

nhra  
BAHRAIN



الهيئة الوطنية لتنظيم المهن والخدمات الصحية  
NATIONAL HEALTH REGULATORY AUTHORITY

# Annual Report 2015

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His Majesty

King Hamad Bin Isa Al Khalifa

King of Bahrain

May Allah Protect him



His Royal Highness

**Prince Salman Bin Hamad Al Khalifa**

Crown Prince Deputy Supreme Commander

First Deputy - Prime Minister

May Allah Protect him



His Royal Highness

**Prince Khalifa Bin Salman Al Khalifa**

Prime Minister

May Allah Protect him

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➤ Vision

Safe, trusted, high quality and effective health care.

➤ Mission

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





**His Excellency Lieutenant General Doctor**

**Sheikh Mohamed Bin Abdullah Al-Khalifa  
Chairman of the Supreme Council of Health**

The affiliation of NHRA to the Supreme Council of Health is one of the main steps in the development of the health care system that we aim to achieve universal health coverage. The existence of an independent regulatory body is considered an important cornerstone in the social health insurance system which the Supreme Council is developing in collaboration with the world Bank.

The objective of the social health insurance is to provide general and comprehensive coverage for both citizens and residents, to avoid facing financial burden when seeking health care, through minimizing out of pocket expenditure.

The future perspective for the health system in the Kingdom will change the mechanism of financing the health services; whereby the budget of the Ministry of Health and Governmental Hospitals will be replaced through mandatory subscription for every individual in Bahrain. This subscription is calculated actuarially and should be paid to the Solidarity Fund or Insurance Companies. The government pays on behalf of the nationals, and employers pay on behalf of the non-nationals. In addition, there will be a financial system that includes the principles of dealing between the service providers and buyers, and it will be controlled by the Ministry of Finance, Ministry of Health and Financial Audit Court, from which key performance indicators will be set.

NHRA will regulate the health care providers, and ensure a licensed health sector that provides high quality services and is subject to accountability. In the future, NHRA will also undertake assessment and classification of the health facilities according to the performance indicators. This will create a competition that aims towards providing the best health services and health welfare for the community, creating opportunities for investments and encouraging healthcare tourism.

In order to reinforce the role of NHRA, the Supreme Health Council will work on developing requirements and standards for the health care facilities; as well as reviewing previous resolutions and legislations, to keep pace with the new developments in the health system one hand, and regulating NHRA work on the other hand.

We seek to strengthen and support the role of NHRA to be able to perform its task as provided for by the law of its establishment; i.e. Regulate the provision of healthcare in Bahrain to ensure high efficiency, safety and effectiveness in delivering health services; both in the governmental and private sector based on the best scientific principles and health practice standards accredited in the Kingdom.



**Dr. Mariam Athbi Al-Jalahma**

Chief Executive Officer

National Health Regulatory Authority

As we bid farewell to 2015, we hope to witness a remarkable change in NHRA's procedures and regulations. Since the last amendment to the law of establishing NHRA, where the management board has been replaced by the Supreme Health Council, NHRA and Supreme Council have reconsidered many of NHRA functions and studied re-organization of its procedures. The former CEOs and board of directors have worked hard to develop the infrastructure of the NHRA's responsibilities and basic duties to regulate the health sector in the Kingdom. However, NHRA needs to keep pace with the recent developments in light of applying the social health insurance system.

While we are restudying NHRA's procedures, we bear in mind our partners in the governmental and private sectors. We shall do our best to develop our systems, and facilitate procedures without prejudice to the required quality standards.

We started to work on providing an online service with the Ministry of Industry and Commerce to license the health facilities, and we are currently working on having online services with the Customs Department in order to facilitate the customs release of medical devices and equipment.

One of the most important future steps that NHRA will seek; is to develop a five-year strategic plan to finalize the administrative and legal by-laws, in order to perform its mission appropriately.

In addition, NHRA aims to develop standards and requirements of licensing for all types of private health facilities; and develop standards and requirements of licensing of alternative medicine and fertility centers. Moreover, to standardize physicians license criteria, and approve the allied health professions list. NHRA will also develop a comprehensive information technology system, to include all licensing procedures, renewal and online exams system.

In this report we seek to list all achievements obtained in 2015; whereby all employees of NHRA have worked hard to achieve within the resources and potentials available. We also have allocated part of the report to highlight the implemented recommendations of the Financial and Administrative Audit Court, as well as the future plans of NHRA.

We face a number of challenges; however, we have a lot of opportunities available that will enable us to achieve the vision we aspire for which is:

**“Safe, Trusted, High Quality and Effective Health Care”**

## Introduction

NHRA has gone through a number of developments and changes during the year 2015; both at the level of legislations and laws, and at the administrative and technical level. Decree no. (41) of 2015 was issued with respect to re-formation of NHRA's Board of Directors. This was followed by issuance of Decree of law no. 32 of 2015 with respect to amendment of some provisions of Law No. 38 of 2009 to establish NHRA; whereby the Supreme Council of Health has replaced the Authority's Board of Directors as chaired by His Excellency Lieutenant General Doctor / Sheikh Mohamed Bin Abdullah Al-Khalifa. This amendment is considered a qualitative shift for NHRA, as it is affiliated to the Supreme Council of Health which is responsible body for health policymaking in the Kingdom. The members of the Council are representatives from the governmental, private, academic sectors, health professions and civil societies. On the twentieth of September, the Decree of law no. 62 of 2015 has been issued to appoint Dr. / Mariam Adhbi Al-Jalahema as new CEO of the NHRA.

The Supreme Council of Health is the supreme Authority of NHRA, which the Chief Executive Officer is running technically, administratively and financially. In addition, the Chief Executive Officer represents NHRA before the court and in its relationships with the third parties. The chairman of the Supreme Council of Health undertakes supervision on the Chief Executive Officer tasks.

NHRA is considered the responsible body for regulating professionals, and health services, in both governmental and private sectors in the Kingdom of Bahrain. This involves regulatory procedures, related to licensing the health facilities including; hospitals, medical centers, private clinics, centers for allied health professionals, pharmaceutical centers; as well as licensing health care professionals in these facilities. It also includes registration and pricing of medicine, licensing drugs manufacturers, granting approvals in relation to conducting clinical trials, investigating medical errors claims, conduction disciplinary actions on health professionals in the Kingdom over all aspects of professional violations.

The NHRA's previous Board of Directors has worked on developing a number of systems related to licensing health professionals and health facilities and pricing the medicines as well as regulating performance of the health sector in general. The development of the NHRA and its' systems thereof is continued through the Supreme Council to keep pace with the updates in development in the health care system, and to enable NHRA to be an effective regulator within the upcoming social health insurance system, and creating an environment that encourage investment in the health sector supporting the economic development in the Kingdom.

# NHRA Organization Chart





## Challenges and Opportunities

NHRA confronts a number of challenges hindering it from performing its responsibilities stated by the law of its establishment. However, there is a set of opportunities to be taken advantage of in order to achieve the real successes that will enable NHRA to perform the mission entrusted therewith.

### ❖ Challenges

- **Limited Budget:**

Limited budget is considered one the most significant risk that NHRA faces; whereby the budget allocated did not include funds for operating tasks within its functions, such as the fund required to appoint new staff and run NHRA committees. Such shortage of fund hindered NHRA from performing many functions legally entrusted therewith.

- **Organization Structure and Manpower:**

The shortage of manpower is one of the greatest challenges facing NHRA in light of the steady increase of licenses submitted; whether by professionals or facilities. This led to hiring a number of experienced staff from the Ministry of Health to work in NHRA. This is considered as a temporary procedure and does not ensure feasible and effective continuity.

Moreover, the drug Control Department is also facing inconsistency of organization structure in relation to its' functions. The non-existence of independent unit for inspection with a sufficient number of inspectors also constitutes a challenge leading to deficiency in regulating drugs and pharmaceutical products in the Kingdom. The functions of NHRA, as per law of establishment thereof, are not reflected in the organization structure such as; approval of clinical trials and medical devices, and pricing of medicines. This was clearly mentioned in the two reports of the financial and administrative Audit Court reports.

- **Legislations and Laws:**

There is a need to establish and update many regulations, and procedures to keep pace with the new and amended laws, and the development in all types of health services and new professional specialties that have no regulation yet. This necessitates extra efforts in the coming period to build up the legislative and regulative basis for NHRA responsibilities.

- **Electronic System:**

NHRA needs to develop its information technology system to be able to organize, facilitate, and simplify the procedures of licenses, and to keep pace with the developments in the governmental information system.

- ❖ **Opportunities**

- The political support depicted in replacing the NHRA's Board of Directors with the Supreme Council of Health, is considered one of the most important opportunities provided for NHRA; to support and strengthen its regulations and ensure commitment of both private and public sectors. In addition, the issuance of law no. 21 of 2015, concerning the private health facilities, and Decree by Law no. 20 of 2015 to amend some provisions of Law no. 18 of 1997 concerning regulating the profession of pharmacy and pharmaceutical centers. have broaden the opportunity for NHRA to regulate its requirements and procedures. For example, keeping the functions of licenses within the main works of the NHRA, cancellation of the committees concerned with licenses, maintaining the disciplinary committees, and constitution of accountability committee for the private health facilities chaired by a judge with a representative from NHRA, and Bahrain Medical Society.
- Resolutions issued by the Supreme Council allowed NHRA to define its responsibilities out of those performed by the Ministry of health, such as: defining the responsibility of monitoring over the counter medications, healthy food, controlled drugs and chemical substances, besides facilitating the procedures of registering of medicines and pharmaceutical products.
- NHRA has the technical expertise that enable it to develop and implement regulatory procedures and improve quality of work, provided that sufficient financial resources are available and sustained.
- Recently, NHRA was able to build partnerships with the private and public sectors, as well as the academic institutions; whether through representing such sectors in the Supreme Council, or building cooperative partnerships in its daily work scope.
- NHRA can develop its own financial resources through the fees received for the services provided. Article 19, clause C of Law no. 21 of 2015 concerning the private health facilities can be considered as an example of how NHRA can be funded by self-financing.

Whereby, the Article provided that: private health facilities pay annual fees for audit and assessment procedures to ensure quality of health services, and achieve the highest levels of performance. These fees are maintained within NHRA and is allocated for purposes of audit, assessment and inspection. Such fees shall be placed in a special account in NHRA, funds for audit, assessment and inspection.

- One of the important opportunities are the recommendations of the financial and administrative audit office which revealed many gaps that could be sorted out in order to improve the NHRA procedures and functions.

## New laws & Regulations

During the year 2015, a number of laws have been issued in relation to scope of works and responsibility of NHRA, which includes the following:

- Issuance of Decree no. (41) of 2015 concerning re-formation of NHRA Board of Directors to regulate health professions and services.
- Issuance of Decree by law no. 32 of 2015 concerning amendment of some provisions of Law no. 38 of 2009 to establish the Authority, by which virtue the Supreme Council has replaced the NHRA's Board of Directors. The first Article of the law provided that: "the Supreme Council of Health, as established by Decree no. 5 of 2012 shall exercise the terms of references of NHRA's Board of Directors to regulate health professions and services as provided for in the Law no. 38 of 2009".
- The law of establishing NHRA has determined its responsibility by setting policy of developing services and health care system in the Kingdom. The third Article of this law has defined the objective of establishment thereof, by regulating health professionals and services in the Kingdom of Bahrain, and proposed development thereof so as to ensure high competence, safety, required speed and effectiveness in providing such services; either in the governmental or private sector. Such services should be provided as per the best scientific basics, health practice standards accredited in the Kingdom of Bahrain.
- Decree by law no. 20 of 2015 to amend some provisions of law no. 18 of 1997 concerning regulating the pharmaceutical profession and centers. Following are the most important developments regulated by law:
  - Encourage investment in the Kingdom, facilitate and simplify the procedures.

- Open the field of investment in the pharmaceutical sector for national investors without the condition to be a pharmacist.
- Pharmaceutical plants licensing systems.
- The Supreme Council of Health is concerned with defining the maximum permissible profit out of trading in medicines and pharmaceuticals.
- Giving permissions to open branches for pharmacies; provided not to be more than five.
- Issuance of decree by law no. 21 of 2015 concerning private health facilities. The following
  - is the most important developments regulated by the law:
    - Encourage health investment in the Kingdom, facilitate and simplify the procedures through authorizing the Supreme Council to issue regulations in order to be granted sufficient flexibility to be in pace with the developments of the investment sector in the Kingdom.
    - Cancellation of all technical committees concerned with medical licenses; whether individuals or facilities, and to be replaced by NHRA in order to complete the licensing procedures with the required speed without prejudice to the standards.
    - Permit individuals, companies, authorities, organizations, or foreign health institutions to establish private health facility.
    - Allow Civil Societies to run a health care facility if providing health care is stated in its establishment resolution.
    - Establishment of private health clinics is confined to doctors only.
    - Classification of private health facilities into types and categories.
    - The law regulated the process of auditing and assessing the private health facilities through developing a set of standards for assessing the quality of health services, and levels of performance. The law obligates the facilities to pay annual fees for this assessment. The cabinet will adopt the annual audit report results conducted by NHRA.
    - Establishment of the accountability committee to be chaired by a Judge to investigate and take the necessary measures, as well as urgent procedures concerning the private health facilities upon committing violations of law.

## Resolutions of the Supreme Council of Health

- NHRA ex-Board of Directors and the current Supreme Council of Health has revised many NHRA resolutions, in order to simplify and fasten its procedures. The most important Resolutions approved by the Council for the year 2015 are as follows:
  - Resolution concerning classification of private hospitals.
  - Resolution concerning formation of fact-finding committee in violation no. (15), as indicated in the report of the Financial and Administrative Audit Court.
  - Resolution regulating the registration of drugs, that defined the conditions of importing urgent non-registered drugs and medications for hospital usage. The resolution also allowed the entry of drugs that are registered internationally and in the Gulf area, with a permissible period of one year to complete the registration requirements in the Kingdom of Bahrain. This resolution has led to rapid entry of new drugs and pharmaceutical products inside the country. It also developed procedures relevant to non-registered medicines which are not regulated by the previous resolutions.
  - Resolution regulating the issuance of NHRA disciplinary committees for doctors, pharmacists and allied health professionals. The regulation has included all regulatory matters for committees, defined their working system, rights and duties of the person transferred to disciplinary accountability.
  - Resolution regulating professional's examination committees; including all regulatory matters relevant to professional's examinations, times, and work processes.
  - Defining the number of attempts to attend licensure examinations to be three times, to be followed by two final attempts after receiving a 6 months training in a facility licensed by NHRA.
  - Defining the responsibility of licensing controlled drugs; whereas based on law no. (15) of 2007, concerning the narcotic drugs and chemicals, the Ministry of Health is considered the body authorized by law to license importation of such substances. The responsibilities of NHRA were defined in monitoring prescription of such medicines and usage in the private sector only.
  - Resolution licensing simple drugs; whereby the resolution has authorized the Ministry of health to inspect over shops selling such drugs.
  - Resolution licensing and regulating healthy food; whereby the Council has authorized the Ministry of Health to license and control the shops selling healthy food, after being classified by NHRA.
  - Resolution to form two committees to develop standards for classifying doctors and dentists, that aims to adopt standardized national measures for technical and professional level. The Supreme Council has also raised to the higher Authorities a draft to amend some provisions of Decree no. (5) of 2013 for establishment and formation of the supreme

Council of Health, in order to keep pace with the legislative and legal changes in the past period.

## Resolutions Issued by the Chief Executive Officer

- Resolutions to regulate and re-organize the departments of NHRA, defining the scope of its work and specialties in order to achieve the desired objectives.
- Re- distribution of manpower in NHRA to ensure that expertise is properly allocated.
- staff were reallocated from the Ministry of Health to fill the professional vacancies at NHRA.
- establishing the consultative committee for licensing of physicians and dentists.
- Establishment of the clinical trial committee to study requests for clinical trials in the Kingdom.
- Resolution for regulating work in the advisors Office.
- Resolution for regulating work in the Human and Financial Resources Office
- Resolution for establishing the training and development committee.
- Resolution for establishing equal opportunities committee.
- Resolution for establishing Bonus and Reward Nominations Review Committee.
- Resolution for establishing and formation of coordination committee for licensing private facilities.
- Resolution for re-formation of pharmacists' exams committee.

## Regulation of Health Facilities

### • HEALTH FACILITIES REGULATORY DEPARTMENT

The Health Facilities Regulatory Department is concerned with exercising the functions of NHRA in connections with the health facilities inspection, and observing any violations to regulations, and in particular to the following functions:

- Receive and register requests for licensing and operation of health care facilities, amending the activity of licensed health facilities, approval on partial or total closure, and waiver of the facility. In addition to requests for issuance of any approvals prescribed by Provisions of Decree by law no. (21) of 2015 concerning private health facilities, such as; completion of documents and requirements, and coordination with the engineering and safety consultant in NHRA to ensure that technical and engineering requirements are provided in the facility.
- Inspecting facilities, in coordination with the engineering and safety consultant in NHRA, to ensure the extent of fulfilling technical and engineering safety regulations required for approving license requests prior to renewal of such license, or issuance of final approvals for new facilities.

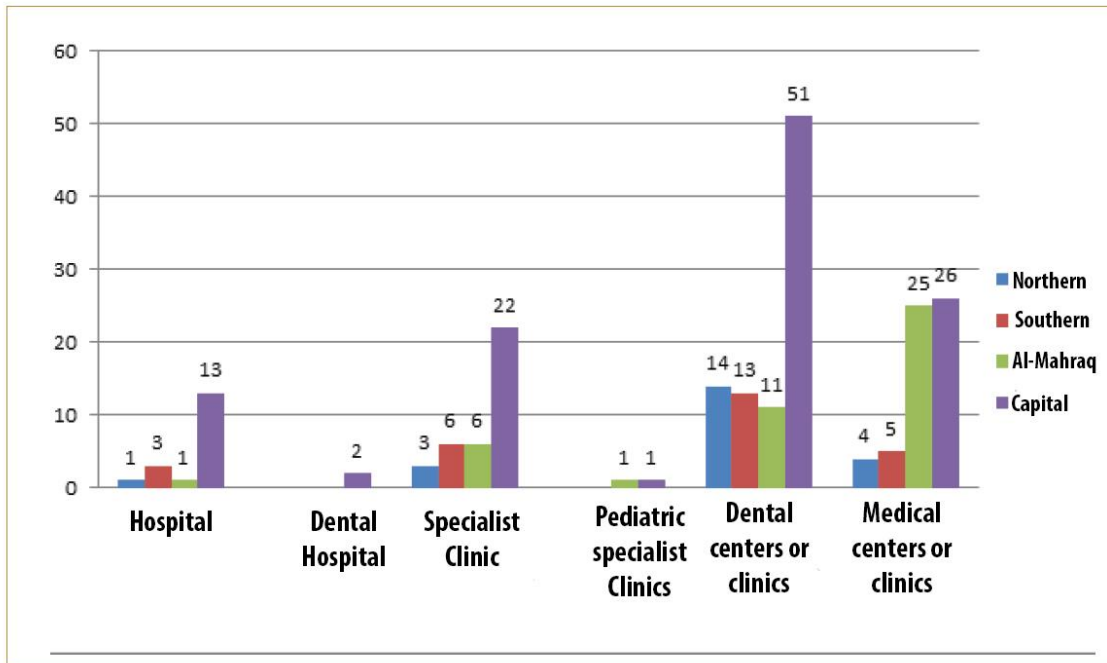
The number of health institutions registered at NHRA amounted to 1034 until the date of this report; including pharmacies and healthy food stores. In the year 2015, NHRA received 500 new requests for establishing new health facilities; as illustrated by Table no. (1), and graph no. (1), distribution of licensed health facilities according to governorates.

**Table (1) distribution of Health Facilities According to Governorates**

Name of Establishment	Capital	Al-Mahraq	Southern	Northern
Hospital	13	1	3	1
Dental Hospital	2	-	-	-
Specialist Medical Center	22	6	6	3
General Medical Center	7	3	2	4
Dental Center	17	8	10	10
24 hour Clinic	2	-	-	-
Full Time Clinic	3	18	3	-
Part Time Clinic	14	4	-	-
24 Dental Clinic	3	-	-	-
Dental Clinic	30	3	3	4
Part Time Dental Clinic	1	-	-	-
24 hour Pediatric Clinic	1	1	-	-

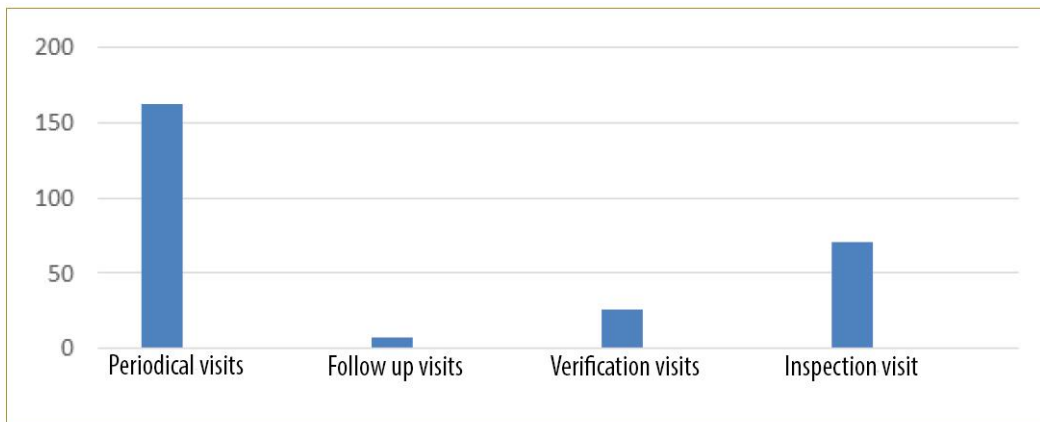


**Graph no. (1) Distribution of Health Institutions Licensed According to Governorates**

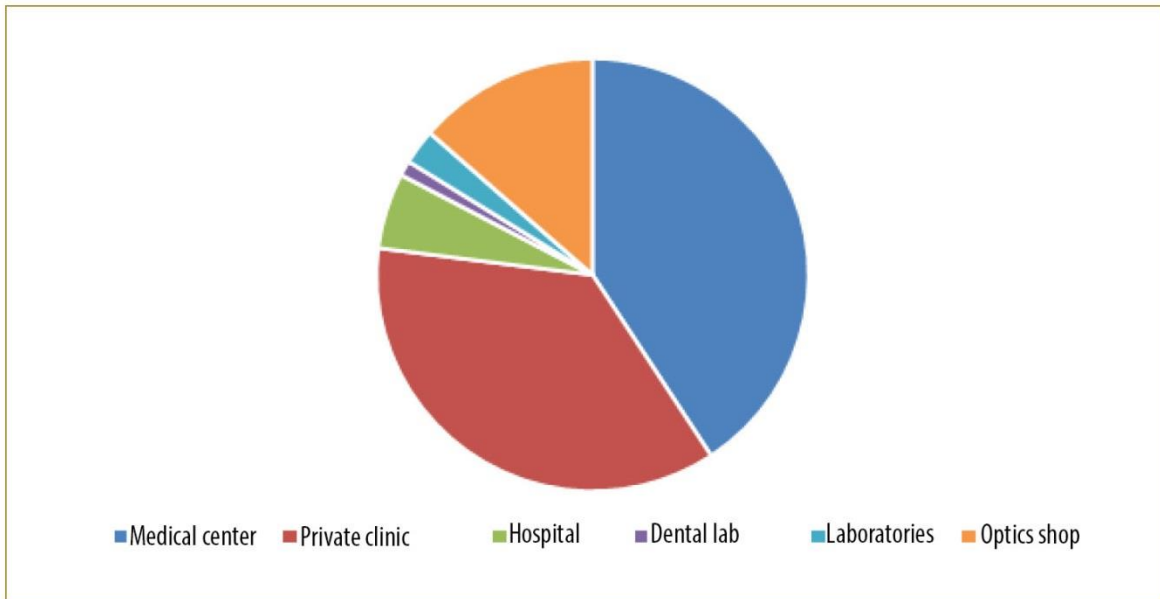


The inspection team has conducted [265] inspection visits that included [96] private clinic, [108] medical center, [15] hospital, [36] optical shop, [3] dental labs, and [7] labs. Graph no. [2, 3 and 4] show statistics, types of visits and the private facilities inspected.

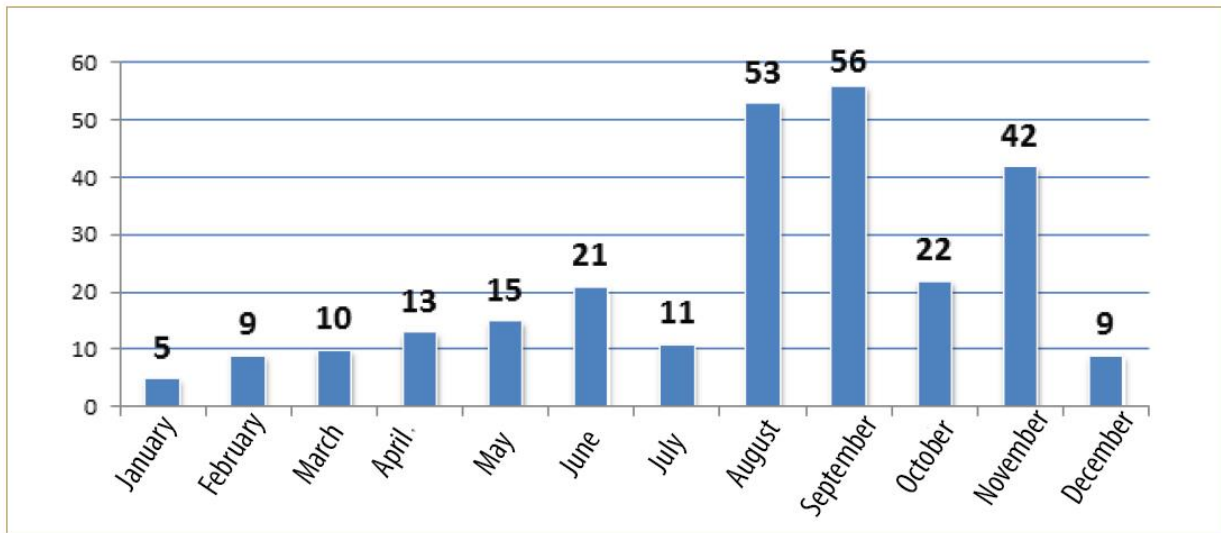
**Graph no [2] Inspection Visits for Health Institutions:**



**Graph no. (3) Types of Health Institutions Inspected**



**Graph no. (4) Statistics of Inspection Visits for the year 2015**



- PHARMACIES REGULATIONS:

#### **LICENSES:**

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- No of licenses given to pharmacies: [8] [imported: 8 - non-imported 0].
- No of licenses given to pharmacies in hospitals and medical centers: [10].
- No of licenses given to health food stores [46].

#### **INSPECTION:**

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- No of pharmacies inspected [271].
- No of health food stores inspected [46].
- No of pharmacies in hospitals and medical centers inspected [34].
- No of drug stores inspected [6].
- No of ambulances inspected [4].
- No of medicine transport vehicles inspected [12].

#### **VIOLATIONS AND RECORDS**

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- [10] Notices have been issued [10] pharmacies due to committing some violations.
- [16] Violation records have been written down.

## Regulation of Pharmaceuticals

### ➤ Pharmaceuticals Regulatory Office

**The Pharmaceuticals Regulatory Office is concerned with applying the provisions of Decree by law no. (18) of 1997 and its amendments by law no. (20) of 2015 concerning regulating the pharmacists and pharmaceutical centers, particularly practicing the following functions:**

1. Licensing importation and exportation of medicines and pharmaceutical products.
2. Ensuring that the conditions of importing drugs and medications for personal use are met, and granting the approvals needed.
3. Receiving requests of registering the medications and pharmaceutical products, in coordination with the committee for drug registration; according to the regulatory rules issued by resolution of the Supreme Council of Health.
4. Controlling drugs, setting any restrictions on prescription of some drugs, pharmaceutical products, or marketing them, when necessary; based on the resolution issued by the Chief Executive Officer.
5. Controlling prices of medications, ensuring the extent of adherence to such pricing by the pharmaceutical centers, as per the rules issued by the Supreme Council of Health. This will be through pharmacist inspectors mandated for inspection on the pharmaceutical centers.

**The works of the Department in 2015 included the following:**

- **Registration of drugs and Pharmaceutical Products**

The Department has registered 132 new medicines, in addition to renewing the registration of 425 registered drugs, as well as registration of 421 for alterations on drugs. Moreover, 140 health products were registered, 120 items classified within the healthy foods, and classification of (51) product; beside registration of 59 pharmaceutical production companies. Moreover, participations made by the Department in central GCC registration of medicines (alterations, registration of drugs, drugs registration renewal) for two hundred drugs.

- **Pricing of medicines:**

The Department has priced 120 medicines, 50 local pharmaceutical products, and participated in Gulf pricing of 2594 innovative drugs and 914 of generic drugs.

Table no. (2), refers to all activities performed in the Department.

<b>Table no. (2), Activities performed in Pharmaceutical products Regulations Department</b>	
<b>Activity</b>	<b>January - December</b>
Medicines Variations	421
New Medicines Registration	132
Medicines Registration Renewals	425
Manufacture Site Registration	59
Registration of Health Products	140
Functional Foods Registration	120
Products Classification	51
Local Pharmacy inspections	156
Gulf inspections of factories (Good Manufacturing Practice)	11
GCC Central registration (variations, medicines registration, renewal of medicines registration)	200
Pricing	Medicines 120 Health Products 50
Gulf Unified Pricing	Innovators 2594 Generics 914
Narcotics and Psychotropic Medicines	NDPR 254 CDPR 802
Narcotics and Psychotropic Medicines Destructions	93
Personal Parcels (average)	2616
Customs Shipments Clearance (average)	11000
International Narcotics Control Board Reports	10
Importation Certificates Narcotics/Psychotropic Medicines	Narcotics 37 Psychotropic 157
Permission of Nonregistered medicines and Pharmaceuticals Products	300
Pre-approval for medicines and Pharmaceuticals Products importation	2103

## Health Professions Regulation Office

### ➤ Physicians and Dentists licensing

The Health Professions Regulation Office is concerned with receiving requests for licensing health professionals, and all what is related to following up the procedures of issuance, renewal and transferring these licenses. In addition, it is concerned with taking the necessary actions regarding following up the positions of health professionals as licensed by NHRA. The Health Professions Regulation Office comprises of quality team, three quality groups including medical profession regulation team and allied health professions regulation group, nursing regulatory group, and registration procedures group.

The Office has issued more than 3500 new licenses and relicensing of health professionals. The activities performed by the Office in the year 2015 included the following:

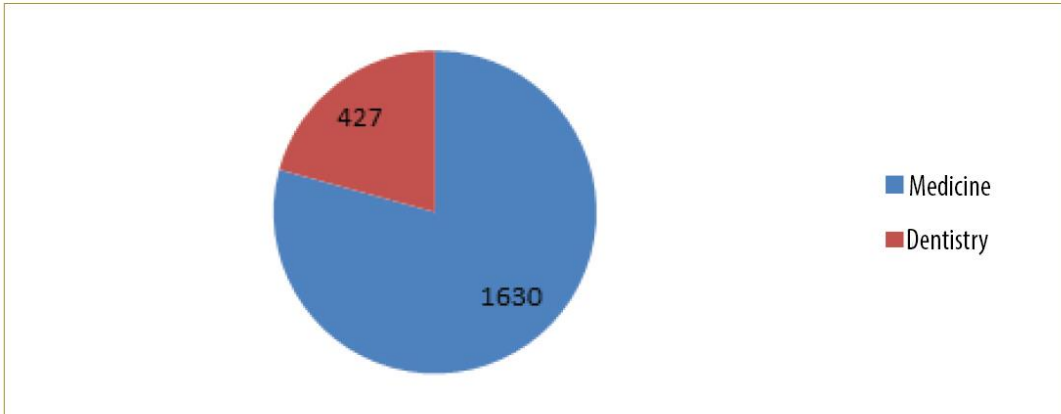
#### • Licenses for Doctors:

The medical licensing committee has organized thirty two (32) meetings during 2015. The average length of each meeting is two hours and a half. The activities of the committee included the following:

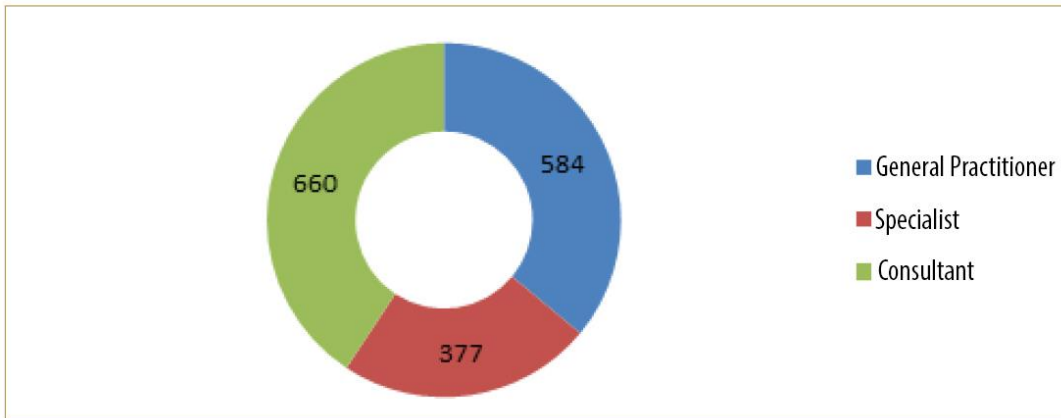
- A. Consideration of requests for licensing medical and dental professionals in the public and private sectors; whereby the technical and professional level is defined for doctors to grant them licenses matching their qualifications as per the policy approved by NHRA's Board of Directors.
- B. Consideration of the cases referred by courts with their different degrees to report whether there is a medical error or not.
- C. Conducting disciplinary accountability procedures for medical and dental professionals and individuals referred to disciplinary accountability by virtue of a referral resolution from the CEO of NHRA.

The total number of doctors licensed to practice the profession amounted to (2057) in 2015, as indicated in the graphs (5, 6 and 7), which show the statistics of professions practice.

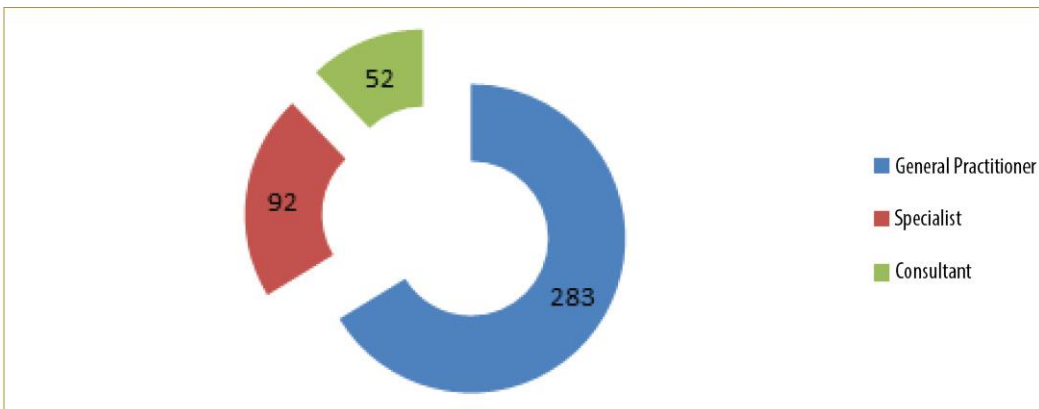
**Graph no. (5) Total Number of Doctors Registered in NHRA**



**Graph no. (6) Classification of Doctors Registered in NHRA According to Specialty**



**Graph no. (7) Classification of Dentists Registered in NHRA According to Specialty**



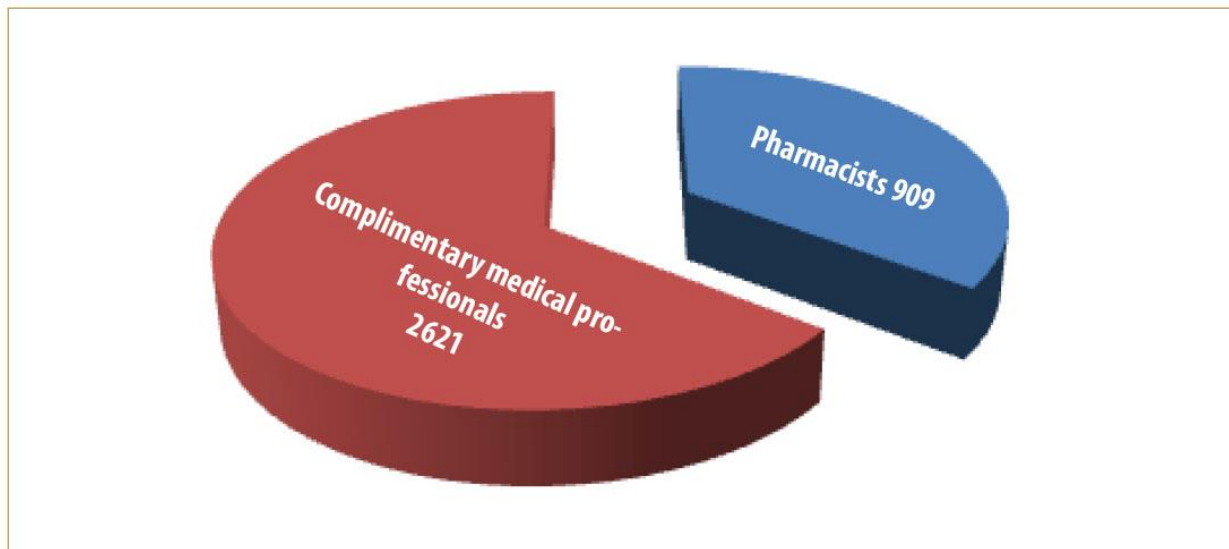
➤ **Allied health Professionals:**

The number of allied health professionals licensed for practicing the profession in the Kingdom of Bahrain and registered at NHRA; including pharmacists amounted to 3530 practitioners. Graph no. (8), illustrates the total number of allied health professionals and pharmacists. Table no. (3) also illustrates complimentary health professions classified at NHRA.

<b>Table no. (3) Allied Health Professions Classified at NHRA</b>	
Number	Profession
1	Pharmacist
2	Pharmaceutical Technician
3	Drugs Promoter
4	Medical laboratory Technician
5	Medical Laboratory Technician
6	X-ray Technician
7	X-Ray Technician
8	X-ray Technician Specialist
9	Physiotherapy Technician
10	Physiotherapist
11	Physiotherapist Specialist
12	Dental Technician
13	Oral and Dental Health Technician
14	Nutrition Technician
15	Nutritionist
16	Therapeutic Nutritionist
17	Optician
18	Medical glasses technician
19	Medical Contact Lenses Installation Technician
20	Communication Specialist
21	Acoustics Specialist
22	Electrocardiography (ECG ) Technician
23	Respirators Specialist
24	Health inspector
25	Nuclear Medicine Specialist
26	Prostheses Specialist



**Graph no. (8), for the total number of licensed complimentary Medical Professionals and Pharmacists**



➤ **Nursing**

The number of licensed nurses in the Kingdom amounted to (10222) nurse; of which 7589 are working in the governmental sector and (2633) in the private sector. In addition, (926) new nurses have applied to obtain license for profession practice during this year.

The number of licenses that have been issued for nurses since 2013 and which are valid till December 2015 is (2117) out of original (4411). These licenses vary between midwife license renewal, (37) midwives out of (113), general nursing license renewal, (2029) nurses (male / female) out of (114) and practical nursing (10) practical male nurses out of original (56), working across all health institutions that are licensed by NHRA.

The data of nursing licenses Unit shows that the total staff in the nursing sector registered in the Kingdom of Bahrain, till end of 2015, has amounted to (10222) nurse, of which (7589) nurse working in the governmental sector which represents 74.3%; while the staff working in the private sector amounted to 2633 nurse, with a percentage of 25.7%. The number of staff working in the governmental and private sectors, whose data were updated during the year is (2217) with a percentage of 21.7% out of the grand total; while the percentage amounted to 50.3% out of the grand total for those whose data have been updated since 2013 until present.

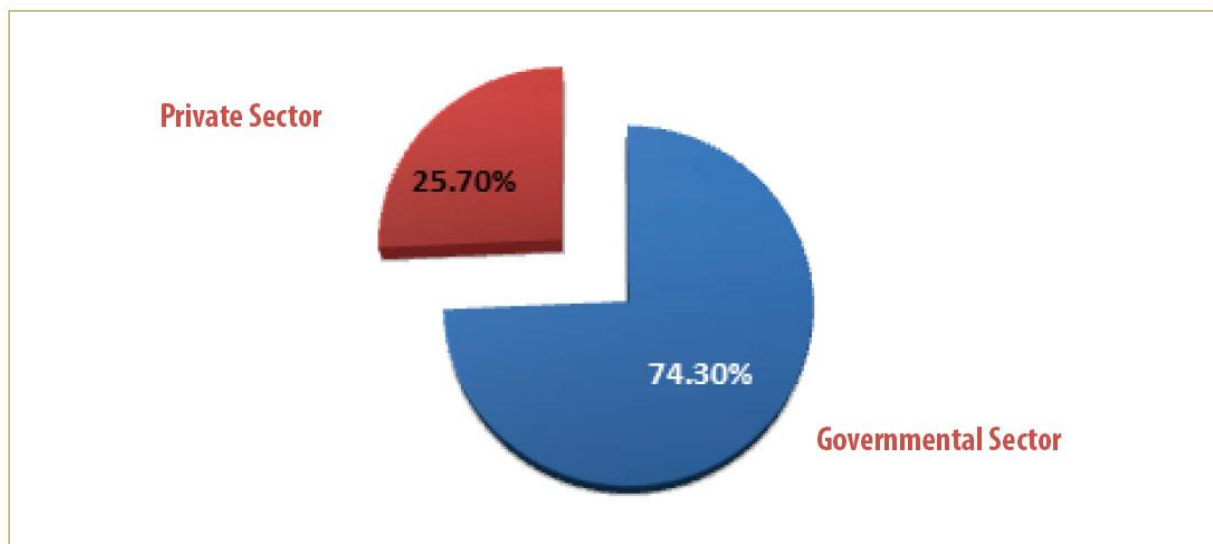
The Unit has worked on updating and assessing the statistics program of the Department. An electronic program was made to minimize human errors, save time and effort, and facilitate the process of issuing approvals to the Labor Market Authority. The program also facilitates the process of issuing Nursing profession practice license verification form, and issuance of balances by NHRA, payable from the licensor and Ministry of Health.

Currently, the electronic delivery lists of the program are joined in order to be applicable on other departments.

Table no. (4), shows the number of nurses registered in NHRA according to category of specialty. Graph no. (9), indicates distribution of nurses according to their work in the public and private sectors.

Table no. (4) Number of Nurses Registered in the Kingdom of Bahrain according to specialty category	
Number	Category
9955	Registered Nurse
100	Legal Midwife
75	Practical Nurse
92	Specialist Nurse
<b>Total</b>	<b>10222</b>

**Graph no. (9) Distribution of Nurses Registered in NHRA according to workplace**



## Complaints Unit

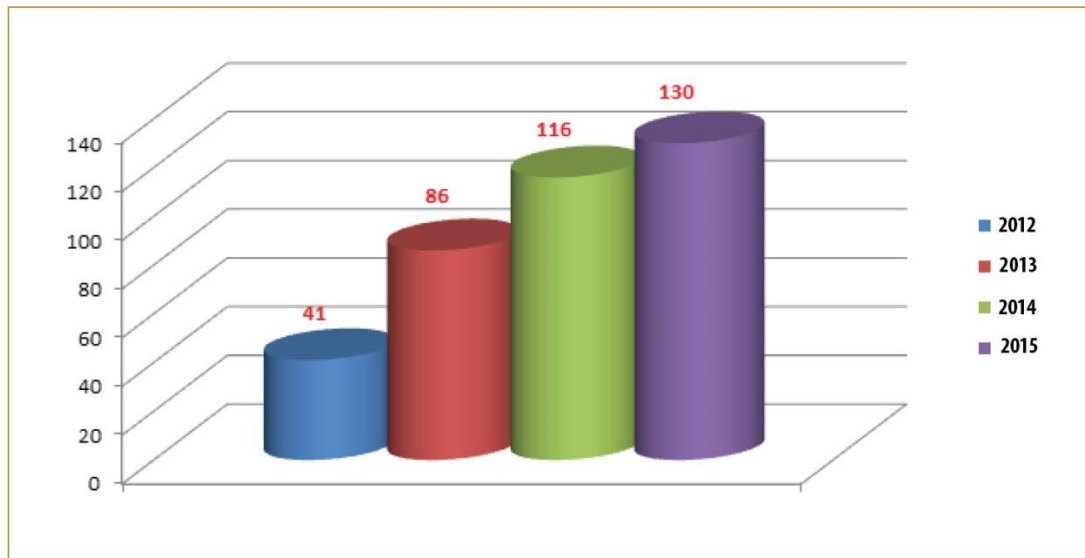
The Complaints Unit is concerned with taking the necessary measures toward the complaints and reports claiming the occurrence of medical errors, or violation of the principles, duties, requirements and ethics of practicing the health professions. In addition, it is concerned with the relevant judicial assignments regarding the occurrence of medical errors, or violation of the principles and duties, requirements and ethics of practicing the health professions in relation to legal claims considered by the judicial authorities in the Kingdom of Bahrain, or judicial investigation conducted by such authorities.

This does not include considering any requests related to material indemnity for such errors or violations, or refund of treatment costs, or providing treatment, as this is out of NHRA's specialty.

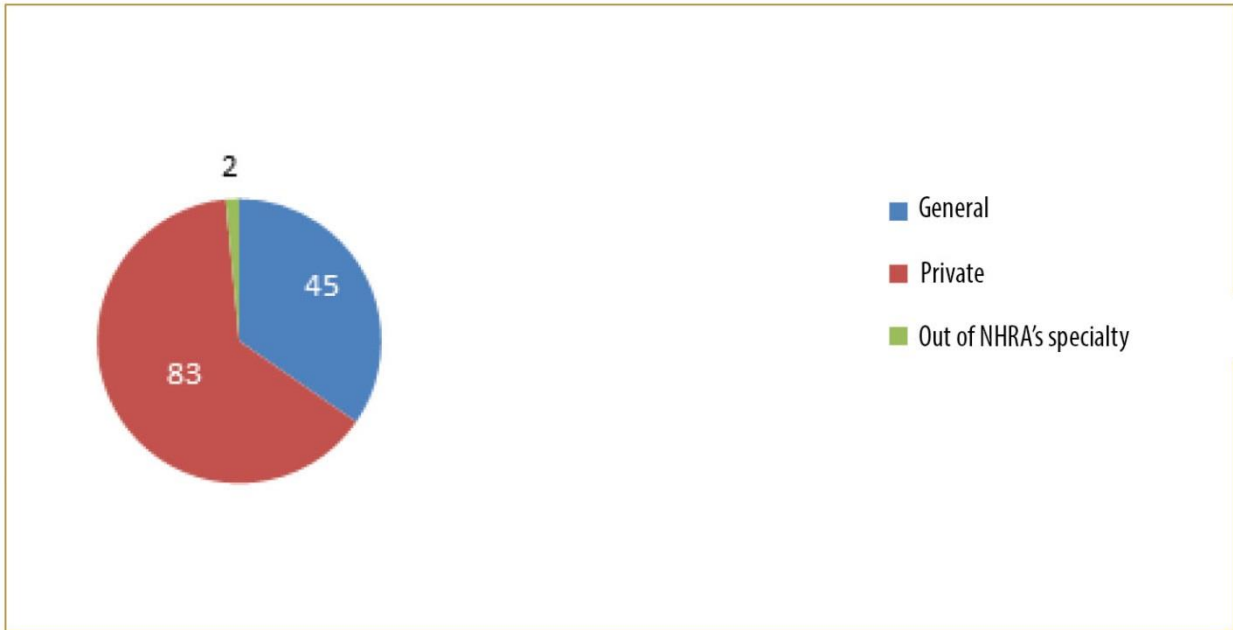
- **Statistics of Complaints:**

The total number of complaints submitted to the medical complaints unit in NHRA since the beginning of 2015 until the first week of December, amounted to one hundred and thirty (130) complaints as indicated in the Graphs no. (10) , and (11).

**Graph No. (10) Total Number of Complaints (2012 - 2015)**

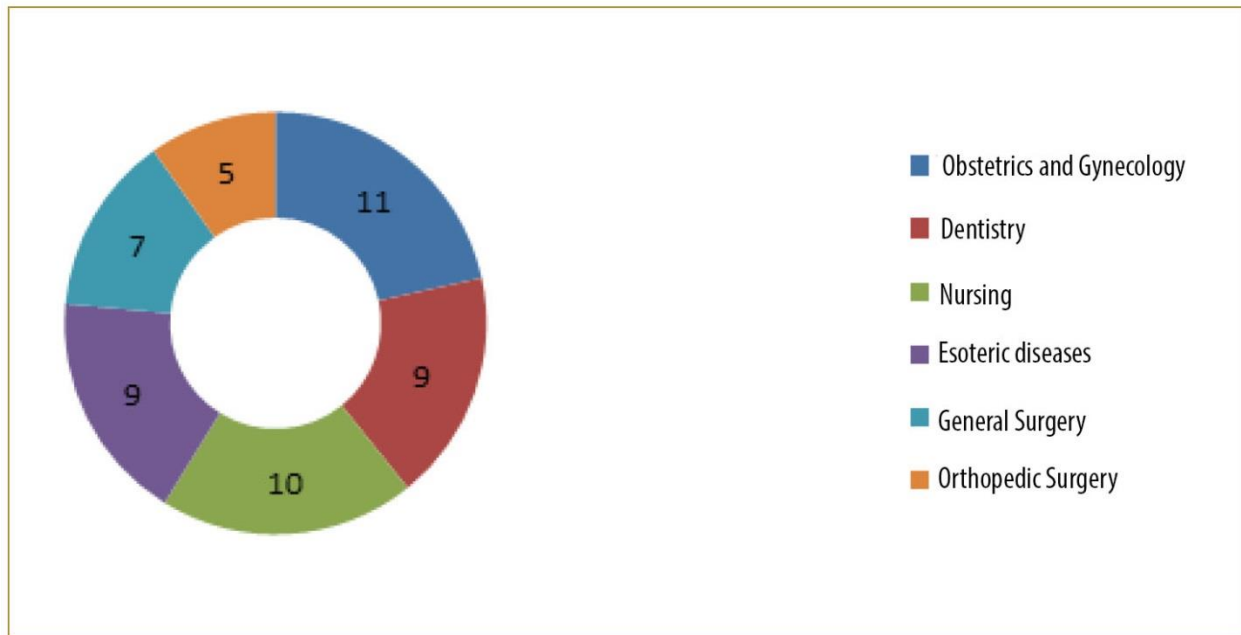


**Graph no. (11) Complaints According to the Health Sector in the year 2015**



Graph no. (12), shows most specialties complained against most to least: Obstetrics and Gynecology, Nursing, Dentistry & Esoteric diseases, General Surgery and Orthopedic Surgery.

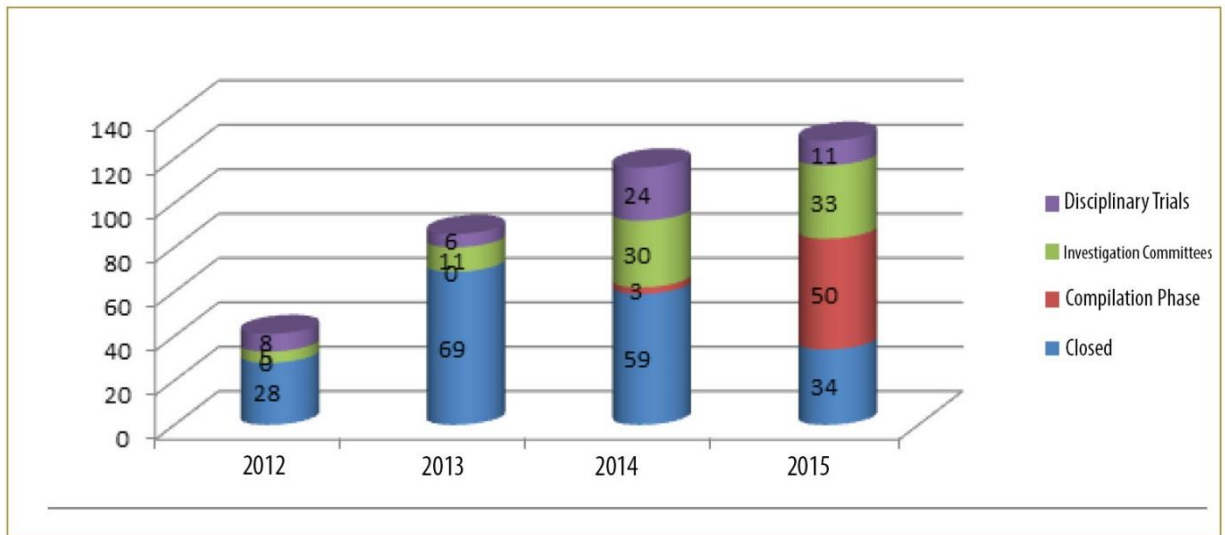
**Graph no. (12) Specialties complained against**



<b>The other Specialties complained against include the following:</b>	
Specialty	No. of Complaints
Prescription of drugs under control	6
Ear, Nose and Throat	3
Emergency Medicine	4
Ophthalmology	2
Neurosurgery	2
Pediatrics	3
Primary healthcare	2
Dermatology	1
Cardiology	1
Anesthesia	1
Pharmaceutical	1
Physiotherapy	1
Ethics	1
Radiology	1
Other specialties	28

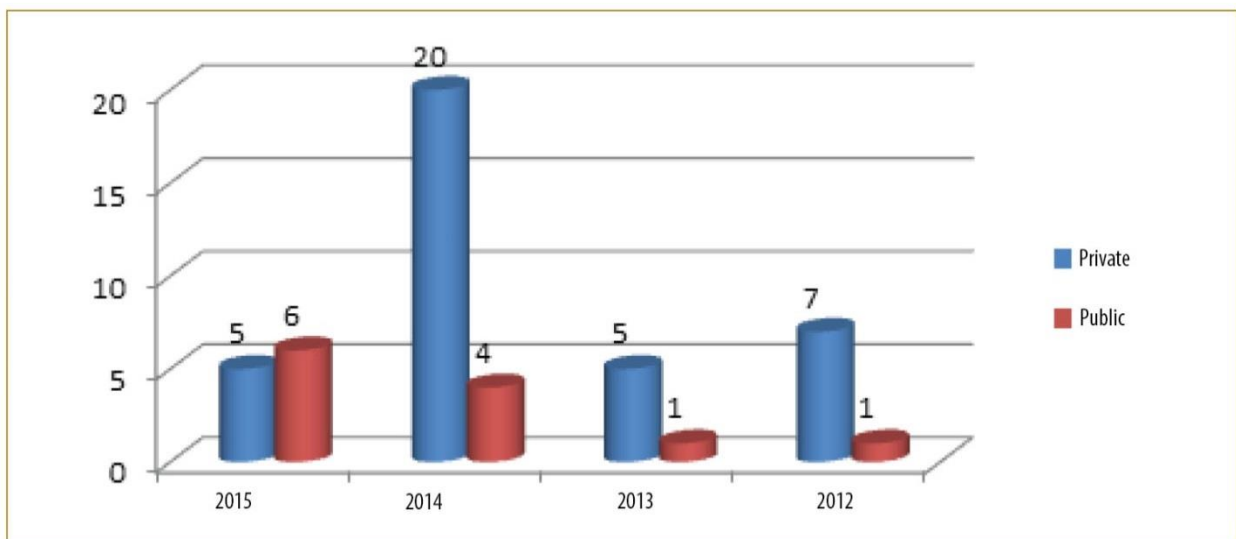
Graph no. (13), shows the phases of medical complaints investigations. Thirty four (34) complaints have been investigated and closed while thirty three complaints (33) are still under investigation. In addition, the necessary documents are still being collected for (50) complaints while (11) complaints were raised to the disciplinary committee in order to take the necessary disciplinary action.

**Graph no. (13) Phases of Complaints' Investigation in 2012 - 2015**



By auditing the disciplinary cases filed against health professionals, and classifying them to private and public sectors, it was clear that (6) disciplinary accountability cases were filed against professionals in the public sector, while (5) disciplinary accountability cases were filed against professionals in the private sector, as indicated in the Graph no. (14)

**Graph no. (14) Disciplinary Accountabilities according to the Health Sector**

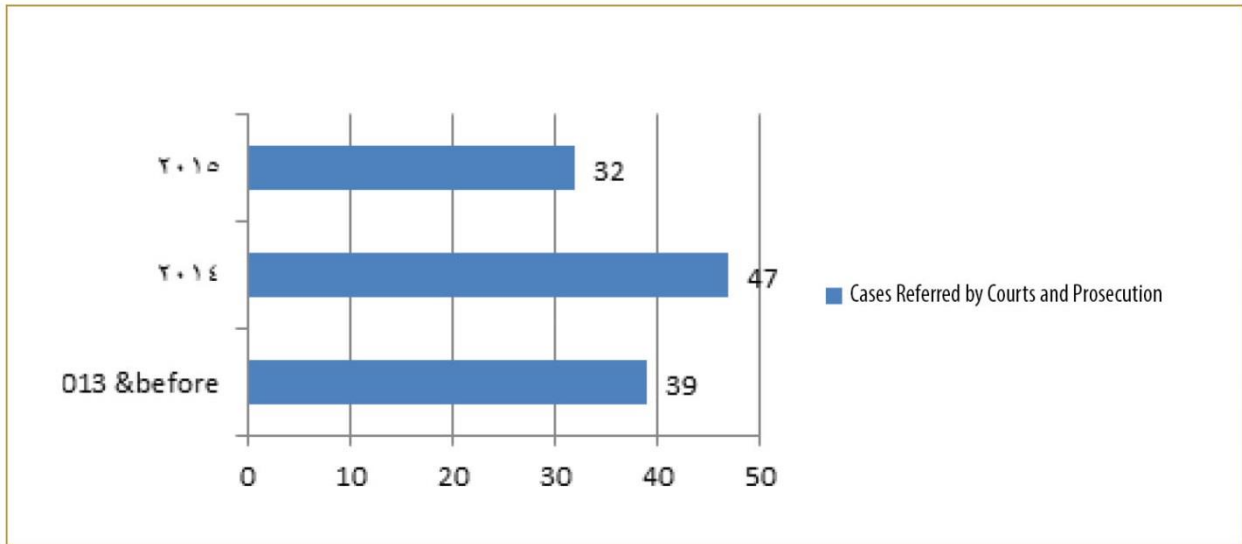


- **Cases Referred by Courts and Public Prosecution:**

Cases are referred to NHRA by courts of different degrees in the Kingdom of Bahrain, the Public Prosecution, and the Military Prosecution to determine whether there is a medical error or not.

The number of cases referred from those bodies since the beginning of 2015 until November 2015 amounted to thirty two cases (32) as indicated in Graph no. (15)

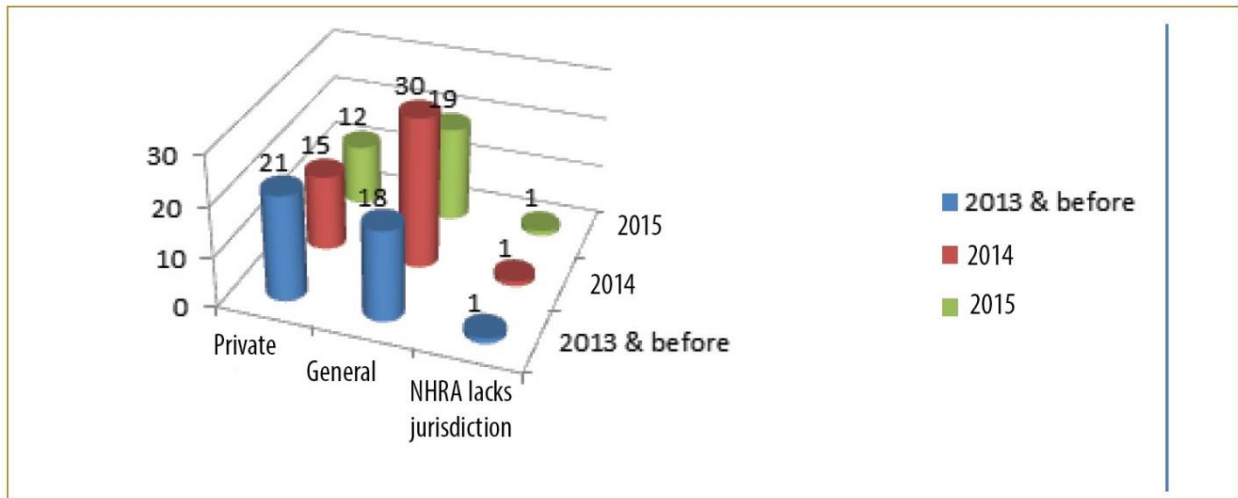
**Graph no. (15) Cases Referred from Courts and Prosecution**



Upon examination of the cases according to the sector complained against, they are classified as per the classification indicated above (public and private sectors) as shown in Graph no. (16).



**Graph no. (16) Cases According to the Health Sector**



## ➤ Medical Devices and Equipment

The number of devices and medical equipment imported to the Kingdom of Bahrain during the 2015 amounted to approximately one million device and equipment, with a ratio of 80,000 device and equipment monthly.

NHRA has registered 10,000 new device and equipment; while around 40 devices were prevented to be imported as these devices do not comply with the standards and regulations; or were withdrawn by the USFDA (Food and Drug Administration Authority) in the United States.

Coordination is made to link NHRA with the Electronic costumes release System (OFOQ) to facilitate the procedures of importing medical devices and equipment.

## ➤ Clinical Research Unit

The Clinical Trials Unit is concerned with issuing approvals to conduct clinical trial and monitor the implementation of such trials. In particular, the Unit is performing the following functions:

- 1- Receiving the requests of approvals issuance required to conduct the clinical trials; and submitting the required documents and information.
- 2- Examining the requests of approvals issuance required for conducting the clinical trials and referring them to the Clinical trials Committee, to raise its primary recommendations thereof to the Chief Executive Officer, take the necessary actions concerning the approval, or rejecting the request, and conducting a detailed examination.

The Unit was just activated in October this year, by appointing Director for the Unit and forming the Clinical Trials Committee by a resolution issued from the Chief Executive Office. The Committee was formed to undertake the examination of the clinical trilas applications referred to by the Chief Executive Officer and raise the necessary recommendations. The committee is formed of representatives from the academic sectors in the Kingdom.

The committee is currently examining three clinical cases until the date of this report.

## Human and Financial Resources Department

The Human and Financial Resources Department is concerned with running and regulating the affairs of NHRA relevant to the functional positions of staff. In addition, it is concerned with running and regulating NHRA's financial affairs, providing the necessary requirements for NHRA to practice its functions, in coordination with the concerned bodies. In addition, the department provides NHRA with the necessary materials, equipment, devices, computers and electronic programs, with their annexes and accessories. The department takes the necessary actions to maintain and utilize them perfectly and issue contracts, follow up the implementation of these contracts, in collaboration with the concerned bodies in NHRA.

### MOST PROMINENT ACHIEVEMENTS OF THE DEPARTMENT:

- Developing Clinical Trail Unit.
- Amending the Medical Complaints Unit in the organizational structure of the NHRA.
- Developing "Health Inspector" job in Health Facilities Regulatory Department of the NHRA.
- Increasing recruitment with the percentage of 37% during the year so that the total number of employees in NHRA became 59 employees.
- Optimizing the usage of the available human and financial resources, while maintaining quality and efficiency of work.
- Collecting the government debts from the Ministry of Health in favor of health professionals for the last years.
- Completion of Information Technology set up Project.
- Preparation of NHRA's financial regulation project.
- Signing public relations contract with Ertiqa Company.
- Introducing digital queuing system to manage the queue of clients in NHRA.
- Formation of the main committees concerned with the human resources in the NHRA; such as: Equal Opportunities Committee, Training and Development Committee, Bonus and Reward Nominations Review Committee.

## RECOMMENDATIONS OF FINANCIAL AND ADMINISTRATIVE AUDIT COURT- 2015

Based on the recommendations of the Financial and Administrative Audit Court and to overcome the challenges, NHRA has developed a plan to implement these recommendations for 2015. The plan includes three phases; short-term, medium-term and long-term. NHRA has worked on implementing the recommendations mentioned in the two reports as follows:

- 1- Correction of all violations related to licensing profession practice.
- 2- Restudying NHRA organizational structure and raising the proposals of amendment to the Supreme Council of Health.
- 3- Give NHRA'S inspectors the capacity of being judicial officers in order to monitor violation and take legal actions against those violations.
- 4- Develop a mechanism to issue periodic reports and statistics that reflect the inspections performed by NHRA and the results of these works on all those who are subject to its law.
- 5- Develop a mechanism in coordination with the prosecution to follow up the different cases filed against health professionals licensed by NHRA, in order to activate the disciplinary accountability procedures towards them.
- 6- Develop a register in which these reports and statistics are recorded to allow NHRA to assess the performance of this activity according to the accredited indicators and standards.
- 7- Develop an annual inspection plan for inspection campaigns for all the governmental and private health institutions under NHRA's control.
- 8- Develop unified forms for violation records and standardized and comprehensive inspection reports.
- 9- Develop a policy for Complaints Unit to define its tasks and procedures.
- 10- Develop the necessary regulations, rules and procedures of committees working in NHRA.
- 11- Study the reasons of drugs registration delay, and issue resolutions to facilitate the registration of drugs.

12- Sign an agreement between NHRA and the medical waste company to indicate the rights, duties, and responsibilities of both parties, as well as the stipulations for disposal of drugs and pharmaceuticals.

13- Prepare survey list that includes all medical and legal regulations and requirements upon carrying out inspections, in a way that guarantees inspection effectiveness.

## **FUTURE PLAN FOR DEVELOPMENT OF NHRA:**

NHRA, in the next phase, will work on the improvement and development of its procedures to be in line with the developments in the health sector through developing and issuing many resolutions, regulations and procedures related to regulate, licenses and asses; whereby, NHRA will seek to implement the following in the coming phase:

1- Develop a strategic plan for NHRA for the coming five years that aims to complete the administrative and legal system of NHRA, to perfectly perform its mission.

2- Develop media plan to spread awareness about NHRA, its role, duties and responsibilities assigned to health professionals, citizens, investment companies and private sector.

3- Review NHRA's current organizational structure and determine the human resources requirements to fill the available vacancies, and modify the structure to match NHRA's assigned tasks; such as: developing unit or independent section to be concerned with the management of inspections over all professions, health institutions, and section for safety and medical devices.

4- Review NHRA's operational budget and raise proposal for its amendment.

5- Prepare draft of by-laws to regulate the workflow in NHRA, which includes regulation of all administrative work, the powers authorized for NHRA officials and the procedures that must be taken for practicing those responsibilities.

6- Prepare draft of NHRA's financial by-laws in collaboration with the Ministry of Finance.

7- Prepare regulation draft of technical regulations and standards required for licensing private health facilities and their classification.

8- Prepare draft of professional standards regulation required for licensing the health professionals.

- 9- Prepare draft of executive regulation for law of practicing pharmaceutical profession, the pharmaceutical centers.
- 10 -Prepare a resolution draft to regulate technical standards for fertility centers.
- 11 -Prepare resolution draft to regulate technical standards for alternative medicine.
- 12- Raise proposal with categories of fees accrued on services and license requests, in coordination with the Ministry of Finance to be approved by the cabinet.
- 13 -Develop conditions and standards to define types and categories of the private health facilities, which should have insurance policy for errors of profession, or those of any medical, technical, nursing crews operating in the facility.
14. Formation of accountability committee for the private health facilities by ministerial decree.
- 15 -Prepare a list of the committees mandated by NHRA law and laws of practicing professions, and form committees for which no resolution were taken to establish them.
- 16- Develop a system to approve the hours of continuing professional development for health professionals, and link it with the licenses renewal.
- 17 -Develop regulations and codes of ethics for health professions.
- 18 -Develop procedures and requirements to apply for licensing clinical trials.
- 19 -Approval of the guideline for classification of pharmaceuticals and healthy food.
- 20 -Development of new medicines registration procedures.
- 21 -Determine the controlled drugs list to be permitted in private clinics
- 22 -Issuing the allied health professions list by a resolution from the cabinet.
- 23- Issuance of license regulations to practice the alternative and complementary medicine professions, and licensing alternative and complementary facilities.
- 24 -Developing standards for quality assessment of health services, and performance measurement indicators of private health facilities, according to the best practices recognized internationally. And issuing a resolution indicating the processes and mechanisms of auditing and assessing health services quality and performance levels of private facilities.
- 25 - Setting comprehensive electronic system to manage all NHRA's data; including licenses records of professions and health facilities, complaints and violations register, and method of printing out the licenses.

26- Setting an electronic system for licensure exams.

27- Setting an electronic link with Customs Department to facilitate importing medical devices and supplies.

28- Reviewing rules and procedures proposed by the Irish Consultation Company.

29- Amending laws or previous resolutions and prioritize them according to importance and urgency.

30-Completing the legislative system of NHRA, preparing the legislative and legal resolutions and regulations required for NHRA to perform its duties.

البحرين الوطنية للتأمين الصحي والخدمات الصحية

أخبار الوطن 6

## الجاهزة: 3500 ترخيص جديد و5580 مزاول للمهن الصحية في 2015

130 شكوى طبية و32 قضية محالة لتحديد وجود خطأ من



1034 منشأة صحية  
35230 مزاول  
132 مؤسسات صحية  
425 ترخيص

رئيسة اللجنة التنفيذية للهيئة الوطنية للتأمين الصحي والخدمات الصحية

## الرئيسة التنفيذية للهيئة الوطنية للتأمين الصحي والخدمات الصحية

1034 منشأة صحية  
35230 مزاول  
132 مؤسسات صحية  
425 ترخيص

رئيسة اللجنة التنفيذية للهيئة الوطنية للتأمين الصحي والخدمات الصحية

## التشريعات الجديدة نقلة نوعية في تطوير القطاع... الجاهزة: أكثر من 5 آلاف مزاول للمهن الصحية في

الهيئة الوطنية للتأمين الصحي والخدمات الصحية

## الجاهزة: 1034 منشأة صحية وأكثر من 5000 مزاول للمهن الصحية خلال العام 2015

130 شكوى طبية و32 قضية محالة لتحديد وجود خطأ من



1034 منشأة صحية  
35230 مزاول  
132 مؤسسات صحية  
425 ترخيص

رئيسة اللجنة التنفيذية للهيئة الوطنية للتأمين الصحي والخدمات الصحية

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رئيسة اللجنة التنفيذية للهيئة الوطنية للتأمين الصحي والخدمات الصحية

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الهيئة الوطنية للتأمين الصحي والخدمات الصحية



Barbican Insurance Association (BIA) members met officials from the National Health Regulatory Authority (NHRA) at its headquarters in Beirut. The BIA delegates, led by medical commission chairperson Dr. Marwan Moutaheb, discussed the National Health Insurance Plan (NHIP) with NHRA officials, including NHRA CEO Dr. Al-Sayid, third from right. BIA members and NHRA officials at the meeting.



عدد 5

صحة 2057 وطبياً  
مهلاً معاولاً  
به، بلغت 500 طلباً لإنشاء  
جدة جديدة، 2015  
جوازاً جديداً وتجديد  
1400 مستخدماً.

## أخبار البحرين

**Call for health institutions**  
THE National Health Regulatory Authority received 500 new requests this year for the establishment of health institutions, revealed the authority's professions and health services head Dr Mariam Al Jalalima. She said the authority has issued 3,500 new licences and has 2,057 licensed doctors.

# المهنة والخدمات الصحية؛ وأكثر من 2000 مزاوول ساونة بالبحرين هذا العام

البلاد 6  
عدد 27 ديسمبر 2015  
1437 هـ الموافق

أجرتها "المن" بإشراف لجنة متخصصة وشملت 150 سؤالاً متنوعاً

## امتحانات لـ 265 طبيباً... والنتائج نهاية الأسبوع

الإبادة الصحية.  
وكتبت أنه "سيتم إعلان النتائج مع  
نهاية الأسبوع الجاري لكل من اجتازت  
بدراسة التخصص الآدم، وستتلقى مستوى  
الاجتياز استناداً في تطوير الامتحانات  
القائمة".  
وذكرت أن لجنة متخصصة أقرت على  
الاجتياز، وتضم في عضويتها ألبا، يمكن  
من وزارة الصحة والمستشاري المنسكن  
والهيئة الوطنية لتقييم المنسكن والتفتت  
الصحية وروس في الامتحان أن يمكن طبيباً  
للقيام بالعمل.  
واقدم الرئيس التنفيذي في شام  
تدريجياً بالشكر الجزيل إلى كافة العلوم  
الصحية وجامعة الكويت العربية على دعمهم  
القيمة الإيجابية منها الامتياز.

الاجتياز - الهيئة الوطنية لتنظيم المنسكن  
والخدمات الصحية تلمت الهيئة الوطنية  
لتنظيم المنسكن والخدمات الصحية لرس  
(المنسكن) امتحانات ادر المنسكن من اولة جولة  
الطب الشرعي لرس من كليات الطب التي  
أولاً سنة الاجتياز يمثلها 265 طبيباً، حيث  
تقدم من لبة الامتحان 30 طبيباً.  
واوصت الرئيس التنفيذي للهيئة  
مريم النكامة، أن الامتحان جرى بسلاسة  
وسهولة، حيث أن هذا الامتحان كان اختبار  
مختلفاً من خطة الامتحان، فقد انصهر على  
الأسئلة المتعددة بالاختبارات الخط، وتضمن  
الاجتياز 150 سؤالاً متنوعاً، امتحانات على  
مسور وإبانات لأشعة وصور التصوير التفتت  
وسور الأبراس الجديدة، على أن يتم الاجتياز



من رئاسة الفريق طبيبك  
من سببته في خليفة  
التصالح لفة نوعية لا  
المنسكن الأ  
المنسكن برسك  
في المنسكن، وبما  
مفصلين عن الأ  
والطبياسة وال  
الصحية وال  
وغيرها  
هو كسك  
رئيسياً  
وإبانات  
المنسكن  
الهيئة  
www.nhra.gov.bh  
عدد 27 ديسمبر 2015، مساء 1437 هـ  
No 20 December 2015, Issue No. 2057

27 باب البحرين

## الهيئة الوطنية للمهنة والخدمات الصحية تحتفل بالأعياد الوطنية وعيد جلوس جلالة الملك



□ بمناسبة العيد  
الوطني المجيد  
وعيد جلوس جلالة  
الملك المفدى، نظمت  
الهيئة الوطنية  
للمهنة والخدمات  
الصحية احتفالاً بهذه  
المناسبة بمشاركة  
جميع موظفي الهيئة،  
تم خلاله رفع أعلام  
السمكة وصور  
القيادة الرشيدة،  
كما تضمنت عدداً من  
الشكرات المعبرة  
عن هذه المناسبة  
المجيدة.

2015

سنة العاصمات الصحية في  
ضم في حضوره يمكن من  
لكومية والمهنة والكاديمية  
جدة والدمج السن.  
المنسكن الأمل للصحة هو  
عليها، به، ويقدم رئيسها  
بإباناتها فنيا وإباناتها وإباناتها،  
رئيس المنسكن الأمل للصحة  
إ أعمال الرئيس التنفيذي.  
الهيئة أن الهيئة تخصص  
إسمة تطوير نظم الخدمات  
لصحية بالسمكة وإباناتها  
مواهبين والخدمات الصحية  
بحرين والخراج تطويرها بما  
مفاداً عالية والسلاسة والسرعة  
إباناتها في تطوير هذه الخدمات  
لنظام المنسكن أو القطاع  
فقط لأفضل لاسس العلمية  
ممارسة الصحية المعتادة في  
من.