## Chapter-8

## Adequacy and effectiveness of the regulatory mechanisms

National Health Accounts[1] (NHA) is a tool to describe health expenditures and flow of funds in both Government and private sector in the country. Focus of NHA is on describing (1) entities[2] that provide resources to spend for health goods and services in the health system (2) entities[3] receiving and managing funds from financing sources to pay for or to purchase health goods and services; (3) entities[4] receiving finances to produce/provide health goods and services and (4) use of funds across various health care services[5].

The data shows that expenditure was incurred through Government sector as well as private sector to provide health care. Thus, the role of Government is not limited to only Government hospitals but also to regulate the private sector hospitals, clinics, pharmacies, etc. in the healthcare sector. Therefore, the existence of a regulatory mechanism is important to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals and to ensure public health and welfare provided through health programmes.

Regulatory agencies thus monitor individual and corporate healthcare practitioners and facilities, inform the Government about changes in the way the healthcare industry operates, ensure higher safety standards and attempt to improve healthcare quality and follow local, state and federal guidelines.

Implementation of the following Acts have been covered in this audit:

- Clinical Establishment Act, 2010
- Haryana Private Health Sciences Educational Institutes Act, 2012
- Standards prescribed under National Medical Commission Act, 2019

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1 National Health Accounts (NHA) estimates for India for Financial Year 2018-19 released in year 2022.

2 (a) Union Government: 11.71 *per cent,* (b) Enterprises: 5.51 *per cent,* (c) Others: 2.03 *per cent,* (d) State Government: 19.63 *per cent*, (e) Local Bodies: 1.01 *per cent* and (f) Household Revenues: 60.11 *per cent.*

3 (a) Other Schemes: 5.07 *per cent*, (b) Private Health Insurance: 7.25 *per cent,* (c) Union Government: 11.30 *per cent,* (d) Government Health Insurance (GHI): 6.04 *per cent,* (e) State Government: 14.27 *per cent,* (f) Local Bodies: 2.84 *per cent* and (f) Out of Pocket Expenditure: 53.23 *per cent*.

4 (a) Providers of Preventive Care: 5.34 *per cent,* (b) Government Hospitals: 17.34 *per cent,* (c) Others: 2.49 *per cent,* (d) Private Hospitals: 8.69 *per cent,* (e) Patient Transport: 3.40 *per cent,* (f) Government Clinics: 7.75 *per cent,* (g) Private Clinics: 4.37 *per cent*, (h) Diagnostic Labs: 3.92 *per cent,* (i) Pharmacies: 22.60 *per cent* and (j) Admin Agencies: 4 *per cent*.

5 (a) Governance and Administration: 3.96 *per cent,* (b) Preventive Care: 9.44 *per cent,* (c) Other functions: 3.03 *per cent,* (d) Pharmaceutical and other medical goods: 22.49 *per cent,* (e) Patient transport: 3.50 *per cent,* (f) Inpatient Curative Care: 34.55 *per cent,* (g) Outpatient Curative Care: 18.86 *per cent* and (h) Lab and Imaging: 4.17 *per cent*.

- Policy for Establishment by self-financing (Private) Nursing Institutes/ Medical Colleges
- Haryana Nurse and Nurse Midwives Act, 2017
- Haryana State Council for Physiotherapy Act, 2020
- Drugs and Cosmetics Act, 1940 and Rules, 1945
- Bio-Medical Waste Management Rules, 2016
- Atomic Energy (Radiation Protection) Rules, 2004

## 8.1 Implementation of the Clinical Establishments Act and Rules in the State

The Central Government passed the Clinical Establishment (Registration and Regulation) Act, 2010 (Act No. 23 of 2010) (CEA, 2010) dated 18 August 2010. The aim of this Act was to provide registration and regulation of clinical establishment with a view to prescribe minimum standards of facilities and services which may be provided by them so that the mandate of Article 47 of the Constitution for improvement in public health may be achieved. GoI further framed the Clinical Establishment (Central Government) Rules, 2012 in May 2012. The Haryana Government, Health Department vide Haryana Clinical Establishments (Registration and Regulation) Adoption Act, 2018 (HCEAA, 2018) notified through a gazette notification dated 9 April 2018 adopted the CEA, 2010. Subsequently, vide notification dated 13 July 2018 the Haryana Government notified the Haryana Clinical Establishments (Registration and Regulation) Rules, 2018 (HCE Rules, 2018).

As per provision of Section 2(C) of the CEA, 2010, clinical establishment means a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include a clinical establishment owned, controlled or managed by (a) a Government or a department of the Government, (b) a trust, whether public or private; (c) a corporation registered under a central, provincial or state act, whether owned by the Government; (d) a local authority; and (e) a single doctor.

The deficiencies observed in implementation of CEA, 2010 and HCE Rules, 2018 are discussed in the succeeding paragraphs:

### 8.1.1 Registration of Private Clinics/Hospitals in the State under Clinical Establishment Act 2010 was restricted to Clinics/Hospitals with more than 50 beds

As per provisions of CEA, 2010, no person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act. CEA, 2010 provides for both provisional registration (without inspection) and permanent registrations (only after inspections). In case of provisional registration, the Act stipulates that the provisional registration certificate shall be valid only upto a period of twelve months from the date of issue of the registration certificate. Application of renewal of registration is to be made at least one month before the expiry of the existing registration certificate. Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration as prescribed by the Central Government as per CEA, 2010. In cases of clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond a maximum period of two years from the date of notification of standards, and they will have to apply for permanent registration thereafter.

It was observed that 268 private hospitals (more than 50 beds) and 330 diagnostic laboratories were provisionally registered in the State of Haryana as of December 2023. While adopting the CEA, 2010, the State of Haryana restricted the provision of registration to clinical establishments having more than 50 beds, thereby restricting its applicability. Accordingly, private clinical establishments which have bed capacity less than 50 beds are not being registered under the CEA, 2010, and are thereby out of its regulatory ambit. As such, the prescribed minimum standards of facilities and services cannot be ensured in unregistered clinical establishments having less than 50 bed capacity.

Further, it was noted that although the provisional registration certificates were being issued for a period of twelve months and the proforma of provisional registration certificate specified in the HCE Rules, 2018 mentioned that the registration was subject to the provisions of CEA, 2010 and the rules made thereunder, however no specific mention in respect of validity period of provisional certificate was made in the text of HCE Rules, 2018. Further, the condition that in cases of clinical establishments in respect of which standards have been notified by the Central Government provisional registration shall not be granted or renewed beyond a maximum period of two years from the date of notification of standards, was also not included in the HCE Rules, 2018. Further in these cases, they will have to apply for permanent registration thereafter which was only to be given after inspection and compliance with minimum standards.

Thus, the aim of the Act to provide registration and regulation of clinical establishment with a view to prescribe minimum standards of facilities and services was not fully achieved.

During the exit conference, Additional Chief Secretary (ACS), Health and Family Welfare Department stated (January 2023) that the recommendation of audit to extend it to cover all establishments in a phased manner would be considered.

### 8.1.2 Registration of Medical Diagnostic Laboratories (or Pathological Laboratories)

The Central Government had notified the minimum standards in respect of Medical Diagnostic Laboratories (or Pathological Laboratories) in May 2018. The main amendment in the said notification was the definition of minimum standards of facilities and services for diagnostic labs and a schedule detailing the basic requirements for various types of laboratories along with requirement of infrastructure, human resource etc. Section 23 of the Clinical Establishments (Registration and Regulation) Act, 2010 states that in case of Clinical Establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond:

i) A period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act.

ii) A period of two years from the date of notification of the standards for clinical establishments which came into existence after the commencement of this Act but before the notification of the standards; and

iii) A period of 6 months from the date of notification of standards for clinical establishments which came into existence after the standards have been notified.

It was noted that in continuation of the earlier legislations, the Government of Haryana issued a notification on 14 March 2019, vide which it was notified that the HCEAA, 2018 would also apply to all clinical establishments relating to diagnosis or treatment of diseases where any investigative or diagnostic services are carried out with the aid of laboratory or medical equipments. However, no minimum standards were prescribed for human resources or equipments required for the diagnostic laboratories.

The Health Department is continuing the provisional registration of the 330 laboratories in the State and has not registered them permanently even after the passage of more than four years from the date of notification of prescribed minimum standard for labs by the Central Government. It is pertinent to note

that where the clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond the time limit prescribed as per Section 23 of the said Act. However, the condition of permanent registration and accompanying inspections were not made mandatory in the Acts and Rules framed by the Haryana Government.

During the exit conference (January 2023) the ACS stated that about registration of pathological labs continuing provisionally beyond two years, the matter would be taken up with Government of India to allow permanent registration on their portal.

It was further stated that the State Council had noted the issue of non-acceptance of online payments in the Central portal and had directed to State Nodal Officer, State Clinical Establishment Act Cell to pursue the issue with GoI. However, no records were available with regard to communication by the Health Department and Central Clinical Establishment Authority to resolve the issue for initiating the permanent registration of laboratories.

Thus, quality assurance of the diagnostic labs cannot be ascertained in absence of minimum standards. The prescribed minimum standards of facilities and services cannot be ensured in unregistered clinical establishments. As permanent registration was only to be given after inspection and compliance with minimum standards, failure to make permanent registration mandatory resulted in all the labs being run with provisional registration. As such, it cannot be ensured whether or not the labs are following the prescribed minimum standards and the quality assurance of the test conducted by the labs cannot be obtained.

### 8.1.3 Functioning of State Clinical Establishments Council

According to the HCE Rules, 2018, the Government was required to constitute a State Council headed by a Chairman. The State Council is responsible for implementation of the CEA, 2010 and Rules in the State. It was also stipulated in the Rules that the State Council shall meet at least once in six months. The main function of the Authority (i.e State Council) under the HCE Rules, 2018 is to grant, renew, suspend or cancel registration of any clinical establishment, to enforce the provisions of the Act and Rules made thereunder etc.

Haryana State Clinical Establishments Council was constituted in September 2018 under the chairmanship of Administrative Secretary, Health Department. As already highlighted above, only provisional registrations were being done in the State and no minimum standards had been prescribed as of yet. Further, as against the minimum requirements of seven half-yearly meetings till March 2022, only one meeting of the Council could be held (February 2022).

The Department in its reply stated (October 2021) that the meetings could not be held due to the prevailing COVID pandemic. The contention of the Department does not hold good as no meeting was held even before onset of the COVID pandemic. The Health Department should take necessary action to conduct the meetings of the Council regularly.

## 8.2 Directorate of Medical Education and Research

The Directorate of Medical Education and Research (DMER) had been carved out of the Health Department as a separate Directorate in January 2009 for the upgradation and expansion of Medical, Dental, Ayurveda, Homeopathy and Para-medical education. Subsequently, a separate department of Medical Education and Research was established in September 2014.

The shortcomings observed in the regulatory role of DMER are discussed in the succeeding paragraphs:

### 8.2.1 Deficiencies in implementation of Haryana Private Health Sciences Educational Institutes Act, 2012

With a view to provide for the regulation of admission, fixation of fee and maintenance of educational standards in private health sciences educational institutes in the State of Haryana and for the matters connected therewith or incidental thereto, Haryana Private Health Science Educational Institutions (Regulation of Admission, Fixation of Fee and Maintenance of Educational Standards) Act, 2012 (HPHSEI Act) was notified on 11 April 2012. DMER discharges its duties and function regarding regulation of admissions, fee matters and examination in all medical institutions along with formulation of policies for ensuring quality medical education in the light of this act. Under the provisions of the Act, DMER has to ensure fairness and quality of education and safeguard the interest of students through periodical inspections and obtaining periodical returns from all institutions including Govt/private/ autonomous bodies and universities.

Audit observed that DMER had notified policies regarding medical colleges as per National Medical Commission (NMC) norms, prepared a draft medical education policy which is under approval, and carried out assessment works as per NMC norms, along with registration of medical practitioners. However, certain shortcomings were observed as given below:

i. As per Section 9 (3) of HPHSEI Act, 2012 the State Government may require a private institution to file such return, as may be prescribed or provide such information, as it deems appropriate in the interest of quality of education.

   It was intimated (May 2022) by DMER that no such timely returns have been submitted/filed by the private institutes and were obtained as and

when required. However, copies of the same were not provided to audit in support of the claim.

ii. As per provision of Section 16 of HPHSEI Act, 2012 inspection committee may be constituted for inspection of the affairs of private institutes to ensure the quality of education imparted and compliance with the extant provisions.

It was stated that an inspection committee was constituted in August 2018 for inspection of all medical educational institutions under the purview of DMER. It was further stated that although only one inspection was carried out by the Government during the period 2016-17 to 2021-22, annual inspections are being carried out by the respective universities.

iii. Section 10 of the Act provides for the facility to receive complaints and initiate enquiries into the allegations and impose fines or take appropriate action.

It was noticed that during the year 2021, 118 complaints were received and 66 were settled and 52 are still under process. In 2022, (till June 2022), 87 complaints were received and 38 had been settled, while 49 were still pending to be processed. However, for the period 2016 to 2020, no such information with respect to complaints and disposal thereof was available with the office.

### 8.2.2 Establishment and infrastructure of Medical Education Institutes

The National Medical Commission Act (NMC), 2019 provides for a medical education system that improves access to quality and affordable medical education, ensures availability of adequate and high-quality medical professionals and enforces high quality and ethical standards in all aspects of medical services. In exercise of the power conferred by Section 57 of NMC Act, 2019 (30 of 2019), the "Minimum requirements for annual M.B.B.S Admissions Regulations, 2020" were notified on 28 October 2020. The main objective was to prescribe the minimum requirements of accommodation in the medical colleges and institutions and their associated teaching hospitals, staff (teaching and technical) and equipment in the college department and hospitals.

As per norms every medical college/ institute approved for MBBS admissions shall have 24 departments. Every approved medical college shall have the required area, accommodation for staff and equipment for each department as given in Schedule I, II and III prescribed with regulations. The medical college should be established with an annual intake capacity of 100/150 students and can be increased to 150/200/250 MBBS admissions annually, as per the prescribed phase-wise requirements. As per the above minimum requirement regulations prescribed by the NMC, the institutes complying with terms and

conditions and qualifying the minimum standards can only be designated/graded as recognised. A checklist was prepared by Audit on infrastructure and other basic amenities in the educational institutes (Medical Colleges) required as per norms of Schedule I, II and III of NMC Act, 2019 and information in this checklist was collected from the medical colleges of the State.

It was noted during audit that in pursuance of these regulations, only six out of the 12 medical colleges were recognised in the State. DMER intimated (January 2023) that the number of recognised institutes has increased to eight.

However, non-availability of infrastructure and other basic amenities were observed in four educational institutes (Medical colleges) which were required as per norms of NMC Act, 2019. The position is shown in ***Table 8.1***.

**Table 8.1: Status of facility not available in four colleges as on May 2022**

| Name of college | Particular as per schedule 1,2,3 of NMC ACT, 2019 | Requirement as per provision | Actual position in Institute |
|---|---|---|---|
| MCH Nalhar, Nuh | Department | 24 Department | 21 Department |
| | Skill lab | 600 sq. meter | Under process |
| GMCW Khanpur Kalan, Sonipat | Department | 24 | 22 |
| | Pharmacology practical lab | 8 | 3 |
| | Skill lab | 600 sq. meter | Under construction |
| | Gymnasium and synthetic Track | Must be available | Under construction |
| | BMW management | Must be available | Being done but Bar coding is under process |
| | Child Care Centre | Must be available | Under process |
| KCGMC, Karnal | Department | 24 | 21 |
| | Cafeteria and gymnasium | Must be available | Not available |
| | BMWM | Must be available | Certificate only available till 31 March 2022 and renewal awaited |
| | Child Care Centre | Must be available | Not available |
| Sh. A.B. Vajpayee Govt. Medical College, Faridabad | College Council<br>Skill lab of 600 sqm | Must be formed | Not formed |
| | Medical education unit | Must be formed | Not available |
| | Child Care Unit | Must be formed | Not formed |
| | OPD FOR 8 Patients | Must be formed | Under process |
| | Gymnasium/sports complex | Must be formed | Not available |
| | Close circuit television | Must be formed | Under process |

**Source: Information supplied by DMER**

## 8.3 Functioning of State Nursing Council

Haryana Nurses Registration Council was constituted as an autonomous body by Government of Haryana in the year 1973. Thereafter, Haryana Government constituted 'Haryana Nurses and Nurse-Midwives Council' in March 2017 with its headquarters at Panchkula, under a new Act viz. "Haryana Nurses and Nurse-Midwives Act, 2017". This Act provided for the constitution of the Haryana Nurses and Nurse-Midwives Council for registration of Nurses, Nurse-Midwives and for the registration of institutions imparting training and prescribing qualifications to such institutions and for matters connected therewith or incidental thereto.

It was noted that the Council was carrying out the functions of registration of courses, institutes and nurses along with conduct of exams. However, the

Council was found wanting in case of carrying out the inspections of the respective institutes.

As per section 26 of the Act, the Council may conduct periodical inspections and appropriate enquiry to ensure the maintenance of required standards. Further as per section 27, in case of failure to comply with terms and conditions of the recognition, the Council may withdraw such recognition. As per the decision in the 44th General Body Meeting held in January 2020, the Council decided to inspect the nursing institutes every three years instead of every year. However, it was noticed that after enforcement of Haryana Nurse and Nurse Midwives Act, 2017, only one inspection was conducted in May 2018. The next inspection which was due to be conducted in 2021, was not conducted. Thus, in the five-year period (2017-2022), only one inspection could be conducted.

In its reply (May 2022), the Department informed that though the inspection was due to be conducted in 2021 but since the Nursing policy of 2019 has been amended by the State Government in 2021 and the amended policy is under litigation, the Department could not decide whether the Nursing policy 2019 or the Nursing policy 2021 is to be followed for taking any action.

## 8.4 Functioning of State Council for Physiotherapy

The State Government notified the "Haryana State Council for Physiotherapy Act, 2020" in March 2020. This Act provided for the constitution of 'Haryana State Council for Physiotherapy' for the purpose of registration of physiotherapists, recognition of training institutions and for coordination and determination of standards of education in the field of physiotherapy.

The main function of the Council is to regulate the practice of profession by persons with recognised physiotherapy qualification and to maintain the register of physiotherapists for Haryana. As per provision 21(2) of the Act, any recognised university or institution in India other than the State of Haryana which grants qualifications in Physiotherapy may apply to the Council seeking recognition of the physiotherapy qualification being imparted by them. The Council shall further submit the proposal to the Government along with its recommendation to grant recognition to the physiotherapy qualification provided by such recognised university or institution, by notification in the official gazette.

During audit, it was observed that proposal for constitution of members as per provisions contained in Sections 3 and 4 of Haryana State Council for Physiotherapy Act, 2020 had been sent to Government (September 2022). Since the constitution of the Council was under process and was pending at the level of the State Government, no meeting was conducted till the date of audit although the function of registration of practitioners was being carried out. In the absence of records, it could not be ensured in audit as to whether or not the functions related to recognition of physiotherapy institutions were being carried out.

During the exit conference, Registrar, Director, Haryana State Council for Physiotherapy stated that now the Council has been constituted and one meeting has been conducted **(**December 2022**)**.

## 8.5 Director General of Ayush

In Haryana, the registration of Ayurveda and Unani practitioners is regulated by the Council of Indian Medicine, Haryana under the Punjab Ayurvedic and Unani Practitioners Act, 1963[6], which was notified on 13 December 1963. It was framed to consolidate and amend the law relating to registration of Practitioners of Ayurvedic and Unani System of Medicine and to regulate the practice in such systems.

Similarly, Punjab Homoeopathic Practitioners Act, 1965[7] regulates the registration of Homeopathy Practitioners in the State, and was notified on 18 June 1965. This Act was framed to regulate the qualifications and to provide for the registration of Practitioners of Homeopathic System of Medicine in the State of Haryana.

**(A)** GoI notified the National Commission of Indian System of Medicine Act, 2020 (NCISM) on 21 September 2020, to provide for a medical education system that improves access to quality and affordable medical education and ensures availability of adequate and high-quality medical professionals. It was noted that although this Act extended to the whole of India, the notification regarding implementation of the Act in the State of Haryana was still under consideration of the State Government (July 2022). Thus, the Ayurveda and Unani practitioners still continue to be regulated by the Punjab Ayurvedic and Unani Practitioners Act, 1963 in the State of Haryana.

As per provision of the Punjab Ayurvedic and Unani Practitioners Act, 1963, there should be a Council consisting of a Chairman and 11 other members, for carrying out the provisions of the Act. Out of 11 members, four members would be appointed by the State Government and the remaining seven members would be elected by the registered practitioners amongst themselves. The tenure of the Council would be five years from the date of its first meeting.

The first meeting of the current Council was held on 28 May 2014 and hence its tenure ended on 27 May 2019. However, the election of members of the Council could not be held up to July 2022, and the incumbent Council members were carrying out the various official functions.

As per provisions of the Act the Council would appoint a Registrar, whose main function was to maintain a register of practitioners in the prescribed form containing the name, address and qualifications of every registered practitioner

[6] Punjab Ayurvedic and Unani Practitioners Act 1963 is also applicable in Haryana.

[7] Punjab Homoeopathic Practitioners Act 1965 is also applicable in Haryana.

together with the dates on which qualifications were acquired. Further, every registered medical practitioner should get his registration renewed within one month of expiry of the period of 5 years of registration. If the registration is not renewed as per the prescribed provision, the name shall thereafter stand removed from the register. It was observed that although registrations were being carried out, there were deficiencies in the renewal process. It was intimated (July 2022) by the Registrar that 276 practitioners who had been registered during the year 2016-17, were required to get their registrations renewed in the year 2021-22. However, till January 2023, only 155 registrations had been renewed and the remaining 120 practitioners did not apply for renewal. As no follow-up by way of inspections etc. was carried out with regard to these 120 pending renewals, it could not be ascertained in audit as to whether these practitioners had continued to operate without compliance of the requisite registrations and associated regulations.

In relation to the notification regarding full implementation of NCISM Act, 2020 in the State, the Council replied (July 2022) that there already exists a Council, however, the notification regarding implementation of NCISM Act, 2020 is yet to be issued by the State Government. It was further stated that the matter of election of members was under active consideration by the Government. With regard to the pending renewal of 120 practitioners, Department accepted that these practitioners are required to be renewed.

**(B)** GoI notified the National Commission for Homeopathy Act, 2020 (NCH) on 21 September 2020, with the purpose to provide for a medical education system that improves access to quality and affordable medical education and ensures availability of adequate and high-quality medical professionals in the field of homeopathic medicine. It was noted that although this Act extended to the whole of India, the notification regarding implementation of the Act in the State of Haryana was still under consideration of the State Government (July 2022). Thus, the Homeopathic Practitioners continue to be regulated by the Punjab Homoeopathic Practitioners Act, 1965 in the State of Haryana.

As per provision of the Punjab Homeopathic Practitioners Act, 1965 there should be a Council consisting of a Chairman and 11 other members, for carrying out the provisions of the Act. Out of 11 members, three members would be appointed by the State Government and the remaining eight members would be elected by the registered practitioners from amongst themselves. The tenure of the Council would be five years from the date of its first meeting.

The first meeting of the current Council was held on 18 July 2016 and hence its tenure ended on 17 July 2021. However, the election of new Council members was not initiated yet, and the incumbent council was carrying out the various official functions of registration and regulation of the practitioners.

During the exit conference, the Department stated (January 2023) that the appointment of Chairman and other members was in process.

## 8.6 Drug Controller of the State- Non-achievement of targets fixed for inspection

Department of Food and Drug Administration was carved out as an independent department from the Health Department in Haryana in January 2011 for more effective administration of Food Standard and Safety Act 2006 and Drugs & Cosmetics Act, 1940 and Rules, 1945. These statutes are aimed at ensuring supply of quality medicines, cosmetics and foodstuff to the public at large at affordable prices and also safeguarding the unwary public from misleading advertisement of drug/food articles and drugs abuse. Prior to this, food and drugs control programme in the State was functioning under the Director General Health Services.

As per provisions contained in Drugs and Cosmetics Act, 1940, District Drug Control Officer (DCO) has to conduct inspection of retail and wholesale firms for further quality analysis. Information supplied by the Department revealed that there had been shortfall in the achievement of targets fixed for inspections to be conducted by the DCOs.

The percentage of shortfall in achievement of targets fixed for inspection is shown in ***Table 8.2***.

**Table 8.2: Shortfall in achievement of targets fixed for inspection**

| Year | Sanctioned Strength of DCOs | DCOs in position | Annual target for inspection | Achievement | Shortfall | Shortfall (In *per cent*) |
|---|---|---|---|---|---|---|
| **2016-17** | 46 | 18 | 20,040 | 9,406 | 10,634 | 53% |
| **2017-18** | 46 | 16 | 20,040 | 11,772 | 8,268 | 41% |
| **2018-19** | 46 | 15 | 20,040 | 13,273 | 6,767 | 34% |
| **2019-20** | 46 | 15 | 22,524 | 20,290 | 2,234 | 10% |
| **2020-21** | 46 | 14 | 22,524 | 18,058 | 4,466 | 20% |
| **2021-22** | 46 | 12 | 22,524 | 16,611 | 5,913 | 26% |

**Source: Departmental information**

It is evident from the table that there has been shortfall in achievement of targets fixed for inspection to be conducted by DCOs which ranged between 10 *per cent* and 53 *per cent* mainly due to shortage of DCOs.

The Commissioner, Food and Drugs Administration Haryana, Panchkula while accepting the audit observation stated (January 2023) that the main reason for shortfall in achievement of targets in the years 2016-17 and 2017-18 was shortage of Drugs Control Officers in the Department. However, the reply was silent about the remaining period.

## 8.7 State Pharmacy Council

State Pharmacy Council is a statutory body constituted under the Pharmacy Act, 1948 (Central Act) which extends to the whole of India. As per the Act, the State Council should be constituted which will consist of a total of 15 members (seven elected members[8]; five members nominated by State Government and three ex-officio members[9]).

As per information supplied by the State Pharmacy Council in exercise of the powers conferred under Section 19 of the Pharmacy Act, 1948 the State Government constituted the State Council (March 2014) with six elected members, five nominated members and three ex-officio members. Thus, the Council consisted of (as of July 2022) 14 members only, instead of the stipulated 15 members.

Further, as per provision of Section 26A of the Act, the Council with the prior approval of the State Government should appoint Inspector for inspection, to enquire, and investigate the complaints made in writing in respect of any contravention of the Act. It was observed that the Council had made no such appointments till June 2022. The Council in its reply informed that the proposal for appointment of pharmacy inspectors is under process (since January 2016) at the State Government level.

## 8.8 Bio Medical Waste Management

GoI in exercise of the powers conferred by the Environment (Protection) Act, 1986 and in supersession of Bio-Medical Waste (Management & Handling) Rules, 1998, published the Bio-Medical Waste Management Rules, 2016 (BMWM Rules, 2016) on 28 March 2016. These rules stipulate duties of the occupier or operator of a common Bio-Medical Waste Treatment Facility as well as the identified authorities. These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose or handle bio-medical waste in any form including a healthcare facility. The prescribed authority for enforcement of the provisions of these rules in respect of all the health care facilities in any State/Union Territory is the respective State Pollution Control Board (SPCB)/Pollution Control Committee.

As per BMW Rules, 2016 "Bio-medical waste" means any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities. "Bio-medical waste treatment and disposal

[8] Six from amongst themselves by registered pharmacists of the State and one from amongst themselves by the members of each medical council or the Council of medical registration of the State.

[9] Chief Administrative Medical Officer of the State; officer-in-charge of Drugs Control Organisation of the State & The Government Analyst defined under the Drug and Cosmetics Act, 1940, ex-officio, or such one as the State Government may appoint.

facility" means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment and disposal are carried out and includes common bio-medical waste treatment facilities. “Health Care Facility” (HCF) means a place where diagnosis, treatment or immunisation of human beings or animals is provided irrespective of type and size of health treatment system and related research activity. "Occupier" means a person having administrative control over the institution and the premises generating bio-medical waste. "Operator of a common bio-medical waste treatment facility" means a person who owns or controls a Common Bio-medical Waste Treatment Facility (CBMWTF) for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste.

During scrutiny of records of Haryana State Pollution Control Board (HSPCB), it was noted that the Department was publishing on its website the list of authorised HCFs with regard to BMW generation, treatment and disposal. Further, inspections of HCFs were being conducted regularly, along with conduct of co-ordination meetings with the Health Department and conducting awareness/ training programmes, to increase the awareness, adoption and compliance with the BMW rules. Further, while no specific grievance redressal mechanism with regard to bio-medical waste management was in operation, however, all types of complaints related to various types of pollution received through online portals such as CM Window, Public Grievance (PG) portal and Social Media Grievances Tracker (SMGT) portal were being disposed of after taking required action.

However, some shortcomings with regard to the authorisation and operation of HCFs were noticed and are discussed in the succeeding paragraphs:

### 8.8.1 Healthcare Facilities generating Bio Medical Wastes without obtaining authorisation from HSPCB

Bio-Medical Waste Management Rules, 2016 provides that every occupier or operator handling bio-medical waste, irrespective of the quantity shall apply to HSPCB, for grant of authorisation, who shall grant the provisional authorisation. Further, these rules provide that every occupier or operator of common bio-medical waste treatment facility shall submit an annual report to the prescribed authority on or before the 30$^{th}$ of June of every year, giving the details of the respective treatment facility including location, waste quantities generated etc. This information is to be compiled, reviewed and analysed for the whole State and sent to the Central Pollution Control Board (CPCB).

During scrutiny of records, it was noted that there were many HCFs which were in operation without applying for the authorisation from HSPCB. It was further noted that all the authorised HCFs were not submitting the annual reports. As per annual reports available on the website of HSPCB, year-wise details of such HCFs are shown in ***Table 8.3***.

**Table 8.3: Operation of unauthorised HCFs during the years 2016 to 2022**

| Year | Total Number of HCFs in operation | Number of HCFs operating without authorisation | Percentage of HCFs operating without authorisation | Number of Occupiers who did not submit annual report | Percentage of cases of non-submission of annual report |
|---|---|---|---|---|---|
| **2016** | 3,167 | 24 | 1% | 294 | 9% |
| **2017** | 3,412 | 352 | 10% | 215 | 6% |
| **2018** | 4,079 | 133 | 3% | 157 | 4% |
| **2019** | 5,526 | 193 | 3% | 1,217 | 22% |
| **2020** | 6,320 | 157 | 2% | 2,332 | 37% |
| **2021** | 6,898 | 179 | 3% | 1,988 | 29% |
| **2022** | 7,107 | 169 | 2% | 2,281 | 32% |

**Source: Information taken from Annual Reports uploaded on the portal of HSPCB**
**Colour code: Color coding done on graded colour scale with red colour depicting most non-compliance; yellow colour depicting moderate non-compliance and green colour depicting least non-compliance.**

From the above table, it is evident that during the years 2016 to 2022, except for the year 2017, one to three *per cent* of the HCFs had been in operation without authorisation. There has been an average number of 166 HCFs operating without authorisation during the years 2018-2022. Further, it is also evident that compliance to the provision for submission of annual reports has deteriorated during the years 2019-2022. Range of non-submissions of annual reports varied from 22 *per cent* to 37 *per cent*, during the years 2019-2022 with an average of 1,955 units. This indicates an inadequate regulatory mechanism on Bio Medical Waste Management in the State.

In its reply, the Board informed (January 2024) that the number of non-applicant HCFs has reduced to 150. Show cause notices have been issued to the remaining violating HCFs. The next course of action will be initiated against the violators for which necessary directions are being issued to the respective regional offices of the Board. The fact remains that stringent action has not been taken by the Board for non-compliane of BMW Rules, 2016.

### *(i) Non-adoption of Bar code system*

As per Rule 8 of the BMWM Rule, 2016, bio-medical waste shall be segregated into containers or bags. Further, bar code and global positioning system shall be added within one year from the date of notification of these rules (i.e. from 28 March 2016).

The Board stated (June 2022) that 4,021 HCFs (out of 6,815 HCFs) adopted bar coding system till the month of June 2022 which was 59 *per cent* only, whereas it was required to be completed within one year after the date of notification (i.e. 28 March 2016).

In 2022, Board has started the process of implementation of the barcode system. However, the system is yet to be made fully operational.

### *(ii) Non-conduct of third-party inspection of the existing Common Bio Medical Waste Treatment Facilities*

Schedule-III of BMWM Rules, 2016 specifies that it is the duty of the SPCB to undertake and support third party audits of the common bio-medical waste treatment facilities (CBWTF) in the State.

During scrutiny of records of HSPCB, as per annual report submitted to the CPCB for the year 2021, it was noted that there were 11 CBWTFs in operation in the State but no third-party audit had been conducted so far. In this regard, it was stated (June 2022), that the Board was in the process of assigning third party audit to some reputed institutes. The fact remains that no third-party audit had been conducted for six years from the date of notification of the above rules.

## 8.9 License for imaging equipment and their operation

As per Rule 3 of Atomic Energy (Radiation Protection) Rules, 2004 (AERP Rules, 2004) issued by Department of Atomic Energy, Government of India, no person shall, without a licence (a) establish a radiation installation for siting, design, construction, commissioning and operation; and (b) decommission a radiation installation. Further, no person shall handle any radioactive material or operate any radiation generating equipment except in accordance with the terms and conditions of a licence. A license shall be issued for sources and practices associated with the operation of computed tomography (CT) and interventional radiology x-ray unit.

Government of Haryana (GoH) vide its notification Number 30/7/2002-6HBII dated 23 February 2005 and 49/40/2014-6BHII dated 10 July 2015 established the Office of Directorate of Radiation Safety (DRS) as an independent agency under the Health Department of Govt. of Haryana for implementing the Atomic Energy Act, 1962 and Atomic Energy (Radiation Protection) Rules, 2004. As per the notification, DRS will perform the following functions to implement the Act and Rules effectively:

i. To review the inspection report of each and every X-ray unit in the State submitted by authorised radiation safety inspector and after being satisfied with the safety status of the unit shall recommend to the Atomic Energy Regulatory Board (AERB) that it can be issued a registration number.

ii. Send a progressive report of activities of the DRS associated with the rules to AERB once in a six month period.

No records relating to inspections conducted at district level or progress reports being sent to AERB were found available with the Department, which reflects non-performance of duties and functions by DRS. The Department in its reply (June 2022) stated that necessary directions in this regard had been issued to all

the civil surgeons from time to time to ensure the compliance of AERP Rules, 2004. The reply is not tenable as there was no record available with the DRS regarding instruction issued to the Rediological Safety Officers (RSOs) at field level (Civil Surgeons) and also DRS did not conduct any inspection and never sent any scheduled compliance report/progress report to the AERB, which were required to be sent every six months.

## 8.10 Conclusion

While the Legislature has developed a statutory framework for regulation of the medical sector, implementation of the Rules by the Government was not effective. While adopting the CEA Act, 2010, the State Act was made applicable only to clinical establishments having more than fifty beds, and thus, private clinical establishments having less than 50 beds were kept out of the regulatory mechanism. Resultantly, the prescribed minimum standards of facilities and services cannot be ensured in these unregistered clinical establishments. Further, even after four years from the date of notification of minimum standards in respect of Medical Diagnostic Laboratories, the Health Department is continuing provisional registration instead of permanent registration. The functioning of other regulatory bodies was also not in full compliance of the respective acts, with issues of non-constitution of requisite councils, lack of regular meetings, irregular inspections, lack of monitoring etc. being noticed. Thus, the mechanism developed by the legislature to regulate the various constituents of medical sector remained ineffective as the Government did not implement the provisions in true spirit and the enforcement remained ad-hoc and perfunctory.

## 8.11 Recommendations

1. **Government should extend provisions of CEA, 2010 to all clinical establishments including both private hospitals and diagnostic laboratories in a phased manner.**

2. **Government may adopt the GoI standards notified for diagnostic labs and make permanent registration mandatory to ensure compliance with minimum standards as per CEA, 2010.**

3. **Government may take up the matter with GoI for resolving issues related to the online portal for permanent registration of Medical Diagnostic Laboratories.**

4. **Government may ensure that the targeted number of inspections of firms engaged in retail and wholesale selling/supply of drugs are carried out to ensure quality of the drugs sold.**

5. **Government may ensure that all utilities generating bio-medical waste comply with the provisions with regard to authorisation, bar coding, annual returns along with third party inspection to regulate the generation and disposal of bio-medical waste.**

6. **Government may ensure that the regulatory body of State Council for Physiotherapy is constituted as per the respective statutory norms.**

7. **Government may ensure that the various regulatory bodies may adopt an adequate and effective monitoring mechanism to guarantee conformity with the necessary minimum standards.**