Chapter VIII

Adequacy and Effectiveness of the Regulatory Mechanisms

Chapter VIII
Adequacy And Effectiveness Of The Regulatory Mechanisms

The Drug Regulatory mechanism was not efficient considering the shortfall in manpower to monitor the functioning of drug manufacturers and sales units. Autonomy was not given to Drug Control Administration, though recommended by the Dr. R.A. Mashelkar Committee. Though funds were provided by GoI for strengthening of Drug Regulatory System, GoAP did not release to Drug Control Administration in full. The State Level Authority constituted under Pre-Conception and Pre-Natal Diagnostic Techniques Act had inspected only two per cent of the registered centres during the five year period. Effluent Treatment Plants were not installed in the test checked HCFs. The Sewage Treatment Plants installed at Government General Hospitals, Srikakulam and Nellore were non-functional. Sewage Treatment Plants were not installed in any of the test-checked DHs and AHs. Bar coding system that tracks Biomedical waste was implemented partially.

8.1 Introduction

The role of regulatory bodies is to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals and ensure that public health and welfare are served by health programs. Regulations are necessary to standardise and supervise healthcare, ensuring that healthcare facilities extended comply with public health policies.

The purpose of regulation is to ensure access to health services, maintain quality standards, protect the rights of patients from opportunistic behaviour and ensure accountability of service providers. The most used instruments for regulations are Acts, laws, schedules, rules and regulations, *etc*.

Statutory Regulatory Bodies for Health care facilities include external agencies like Drug Control Administration (DCA) and Andhra Pradesh Pollution Control Board. Internal regulatory mechanism includes implementation of Andhra Pradesh Allopathic Private Medical Care Establishments (APAPMCE) Act and Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994. The implementation of these regulatory activities is discussed in the following paragraphs:

8.2 Drug Control Administration

The Drug Control Administration (DCA) regulates the manufacture, sale and distribution of drugs in the State by implementing the relevant legal provisions *viz*. Drugs and Cosmetics Act, 1940 and Rules 1945, Drugs and Magic Remedies (Objectionable Advertisement) Act,1954 & Rules, 1955, Drugs (Price Control) Order,

1995 & Essential Commodities Act, 1955 and AP Narcotic Drugs and Psychotropic Substances Rules, 1986 (for limited purpose).

The Government of India constituted an Expert Committee[202] to examine all aspects of regulatory infrastructure including the extent and problem of spurious/substandard drugs in the country. The Committee recommended (November 2003) that there should be one Inspector for 50 manufacturing units and one for 200 sales units. Further, a Committee constituted (2019) by GoAP on Health Reforms recommended strengthening the DCA with 150 Drug Inspectors.

8.2.1 Shortfall in inspections

As per the provisions of the Drugs and Cosmetics Act, 1940, Drug Inspectors (DIs) are required to inspect the manufacturing and sales units of drugs and cosmetics once in a year, to ensure compliance of conditions of license, *etc*., and also to draw drug samples for quality test.

Scrutiny of records revealed that out of the total 275 sanctioned posts of various cadres, 128 posts were vacant since May 2021. More importantly, 11 posts of Drug Inspectors (DIs) were lying vacant out of the sanctioned strength of 59. There are 42,283 sales and 384 manufacturing units, in the State. According to GoI's Expert Committee recommendations, there must be 211 DIs to cover all the sales units in a year. Thus, there was shortfall of 163 DIs (211 minus 48) in the State.

Further, Government had not taken steps to enhance even the strength to 150 as recommended by Health Reforms Committee appointed by GoAP (2019). Though, the Department submitted (May 2021) proposals to the Government, the Government did not take steps to increase the manpower.

Audit noticed that due to non-availability of required number of DIs, there was shortfall in number of inspections conducted ranging between 19.78 and 45.84 *per cent*. The shortfall in inspections was on increasing trend over the five year period, as there was no corresponding increase in manpower to match increase in number of sales units as shown in ***Table 8.1***.

Table 8.1: Number of inspections conducted during 2017-22

Year	Number of licensed units		Number of inspections		Shortfall in inspections (percentage)
	Manufacturing	Sale	to be conducted	Conducted	
(1)	**(2)**	**(3)**	**(4) = (2) + (3)**	**(5)**	**(6) = (4)-(5)/ (4)X100**
2017-18	237	34,070	34,307	27,522	19.78
2018-19	246	35,620	35,866	26,296	26.68
2019-20	286	35,555	35,841	25,174	29.76
2020-21	314	38,991	39,305	26,821	31.76
2021-22	384	42,283	42,667	23,110	45.84

***Source**: Information furnished by the Department*

[202] A Comprehensive examination of Drug Regulatory issues including the problem of spurious drug under the chairmanship of Dr. R.A. Mashelkar was constituted by GoI

Shortfall in the number of inspections would result in inadequate checks on the manufacturing and sale units.

Government accepted (August 2023) the audit observation .

The Drug Regulatory mechanism was not efficient considering the shortfall in manpower to conduct inspections on the functioning of drug manufacturers and sales units.

8.2.2 Autonomous status of the Drug Control Administration

The Committee appointed by GoAP recommended that the Drug Controller Administration must be an autonomous body like Food and Drug Administration on the lines of Maharashtra and Karnataka.

Audit noticed that the recommendation of the Committee was not implemented and DCA continued to be under the Department of Health Medical and Family Welfare.

Reply from the Government is awaited.

8.2.3 Strengthening of State Drug Regulatory System

To upgrade and strengthen the Regulatory system, a Central Assistance to State Plan (CASP) was introduced by GoI (2015). Under the scheme, three projects *viz.* Strengthening[203] of Drug Testing Laboratory including the Head Office at Old Government General Hospital, Hanumanpet, Vijayawada, Strengthening of two Regional Laboratories at Vishakhapatnam & Kurnool and Strengthening of 27 office buildings for Enforcement Officers in Districts were taken up.

In this regard, an amount of ₹53.02 crore (Centrally Sponsored Scheme (CSS) share: ₹31.93 crore and Matching State share (MSS): ₹21.09 crore) was released[204] to DCA in three instalments as detailed in ***Appendix 8.1***.

Audit noticed that out of ₹53.02 crore, an amount of ₹9.91 crore was spent towards construction of drug testing lab, purchase of machinery, equipment, consumables *etc*. and balance of ₹43.11 crore was lapsed (March 2022). Subsequently, DCA requested Government to release the balance lapsed amount. Though Budget Release Orders (BRO) were issued (September 2022) for ₹17 crore by Government, no amount was transferred to Single Nodal Agency (November 2022). The BRO for balance amount ₹26.10 crore (₹43.11 crore - ₹17.01 crore) was not issued as of November 2022.

Thus, the objective of strengthening of Drug Regulatory System could not be fully achieved due to non-release of funds by GoAP.

Department stated (July 2023) that proposal for release of balance amount of ₹26.10 crore was pending with Government.

Reply from the Government is awaited.

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[203] Strengthening includes construction, equipment and consumables.

[204] Central Sponsored Scheme released on 20.02.2017, 27.07.2018 and 13.03.2020; Matching State Share released on:11.07.2017, 24.07.2019,16.10.2020

Inspite of provision of funds by GoI for strengthening of Drug Regulatory System, the funds were not released in full by GoAP and thereby prevented the Drug Control Administration from delivering functions effectively. The recommendation on the autonomy by Dr. R.A. Mashelkar Committee was not extended to DCA.

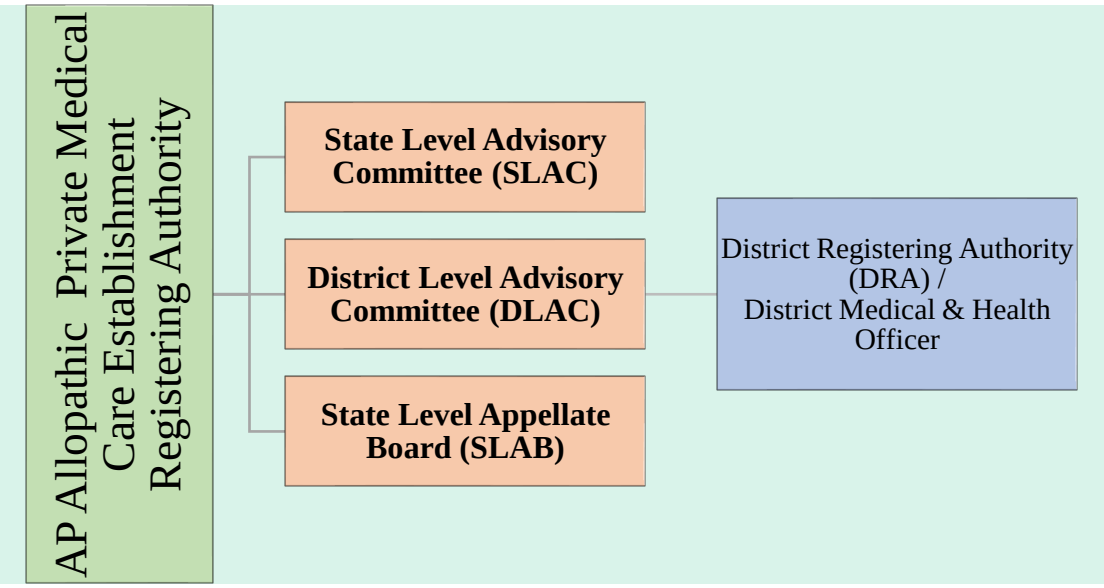
8.3 Implementation of Andhra Pradesh Allopathic Private Medical Care Establishments Act

The Allopathic Private Medical Care Establishments (Registration and Regulation) Rules 2007 (APMCE) framed under Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act, 2002, prescribes minimum standards for different types of Private Medical Care Establishments (PMCE) in Andhra Pradesh.

The minimum standards comprise of general and specific requirements including physical standards of space requirements and hygiene, equipment requirements for delivering specific services and manpower requirements and their qualifications. The standards also specify the minimum list of services for which the medical care establishments need to display the charges levied for the benefit of the patient information.

To oversee the implementation of APMCE Act, there must be Regulatory Authorities at different levels to watch compliance. The regulatory mechanism/authorities at different levels are shown in ***Chart 8.1.***

Chart 8.1: Different levels of regulatory authorities



Source: *Information furnished by Department*

8.3.1 Constitution of Advisory Committees

8.3.1.1 Constitution of State Level Advisory Committee

A State Level Advisory Committee (SLAC) shall be constituted[205] with Special Chief Secretary/Principal Secretary/Secretary to Government, dealing with the subject in Health, Medical & Family Welfare Department as Ex-officio Chairman.

The SLAC shall review the progress made in registration process and give timely advice to the various authorities constituted for the purpose to oversee the proper and effective implementation of the Act, order random inspections of the Private Medical Care Establishments without prior notice, monitor District Level Advisory Committees and review the functioning of the Clinical establishments. SLAC has to meet twice in a year and gap between two meetings should not exceed six months.

Regarding constitution of SLAC, the Department stated that no meetings were conducted during 2017-18 to 2021-22.

8.3.1.2 Constitution of District Level Advisory Committee

A District Level Advisory Committee (DLAC) shall be constituted[206] with the District Collector as Ex-officio Chairman. DLAC shall review the progress of registration process and monitor implementation of the Act at district level. DLAC shall nominate persons for inspection teams and review the contents of the inspection reports as required. DLAC should meet at least twice[207] in a year and gap between two meetings should not exceed six months.

Audit noticed the following in the three test-checked districts:

- In Anantapur district, DLAC was constituted, and meeting was held only once in 2018-19 during the period 2017-18 to 2021-22. In the meeting, DLAC resolved to issue circular to all Private Medical Care Establishments (PMCE) to provide free of cost service to five *per cent* of poor and needy and to submit regular report of births and deaths. However, compliance to the resolution passed by DLAC was not on record. Thus, there is no monitoring mechanism to see that resolutions passed by DLAC.
- The details of constitution of DLAC at District Medical & Health Officer (DMHO) Nellore were not on record.
- In Srikakulam district, the DLAC was constituted and meetings were conducted during the period 2017-22. However, copies of the minutes of the meetings were not furnished to audit.

8.3.2 Renewal of registrations

Every establishment shall apply for renewal of its registration along with payment of prescribed fees, three months before expiry of the registration period. Based on

[205] Section 5A APAPMCE (Registration and Regulation) Act, 2002
[206] As per section 5A of The APAMCE (Registration and Regulation) Act, 2002
[207] As per Rule 3(2) of the APMCE Rules

inspection reports, the Registering Authority shall grant the renewal certificate which is valid for five years.

Audit noticed (June 2012) that ten PMCEs had not applied for renewal of registration within the prescribed period in the test-checked districts. Applications for renewal were received with delays ranging between 103 and 640 days (as detailed in ***Appendix 8.2)***. Renewal of permissions was processed without any action by the DRAs for unauthorised functioning to these PMCEs. There was no data available about the dates of inspections and action taken on delayed applications. This indicated ineffective monitoring by the concerned DRAs.

8.3.3 Action on suspended establishments

The Registering Authority is empowered to suspend PMCE (Rule 7 of APAPMCE rules) on receipt of reliable information that the PMCE has been convicted or has been censured by any judicial or competent authority in relation to their professional conduct. The PMCE can also be suspended if found guilty on a written complaint of violation of any terms and conditions of the registration or contravention of any of the provisions of the Act.

The Registration Authority, after making enquiries thereto and after written explanation from the Establishment on the allegations levelled may order suspension of the certificate of registration for such period as it may think fit. As per the records furnished by the Department, 99 PMCEs were suspended during 2017-22 in the State, The Department attributed suspensions to lack of mandatory facilities/manpower *viz.* non-provision of waiting area, non-availability of sufficient space for laboratory, non-display of rates and non-availability of health staff, *etc*.

The action was taken based on complaints and not based on regular inspections. Thus, it shows that proper inspections are not being carried out as per the provisions of the Act. Further, it was noticed that records relating to suspended or cancelled registrations of PMCEs for the period 2017-22 were not maintained in any of the test checked DRA offices. Reasons for not maintaining these records were not furnished to audit.

Suspension/cancellation of registrations of PMCEs was based only on complaints received. Thus, regular inspections would have brought more such cases and lead to effective monitoring by the concerned DRAs**.**

8.4 Implementation of Pre-Conception and Pre-Natal Diagnostic Techniques Act

Pre Conception- and Pre Natal-Diagnostic Techniques (PC-PNDT) Act, 1994, prohibits prenatal diagnostic techniques for determination of sex of the foetus leading to female foeticide. It regulates the use of pre-natal diagnostic techniques only to detect genetic abnormalities, metabolic disorders, chromosomal abnormalities, certain congenital malformations, haemoglobinopathies and sex-linked disorders. The Act mandates compulsory registration of all diagnostic laboratories, all genetic counselling centres, genetic laboratories, genetic clinics and ultrasound clinics.

8.4.1 Inspections by State Level Authority

As per Standard Operating Guidelines, all the appropriate authorities including State, District and Sub-district notified under the Act *inter-alia*, shall conduct regular inspection of all the registered facilities once in every ninety days and shall preserve inspection report as documentary evidence.

In the State there were 3,047 (as of March 2022) hospitals/diagnostic centres/ laboratories registered under PC-PNDT Act. During 2017-22, the State Level Authority[208] (SLA) had conducted inspection of only 74 registered centres as detailed in ***Table 8.2*** below.

Table 8.2: Showing the number of inspections conducted by Monitoring Committee

Year	Number of Inspections conducted	Month in which conducted	Districts Inspected	Major deficiencies noticed
2017-18	11	June 2017	Guntur, Krishna, West Godavari	Form-F[209] for maintenance of record in case of prenatal diagnostic test, and display boards. Connected records and Form-F were not maintained.
2018-19	3	April 2018	Krishna and Chittoor	Two cases filed for revealing the sex and institutes were seized.
2019-20	11	April 2019	Krishna, Guntur, Prakasam, West Godavari	Connected records and Form-F were not maintained.
2020-21	14	January 2021	Guntur, Chittoor	Records not maintained and Display boards not exhibited
2021-22	35	April 2021 (5) August 2021(11) October 2021(6) November 2021(5) March 2022(8)	Vizianagaram, Kurnool, Prakasam, YSR, West Godavari, Guntur	Connected records and Form-F were not maintained.

***Source**: Information furnished by the Commissioner of Health and Family Welfare*

Thus, the SLA covered only two *per cent* of the registered hospitals/diagnostic centres/labs during 2017-22.

Further, Inspections were conducted in a particular month in one go during the period 2017-22 (except 2021-22). Records relating to Inspection Reports were not produced to audit. No inspections were conducted in the test checked districts of Anantapur, SPSR Nellore and Srikakulam in any of the years during 2017-22 by District and State Level Authority.

[208] Minister for Health as the Chairperson, Secretary in-charge of the Health department as Vice-chairperson, Secretaries or Commissioners in-charge of the Department of Women and Child Development, Social Welfare, Law and Indian System of Medicines and Homoeopathy, Director of Public Health as members along with other members nominated by Government, from various social organisations and an officer not below the rank of Joint Director, in-charge of Health& Family welfare would be the Member Secretary

[209] form for maintenance of records in case of prenatal diagnostic test/ procedure by genetic clinic/ ultrasound clinic/ imaging centre

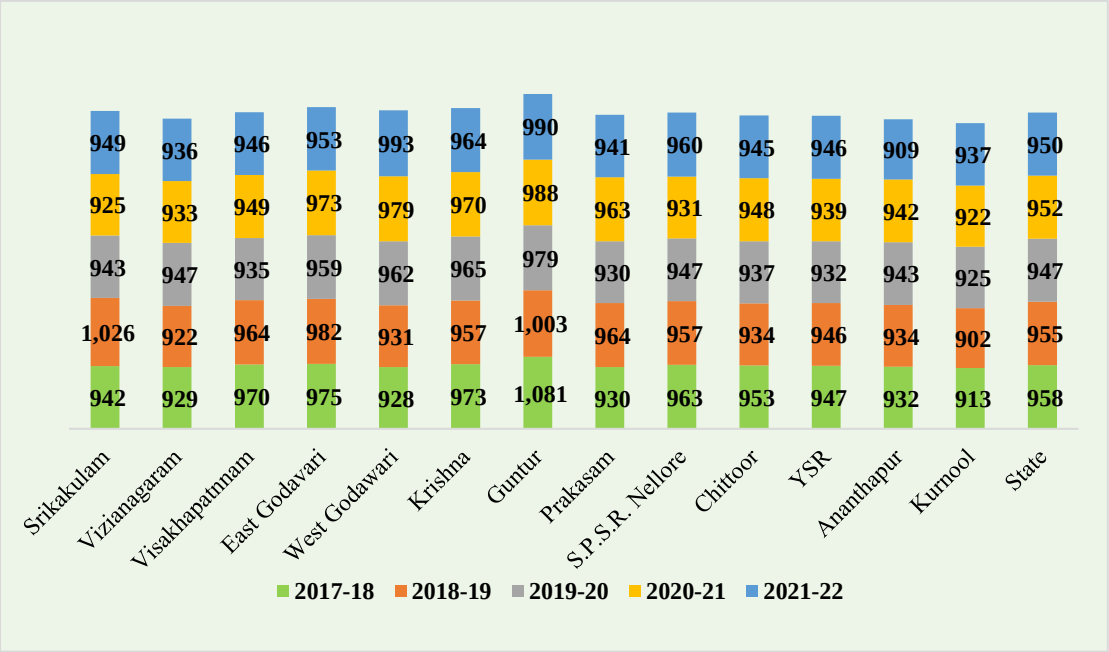
The Commissioner, Family Welfare replied (January 2023) that the Department was planning to increase the inspections by the State Level Committee in all districts.

Regarding non maintenance of records, display boards and Form F, CFW further replied that the district level field inspection reports were uploaded in the web portal. However, Audit could not find any such report in the web portal.

8.4.1.1 Gender ratio at birth

Analysis of population composition from gender perspective is very central in understanding nitty- gritty of social structure of a society and also very crucial for framing policy intervention. Due to this fact, statistics on population characteristics from the gender perspective is considered. Gender or sex ratio at birth is defined as number of female live births per every 1,000 male live births. The district wise proportion of gender ratios during the period 2017-22 is given in ***Chart 8.2.***

Chart 8.2: District wise gender ratio at birth



As seen from the above the gender ratio at birth is neither steady nor increased during the review period. Except Srikakulam, Vizianagaram, West Godavari, Prakasam and Kurnool all the remaining eight districts recorded decrease in female live births per every 1,000 male live births. All these are inherent markers for the department to bring on track the effective vigilance and monitoring mechanism.

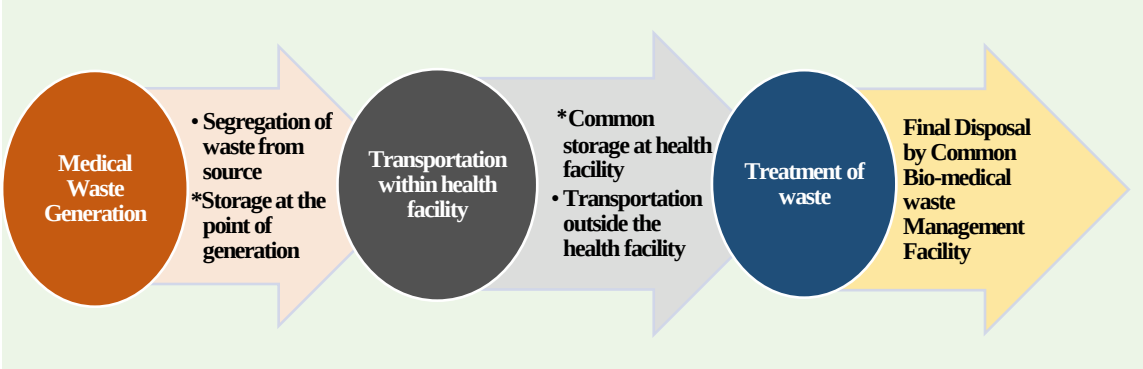
8.5 Bio-Medical waste management

Bio-medical[210] waste shall be segregated into containers/bags at the points of generation prior to its storage, transportation, treatment, and disposal. It shall be the duty of every occupier of an institution generating biomedical waste to take all steps to ensure that

[210] waste means any waste, generated during the diagnosis, treatment, or immunisation of human beings

such waste is handled without any adverse effect to human health and the environment. Steps involved in waste management in Health facilities is depicted ***Chart 8.3*** below:

Chart 8.3: Steps involved in waste management in Health facilities



8.5.1 Bio-Medical Waste management in Primary Health Centres

Every occupier of an institution generating or handling Biomedical Waste (BMW) shall apply (in Form 1) for authorisation to the Andhra Pradesh Pollution Control Board (APPCB). The applicant shall make an application for renewal of authorisation at least 60 days before the date of expiry with the prescribed fee. Grant of authorisation for generating BMW in any form is issued by APPCB.

Scrutiny of records of three-test checked District Medical & Health Offices revealed that all the eight Primary Health Centres (PHCs) in these test-checked districts have obtained authorisation from APPCB for generation, segregation, and safe disposal of BMW. However, the authorisation lapsed on 31 March 2022 in respect of seven test checked PHCs (except Chennur). None of the PHCs had applied for renewal of authorisation prior to expiry and were running without authorisation as of August 2022.

The Medical Officers replied that steps would be initiated to get fresh authorisation from the APPCB.

8.5.1.1 Segregation of Biomedical waste

The health care facilities, while generating the waste are responsible for segregation, collection, in-house transportation, pre-treatment of waste and storage of waste before such waste is collected by Common Bio-medical Waste Treatment Facility (CBWTF) Operator. Further, every occupier, should keep a record of BMW generated, handed over to the treatment facility.

The waste generated by PHCs is being lifted by an agency at regular intervals. However, records relating to quantity of waste generated for each category of waste were not maintained properly[211] indicating lack of mechanism at PHCs for quantifying the waste at the source.

[211] Chennur, Kondapuramu and Kudair

PHC Chennur stated that proper monitoring controls would be inculcated in future and PHC Kondapuramu stated that staff are not aware of the BMW weighment measures. The remaining six PHCs did not respond.

Further, Audit noticed that segregation of BMW at source is being done in all the test checked PHCs. However, in three[212] out of eight PHCs, twin bucket facility for waste disposal was not available.

Figure 8.1: Three bin system at URLAM (June 2022)

Figure 8.2: Bin system at Thummalapenta (July 2022)

Figure 8.3: Waste collection bag PHCs (July 2022)

(b) Disposal of Biomedical waste

As per Bio-Medical Waste Management Rules 2016, Bio-medical waste shall be treated and disposed of (in accordance with Schedule I), and in compliance with the standards prescribed (in Schedule II). Every occupier, where required, shall set up requisite BMW treatment facilities like incinerator, autoclave, microwave system for treatment of waste, or ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility.

Audit noticed that:

- Hypochlorite solution was not available in three[213] test checked PHCs for decontamination of blood spills and medical waste for reduction of microorganisms.

  Government in its reply (August 2023) stated that Hypochlorite solution is not in the list provided by the Government to the PHCs. Hence, no PHC in the State is having Hypochlorite solution.

  However, audit observed that IPHS, 2012 and 2022 recommended to use 0.5 *per cent* Hypochlorite solution for treatment of infective spills like blood.

- For collection, treatment, and disposal of BMW from the PHCs, APPCB identified 11 Common Bio-Medical Waste Treatment Facilities (CBMWTF) to operate in Andhra Pradesh. As per BMW Rules[214], no untreated BMW shall be stored beyond a period of 48 hours from generation. However, BMW was not

[212] Chennur, Kudair and Thummalapenta
[213] Chennur, Kudair and Thummalapenta
[214] 2.1 (2) of Guidelines for Management of Healthcare Waste as per BMW Rules, 2016

lifted within 48 hours in three[215] of the eight-test checked PHCs. Further, BMW was lifted at an interval of 15 days during 2021-22 in PHC Kondarapuram.

BMW from healthcare activities poses a higher hazard of infection and damage, than other types of waste, if not handled properly.

8.5.2 Biomedical waste Management in secondary and tertiary health care facilities

As per Biomedical Waste Management Rules 2016, all health care facilities shall obtain authorisation to generate biomedical waste from Pollution Control Board (PCB). PCB shall select a treatment facility for collecting biomedical waste from the health facility for treatment. The treatment facility shall collect the BMW on daily basis so as not to keep the BMW untreated beyond the period of 48 hours.

We observed that, all the nine-test[216] checked secondary health care facilities under the control of Andhra Pradesh Vaidya Vidhan Parishad had obtained authorisation for generating BMW and liquid waste from APPCB. However, authorisation had expired in March 2023. Out of three test checked GGHs authorisation was expired on June 2021 (GGH Nellore) and January 2023(GGH Anathapuramu) and had not been renewed.

All the nine-test checked secondary health care facilities were segregating BMW at source. Segregated waste was being handed over to the respective Common biomedical treatment facilities. However, the biomedical waste generated was not being lifted on daily basis (except at DH Atmakur). In all other secondary health care facilities, the lifting of BMW ranged between once a week[217] to alternate days.

BMW Rules 2016 stipulate that the health facilities shall furnish annual report regarding generation of BMW to APPCB. However, none of the test checked HCFs furnished such reports.

Government replied (August 2023) that the biomedical waste was being lifted from the six HCFs[218] on daily basis.

8.5.3 Management of liquid biomedical waste

8.5.3.1 Effluent Treatment Plant in Secondary care hospitals

BMWM Rules 2016 (Schedule I (f)) stipulate that, Chemical Liquid Waste[219] shall be pretreated before mixing with wastewater. The health care facilities were required to discharge the lab washing and canteen and domestic wastewater after disinfection for treatment in the Effluent Treatment Plants (ETP). The treated wastewater shall be utilised for utilities, flushing of toilets, on land for gardening within the premises to the

[215] Kondapuram, Kudair and Narpala
[216] DH Tekkali, DH Atmakur, DH Hindupur, AH Seethampeta, AH Kavali, AH Kadiri, CHC Sompeta, CHC Naidupeta, CHC Kothacheruvu
[217] CHC Kothacheruvu
[218] DH Tekkali, DH Hindupur, DH Atmakur, AH Seethampet, AH Kavali and CHC Sompeta
[219] liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities *etc.*

maximum extent possible and the balance may be discharged into sewer, after meeting the standards stipulated.

APPCB, while issuing authorisation to HCFs, stipulated the permissible limit for effluent discharged by each health care facility per day after disinfection and treatment in the ETP. As per Schedule B of BMW authorisation issued by APPCB, HCF shall construct and operate the ETP continuously to treat the wastewater generated to meet the Board standards within three months from the date of authorisation. Audit noticed that ETPs were not established in any of the test checked health care facilities.

Hospital effluent may contain a large variety of potential, hazardous microbiological pathogens, radioactive isotopes, at high concentrations. If the effluent from hospitals is not properly treated, then the environment and human health can be negatively impacted.

8.5.3.2 Installation of Sewage Treatment Plants

As per the instructions issued[220] (October 2012) by APPCB, all health care establishments with 100 and above beds which are not connected to the terminal treatment plant through public sewer should construct and commission Sewage Treatment Plant (STP) duly following the discharge standards prescribed under the Environmental Protection Act 1986.

Audit noticed (April 2023) that:

- In Government General Hospital (GGH) Srikakulam, the installed STP was not functioning for more than two years, and the wastewater was directly discharged into Nagavali river. Even after the issue of Court Notice, no action was initiated to make STP functional.

  The Superintendent GGH, Srikakulam replied that the District Collector was requested to convene a meeting with APMSIDC to make the STP functional.

- At GGH Nellore[221] the STP was not functional. Environmental Engineer, APPCB Nellore had issued notices (July, August, October of 2021) to GGH and ACSR Medical College, Nellore for renewal of authorisation. Despite show cause notice issued (October 2022/January 2023) by the Environmental Engineer/APPCB there was no response from the hospital authorities.

  The Medical Superintendent, GGH Nellore replied that the matter would be brought to be notice of the APMSIDC, Nellore for identification and issue of work order for the functioning of STP.

- At GGH, Anantapur, STP was installed only in November 2022 and is under operation.

[220] Memo No. B-7/APPCB/BMW/Gen/2007 dated 08.10.2012
[221] Sri A.C Subba Reddy Medical college and GGH

- STPs were not available in all the three test checked District hospitals[222] and three Area Hospitals[223].

Reply from the Government is awaited.

Thus, the Sewage Treatment Plants installed at Srikakulam and Nellore were non-functional. Further, STPs were not installed in any of the test-checked District and Area hospitals. There was delay in disposal of waste by some of the test checked HCFs. Bar coding system that tracks biomedical waste, was implemented partially.

8.5.4 Availability of Common Bio-Medical Waste Treatment Facility

There are 11 Common Bio-Medical Waste Treatment (CBMWTF) facilities (as detailed in ***Appendix 8.3***) in operation in Andhra Pradesh for collection, treatment and disposal of bio-medical waste.

Figure 8.4: CBMWTF at Athivaram village in SPSR Nellore district (erstwhile) (April 2023)

CBMWTF at Athivaram village SPSR Nellore district (erstwhile)

Incinerator in CBMWTF at Athivaram village

Shredder for shredding Plastic Waste at Athivaram village

Autoclave at Athivaram village

Audit noticed that:

- CBMWTF (authorisation valid till April 2024) located at Anantapur was non-functional since November 2021 due to complaints received from local villagers. Waste collected (from 1040 Health Care Facilities) was segregated at the treatment facility in Anantapur, however, the waste was transported to the treatment facility at Ongole which is about 300 kms from Anantapur. As per guidelines for management of healthcare waste, generated waste must be

[222] DH Tekkali-200 beds, DH Atmakur-150 beds and DH Hindupur-200 beds
[223] AH Seethampeta, AH Kavali and AH Kadiri, all are 100 bedded hospitals

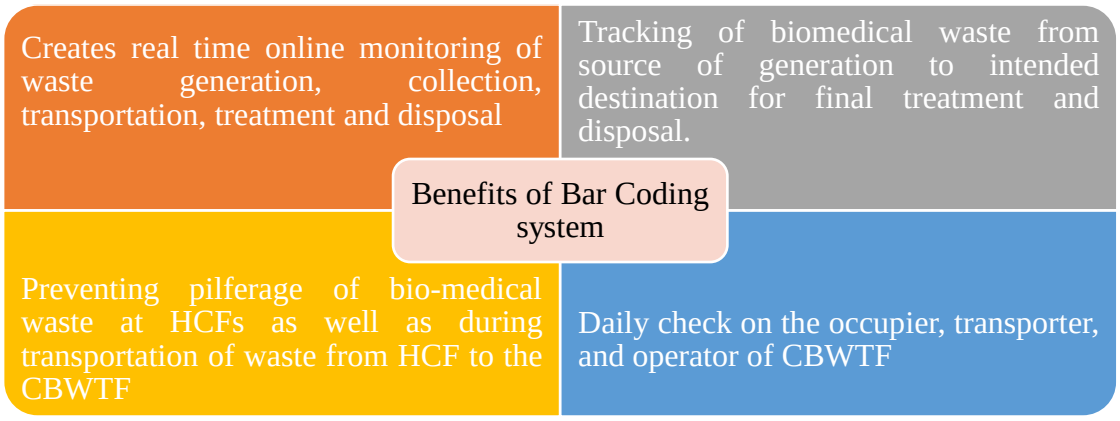
segregated at the point of generation[224] of source and not in later stages. However, during physical verification of treatment facilities, it was noticed that the collected BMW is being segregated at the CBMWTF in both the districts Anantapur and SPSR Nellore instead of segregating at source of generation.

The APPCB replied that some of the HCFs are handing over the waste without segregation.

- Bio-Medical Waste Management Rules, 2016 stipulate that it is the duty of every HCF to establish a bar code system by March 2019 for bags or containers containing BMW to be sent out of the premises or place for any purpose. Further, Rule 5 of the BMWM Rules, 2016 stipulates that it is the duty of every operator of CBMWTF to establish Bar Code system for handling of bio-medical waste.

  As per guidelines for Bar Code system issued (2018) by Central Pollution Control Board (CPCB), the Bar Code system shall be implemented for proper accounting of the quantity of BMW collected, treated and disposed off. The advantages of Bar Code System are shown in **Chart 8.4.**

Chart 8.4: Showing the merits of Bar Code System



It was noticed that the implementation of Bar Code System is partial in Anantapur and SPSR Nellore Districts out of three test checked districts. Environmental Engineer, APPCB, SPSR Nellore replied that the HCFs have implemented Bar Code System in some hospitals. Due to COVID pandemic, the implementation of Bar Code system was partial. Now, APPCB has taken the implementation of Bar Coding for handling of BMW and given directions to the operators of CBMWTF to complete the same by May 2023.

The Executive Engineer, APPCB, Anantapur replied that Bar Code System is being implemented for Hospitals with 50 beds and above.

[224] 'Point of Generation' means the location where wastes initially generate, accumulate and is under the control of doctor / nursing staff *etc*. who is providing treatment to the patient and in the process generating bio-medical waste

8.6 Quality certification from National Quality Assurance Standards

8.6.1 Public health facilities with accreditation certificates

The objective of HCF is to ensure safe, people centred, efficient, and effective delivery of healthcare services and promote health & wellness among communities by active engagement and capacity building of community level platforms and individuals.

Accreditation is one form of external evaluation of Health Care Facilities (HCFs) to determine whether benchmark standards were achieved in line with predefined requirements or standards, to produce an assessment stating whether the facility or organisation has achieved those levels.

In India, the National Quality Assurance standards, measure standards under each level of healthcare institution (DH/CHC/PHC) under eight broad themes[225].

The details of HCFs in the State having accreditation certificates under National Quality Assurance Standards are detailed in ***Table 8.3*** below.

Table 8.3: Showing the Health Care facilities having accreditation

Description	PHCs	CHCs	District Hospitals/Area Hospitals
Total number of Health care Facilities (HCF)	1,145	175	65
Number of HCF accredited	320	12	24
Percentage of HCFs accredited	27.95	6.86	36.92

Source: Information furnished by CFW & DPHFW

As seen from the above table, percentage of accredited HCFs in the State is poor. Accreditation should be viewed as an intervention to support the continuous process required to improve the quality of care and processes in the target facility.

Government is investing considerable amounts in health system hence it is important to know the impact of its investments and outcomes for further planning and to review the areas of concern. Poor percentages in accreditations could not give assurance to the Government as well as public for quality of health services.

8.6.1.1 Internal Monitoring for Sub Centres

IPHS envisaged two levels of monitoring for a Sub-Centre *viz*. internal, and external monitoring.

- Internal monitoring involves supportive supervision and record checking at periodic intervals by the Male and Female Health Assistants (MFHA) from PHC once in a week and Medical Officer visiting an SC once in a month to check the work of the staff and to provide curative services. Nine test checked SCs stated the Medical Officers were visiting the SCs, however no record, evidencing their visits was furnished to audit. Hence, audit could not ensure that internal monitoring was in place in all test checked SCs.

[225] Area of Concerns *viz.,* Service Provision, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control, Quality Management and Outcome in the system

- External monitoring should be done by Village Health Sanitation and Nutrition Committee and evaluation by an independent external agency. However, only three[226] out of nine test checked SCs stated that monitoring by VHSNC was done and no independent evaluation was done in all the test checked SCs.

Government stated (August 2023) that third party inspections were conducted at regular intervals and action was taken on the feedback and ATR was reviewed by the higher authorities regularly. It was further stated that social audit by public representatives was initiated.

8.6.1.2 Internal Monitoring for PHCs

Internal Monitoring mechanism to assess the functioning of PHC involves record maintenance, checking and supervision, medical audits, death audits, patient satisfaction surveys and evaluation of complaints and suggestions. External monitoring framework involves monitoring through PRI / VHSNC / Hospital Development Society, *etc*.

- Out-patient Record was not maintained at Registration Counter. MOs were found maintaining their own registers in the test checked PHCs.
- Hospital Development Society (HDS) is to be constituted to monitor the activities for improvement of the management and service provision of the PHC. We observed one[227] PHC did not constitute HDS committee.

Patient Satisfaction Survey was conducted only in Kondapuramu PHC. Sound monitoring mechanism provide an assurance of service delivery to the beneficiaries. Five[228] of eight PHCs stated that the monitoring mechanism was not available.

8.6.2 Accreditation by National Accreditation Board for Hospitals (NABH) and Healthcare providers

The hospital accreditation program is the flagship program of NABH and was started in the year 2005. This program intends to improve healthcare quality and patient safety at public and private hospitals. The accreditation standards for hospitals focus on patient safety and quality of delivery of services by the hospitals in a changing healthcare environment. Implementation of accreditation standards ensures patient safety and commitment towards quality care resulting in good clinical outcomes and further improves patient satisfaction and increases community confidence over the HCFs.

All the three-test checked GGHs had applied for accreditation however, accreditation was not awarded to any of them as detailed below;

- GGH Anantapur: after elapse of more than three years and making payment of ₹27.38 lakhs during from June 2017 to October 2021, final assessment was not conducted and accreditation was not received.

[226] Goppili, Leguntapadu and Karutlapally
[227] Urlam of Srikakulam district
[228] Karajada, Kondapuramu, Kudair, Narpala and Urlam

- GGH Nellore: an amount of ₹15.40 lakh was paid during May 2019 to November 2021 for accreditation. The final assessment for NABH accreditation was not made.
- GGH Srikakulam: an amount of ₹17.45 lakh was paid during February 2019 to October 2021 for accreditation. However, accreditation was not received.

In all the above cases, the GGHs did not pursue with NABH for final assessment after they rectified all the discrepancies made during the pre-assessment.

Government stated (August 2023) that pre-assessment in respect of GGHs Anantapur and Nellore were completed. Non-conformances (NCs) communicated by NABH Board were complied with and further reports from NABH Board were waited. It was further stated that final assessment in respect of GGH Srikakulam was completed.

8.7 Recommendations

- ***The Department may strengthen the enforcement of Andhra Pradesh Allopathic Private Medical Care Establishments Act and ensure regular inspections, so that all the Private Medical Care Establishments function with valid registration certificates.***
- ***Government needs to strengthen the Regulatory mechanism of Drug Control Administration by deploying more manpower for inspection of manufacturing/sale units of drugs.***
- ***Government may ensure installation of Effluent Treatment Plants in all eligible hospitals. Government may make Sewage Treatment Plants functional for safe handling of liquid biomedical waste, where they were dysfunctional and ensure establishment in 100 and above bedded Government hospitals.***
- ***Government may instruct all the HCFs to maintain minimum quality standards to give an assurance of quality health care to the intended population.***
- ***Government should ensure that various regulatory bodies may adopt an adequate and effective monitoring mechanism to guarantee conformity with the necessary minimum standards.***