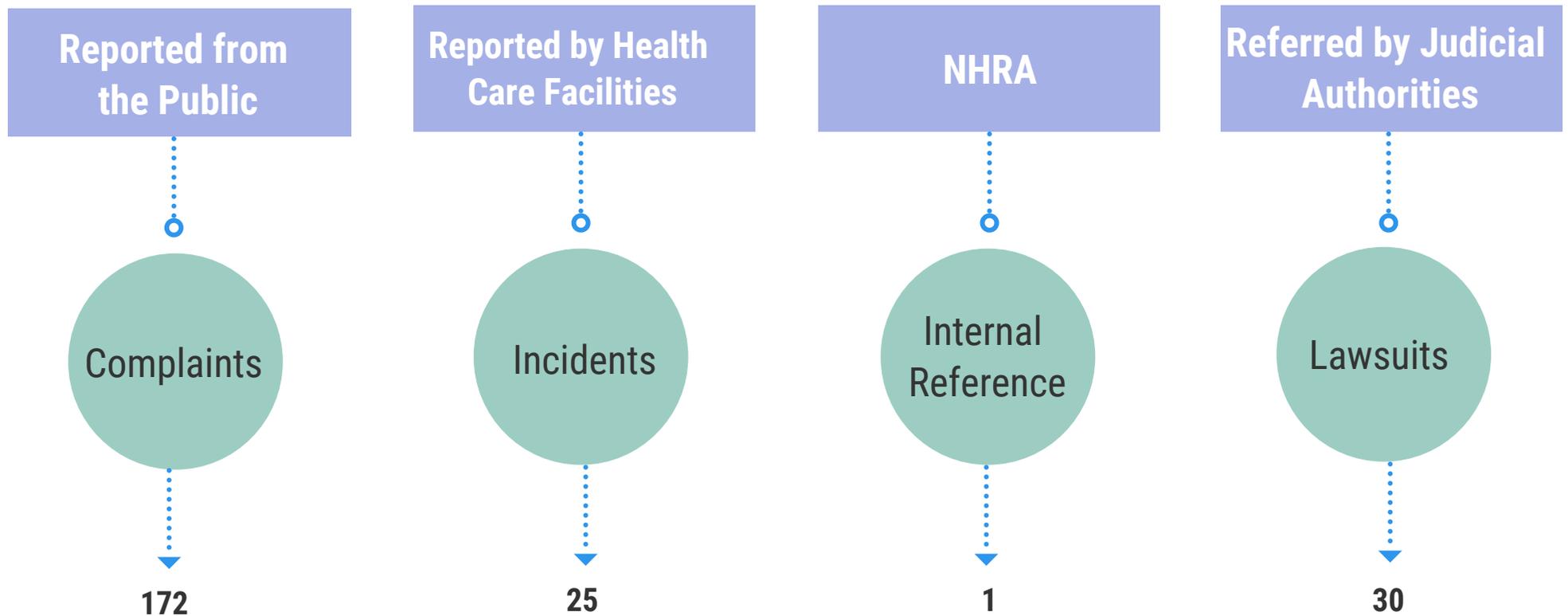
The Complaints Unit received 172 complaints and 30 lawsuits, and the investigation has been completed in 107 complaints and lawsuits.

Updates have been made to the incident reporting policy and a new guide has been published for professionals undergoing the process of investigation for allegations of medical/ethical errors and disciplinary trials. This guide was developed to help professionals understand the investigation and disciplinary trials procedures and inform them of their rights and duties.

Plans for the next year include the development of an electronic reporting system that will help both patients and facilities to report complaints and incidents online.

Breakdown of Cases Received

Total Number of Cases Received by NHRA 228



Distribution of Complaints, Incidents & Lawsuits by Health Sector

Complaints

Public	61
Private	109
Both	1
Others (Not Applicable)	1

Internal Referral

Public	0
Private	1
Both	0
Others	0

Incidents

Public	19
Private	6
Both	0
Others	0

Lawsuits

Public	6
Private	24
Both	0
Others	0

Distribution of Complaints, Incidents & Lawsuits According to Health Profession

Complaints

Doctors	116
Nursing	4
Pharmacists / Pharmacies	9
Allied	1
Others	4
Health Facilities	38
Not Within NHRA Jurisdiction	2

Incidents

Doctors	22
Nursing	3
Pharmacists / Pharmacies	0
Allied	0
Others	0
Health Facilities	0
Not Within NHRA Jurisdiction	0

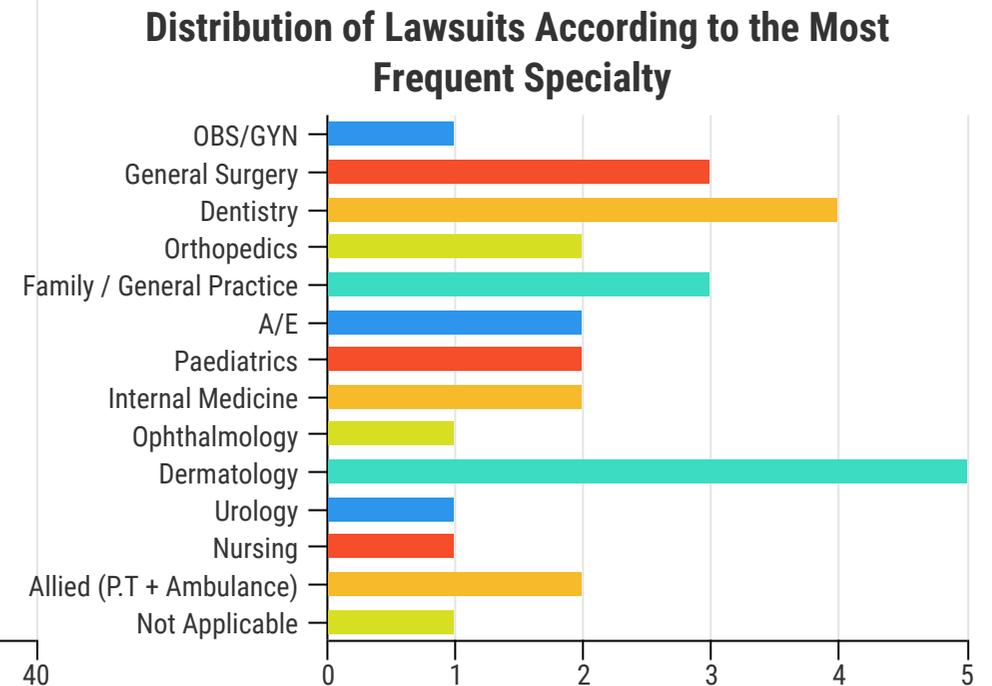
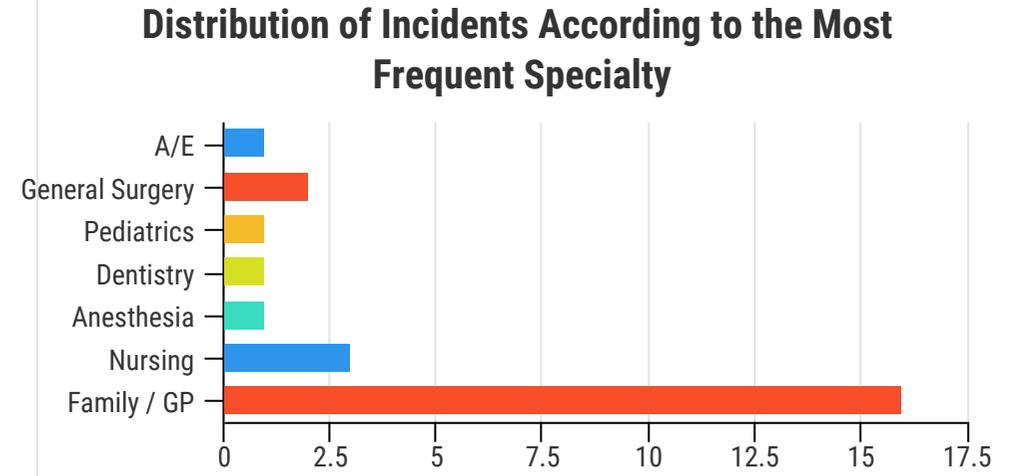
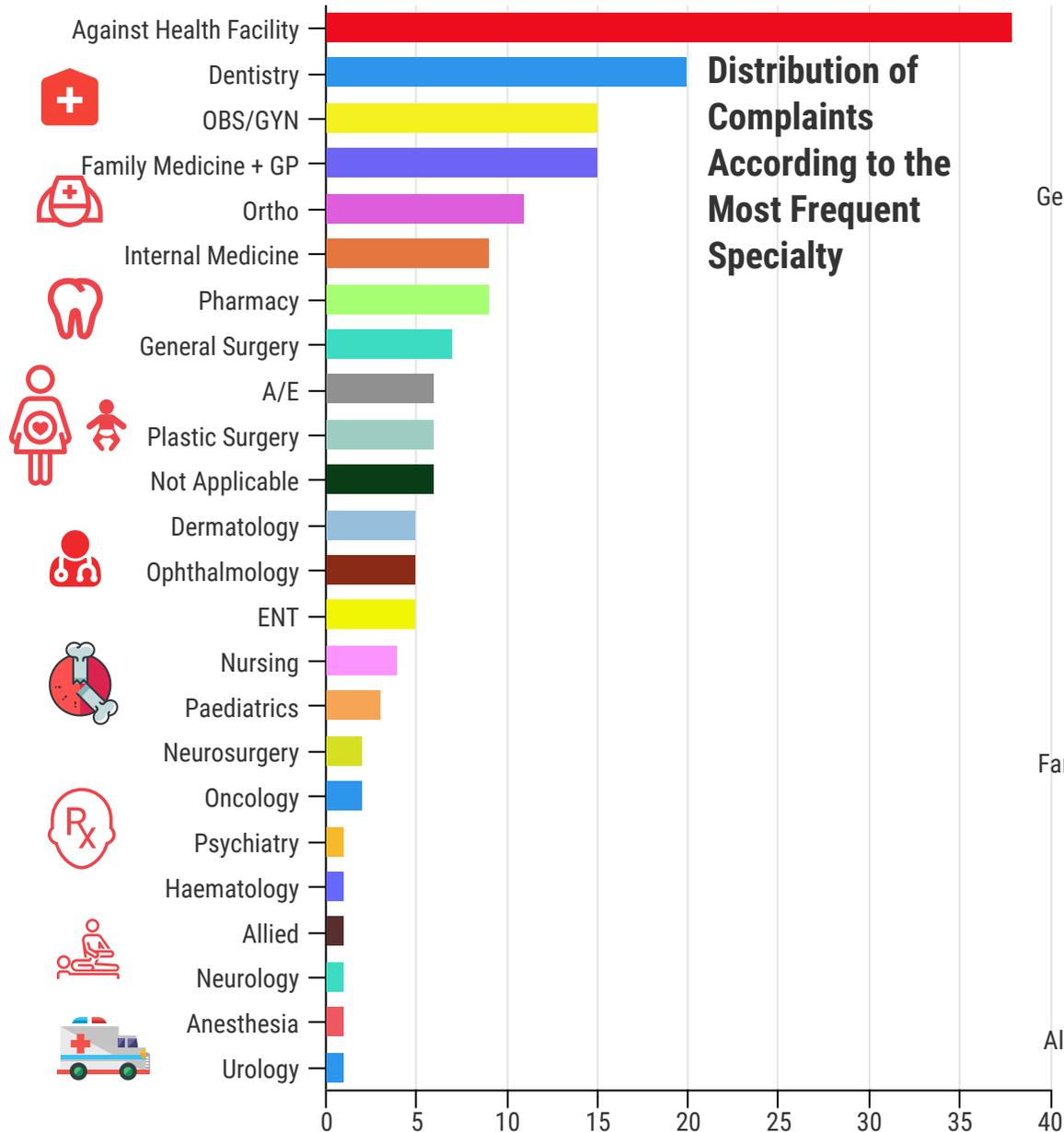


Law Suits

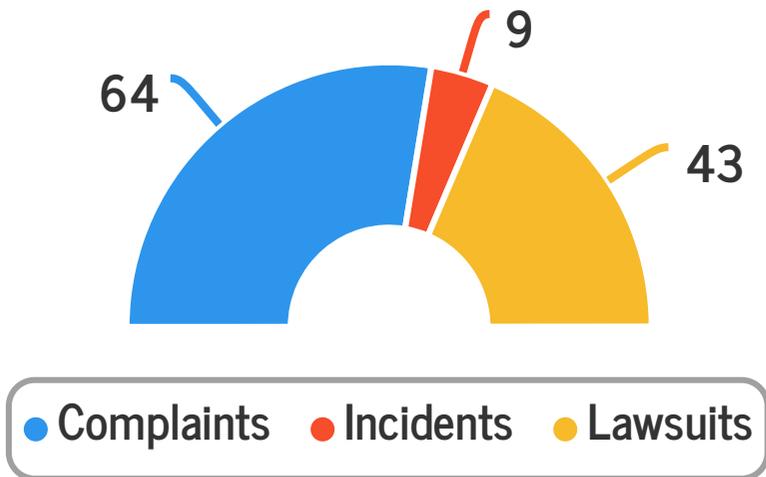
Doctors	12
Nursing	0
Pharmacists / Pharmacies	0
Allied	2
Others	1
Health Facilities	15
Not Within NHRA Jurisdiction	0



Distribution of Cases According to the Most Frequent Specialty



Types of Cases Investigated / Closed



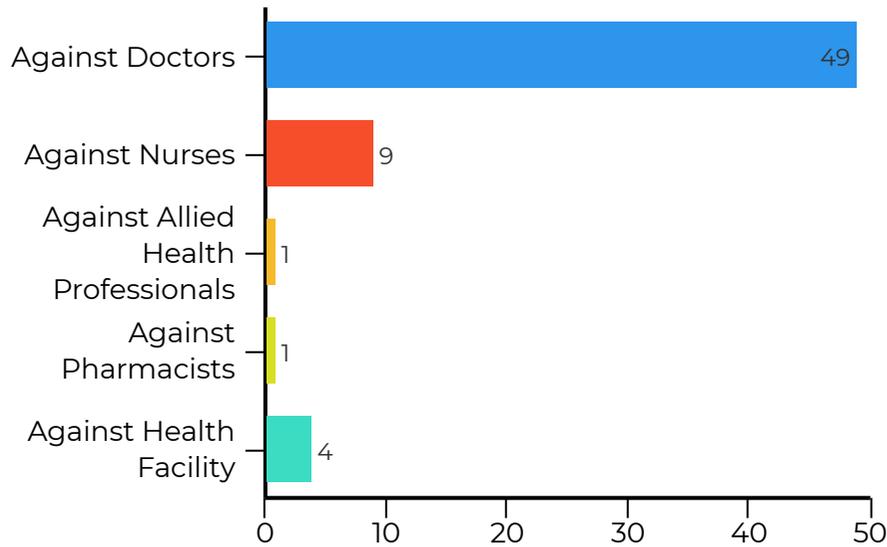
Results of Investigation

- ▷ No Medical Error or violation of the principles, duties, requirements and ethics present **36**
- ▷ Medical Error or violation of the principles, duties, requirements and ethics present **42**
- ▷ Not Within Jurisdiction of NHRA **5**
- ▷ Turning to complaint /lawsuit (closed) **14**
- ▷ Amendment Solution (closed) **4**
- ▷ Closed / reserved due to insufficient evidence or complaint withdrawn **15**

Total Number of Decisions Issued by Disciplinary Committees at NHRA

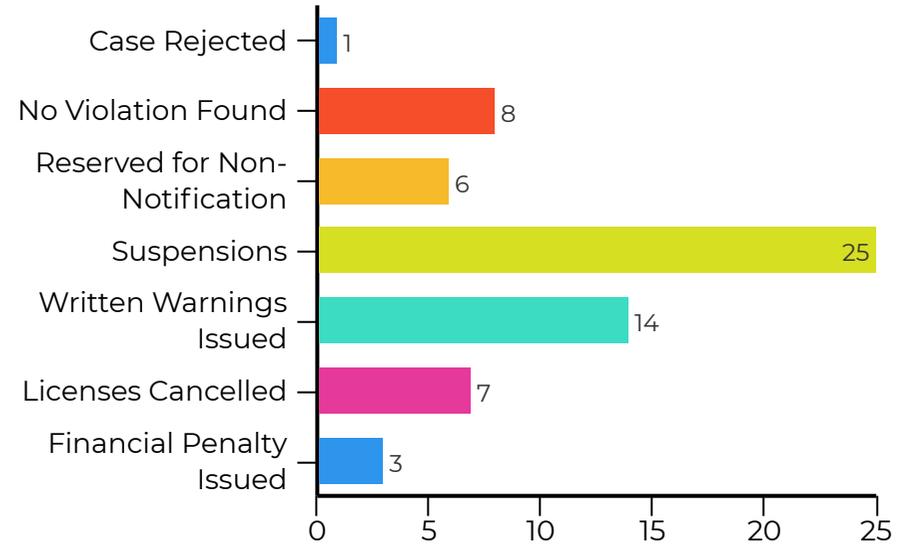
64

Disciplinary Actions Taken by category

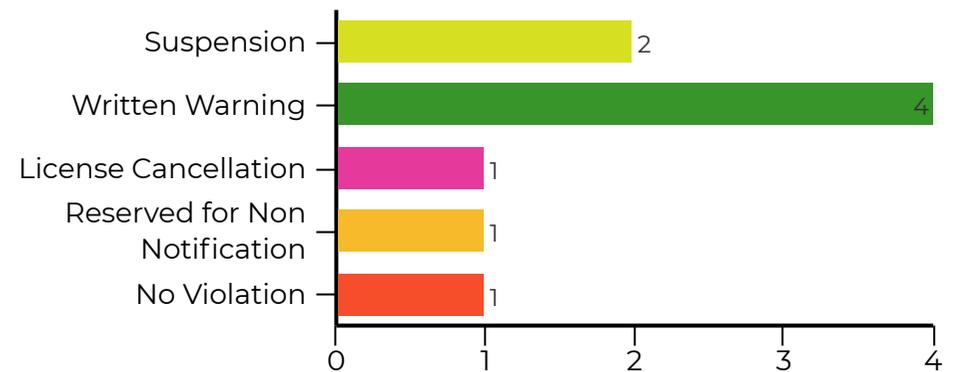
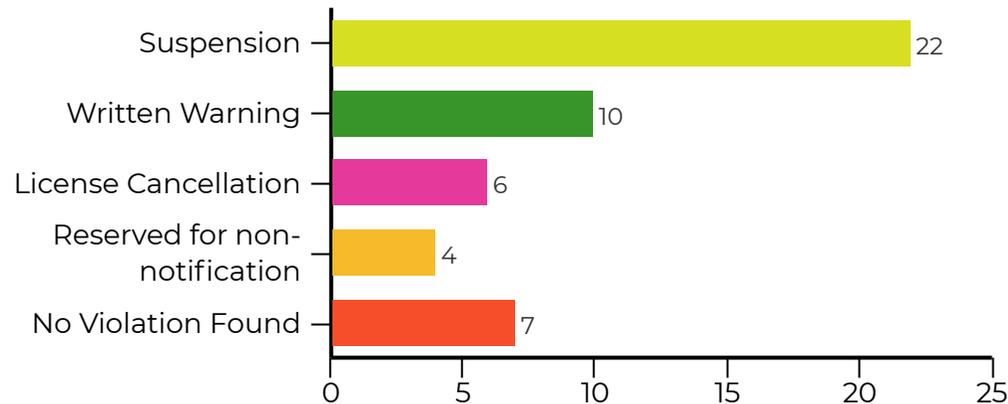


Against Doctors

Disciplinary Actions Issued



Against Nurses





Human Resources and Finance

Surveyors

Clinical Trials

Pharmacy

Facilities

Ayurveda

Regulating Clinical Trials

Clinics

Ethics

CAM

Medical Errors

Standards

Legislation

Licensure

Inspectors

Centers

CPD

Medicine

Devices

Hospitals

Accreditation

Professionals

Allied Health

Physicians

Health Products

Nurses

Regulations

Verifications

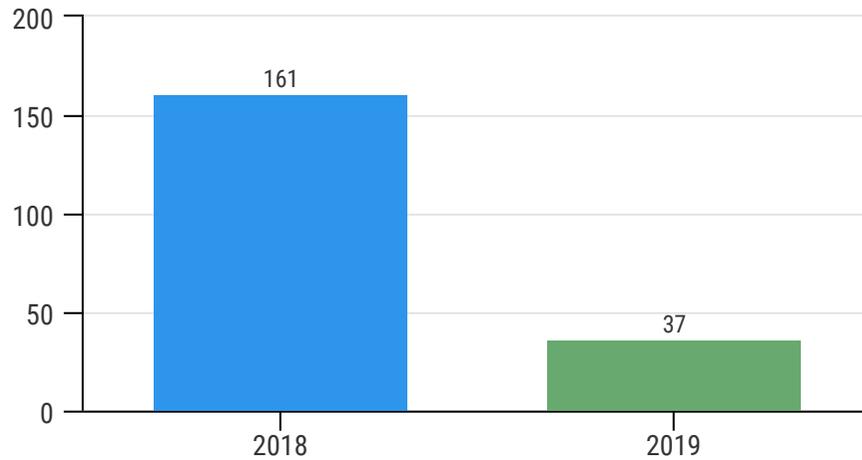
Pharmacies



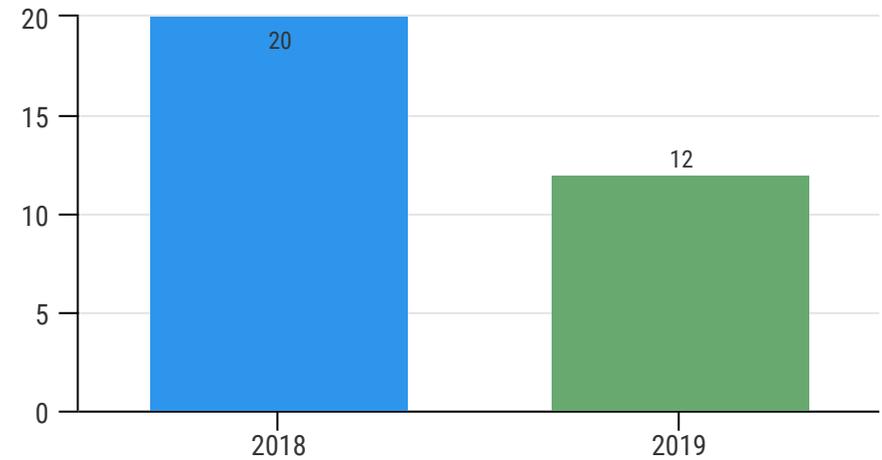
Legal Affairs Unit

Achievements of Legal Affairs Unit

Resolutions Drafted 2018-2019

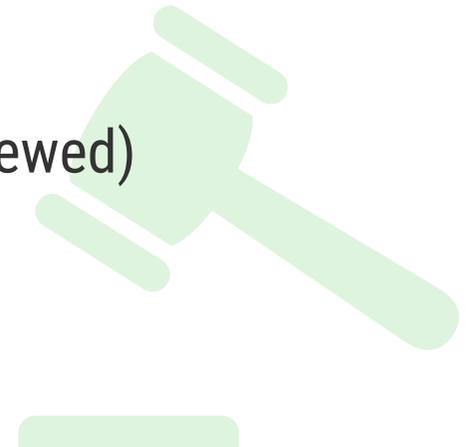


Review of Judicial Control Records and Cases of Public Prosecution(2018 -2019)



Civil and Administrative Issues
(defense memoranda were prepared and reviewed)

28



Laws Drafted (2018 - 2019)

Resolution No.1 of 2018 by issuing a list of organizing technical committees to determine the professional and ethical errors authority

Released

Resolution No.2 of 2019 on the classification of health institutions , health and technical requirements and safety requirements to be met in the facilities and equipment

Released

A list of requirements of pharmaceutical centers and pharmacists

Under Issue

Review of draft decision to issue a regulation for the organization of disciplinary and appellate trial committees for health professionals

Under issue

Review of draft decision list of requirements and standards of licenses of health institutions for the treatment and rehabilitation of addiction

Under issue

Raising and reviewing the reports of the technical, disciplinary and grievance committees in the Commission for 2018/2019

Disciplinary committees for health professionals

74

Technical committees to report the professional and ethical errors of human medicine and dentistry

40

Reports of grievance committees

25



Health Products
Devices **Medicine** **Pharmacy**
Accreditation **CPD** **Centers**
Regulating Clinical Trials
Human Resources and Finance
Facilities **Nurses** **CAM** **Clinics** **Ethics**
Verifications **Physicians** **Surveyors** **Licensure** **Clinical Trials**
Standards **Ayurveda** **Legislation** **Regulations**
Pharmacies **Professionals** **Inspectors** **Hospitals**
Medical Errors **Allied Health**



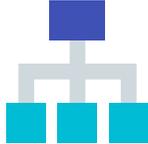
Human Resources and Finance Section

Summary of Financial Accounts 2018

Line Items
ALLOWANCE
EXPENSES
BUDGETS
BENEFITS
TIME
Memorandum
INVENTORY
Budget
ANLAYZE
PROFIT
OVERHEADS
Bahraini Dinar
CAPITAL
CONSISTENCY
SALARY
PLAN
Audit
Economy
ACCOUNTABILITY
Ministry of Finance
INFORMATION
RENT
Approvals

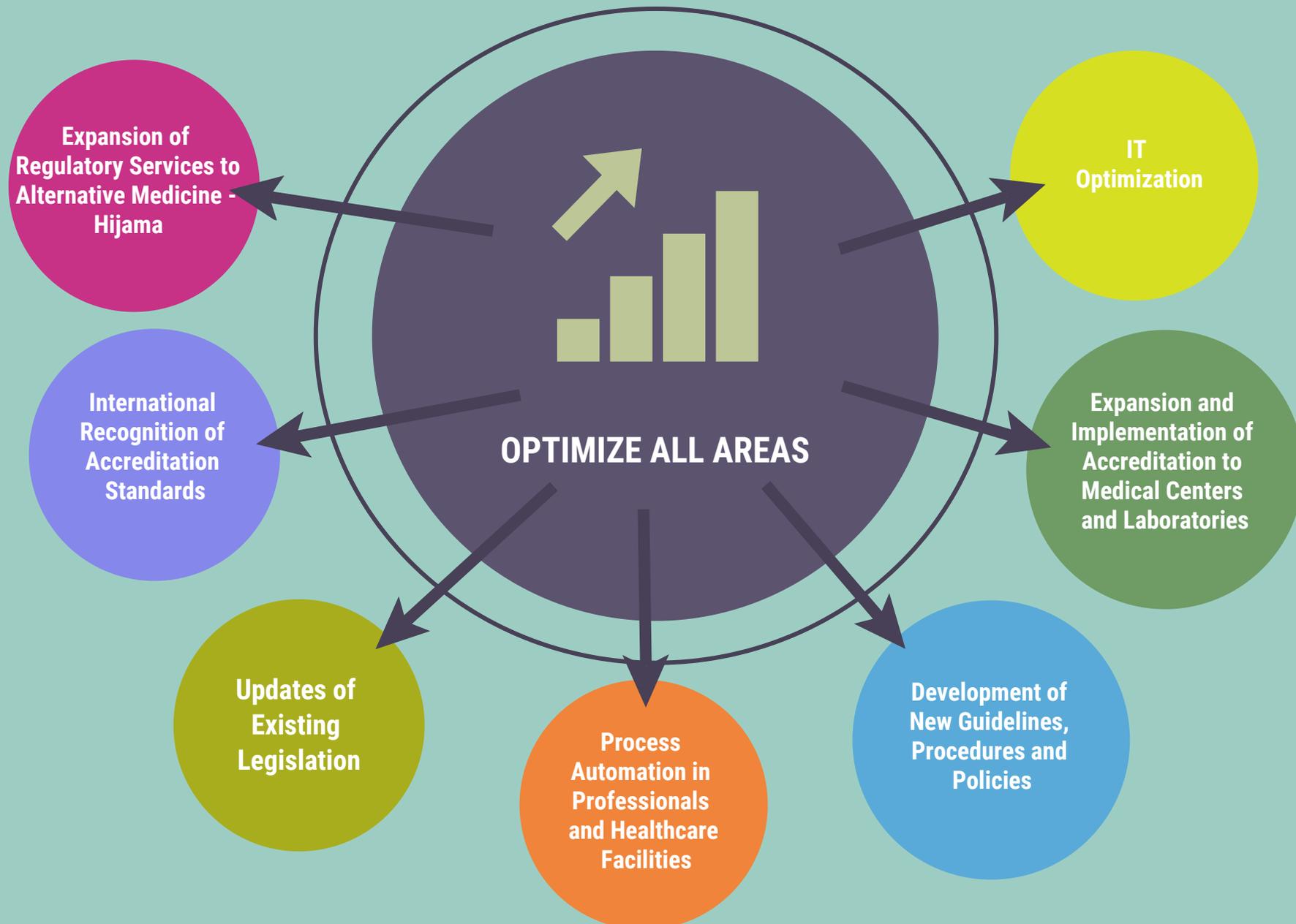
	Actual 2017 الفعلي	Actual 2018 الفعلي	Budget الاعتمادات	
Revenues				الإيرادات
Taxation & Fees	1,655,470	2,045,621	830,000	الضرائب والرسوم
Government Goods & Services	550	250	-	منتجات خدمية وسلعية حكومية
Fines, Penalties & Misc	115,830	191,802	5,000	غرامات وجزاءات وايرادات متنوعة
Total Revenues	1,771,850	2,237,673	835,000	مجموع الإيرادات
Expenditure				المصروفات المتكررة
Manpower	1,529,887	1,700,400	1,700,430	القوى العاملة
Services	672,354	563,586	672,300	الخدمات
Consumables	45,454	45,008	34,500	السلع الإستهلاكية
Assets	20,223	30,346	62,200	السلع الرأسمالية
Maintenance	4,520	11,679	23,000	الصيانة
Total Expenditures	2,272,438	2,351,019	2,492,430	مجموع المصروفات المتكررة
Surplus (Deficit)	(500,588)	(113,346)	(1,657,430)	الوفر (العجز) للفترة

HR Achievements

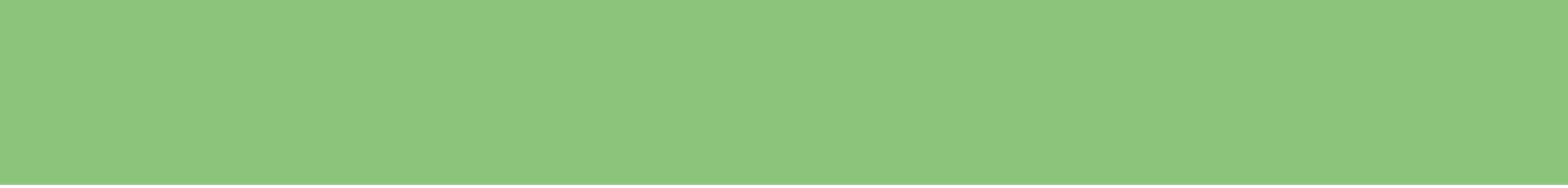
- 22 Employees were recruited. 
- 32 New positions were created in the organization chart.
- 19 Employees were promoted during 2018. 
- 5 Employee incentives were awarded.
- 97 Employees were trained out of 104 employees. 
- 5 Workshops were organized in NHRA.



Looking into 2019 - Strategic Priorities and Areas for Improvement



The National Health Regulatory Authority is committed to its role as the steward of the healthcare system in the Kingdom of Bahrain. This responsibility highlights one of our fundamental roles which is to ensure that the system as a whole delivers the best possible outcomes for the people of Bahrain. The team of NHRA is excited to renew our commitment to improve upon our services and work in collaboration with our clients to ensure the provision of high quality healthcare.



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