REGULATION OF HEALTH CARE DELIVERY IN INDIA

A LANDSCAPE STUDY

HSTP
Health Systems
Transformation Platform

REGULATION OF HEALTH CARE DELIVERY IN INDIA

A LANDSCAPE STUDY

Sunil Nandraj
Pallavi Gupta
Sonali Randhawa

March 2021

Health Systems Transformation Platform (HSTP)
C1 Block, ISID, 4, Institutional Area, Phase II, Vasant Kunj
New Delhi – 110070, India
hstp@hstp.org.in
Phone +91-11-61326500

Contact

Pallavi Gupta | Specialist - Health Systems Governance, HSTP | pgupta@hstp.org.in

This report titled “Regulation of health care delivery in India - a landscape study” has been developed by HSTP.

ISBN: 978-81-949194-5-2

Disclaimer

Health Systems Transformation Platform (HSTP) is a not-for-profit organisation registered in the name of Forum for Health Systems Design and Transformation, a company licensed under Section 8 of the Indian Companies Act, 2013.

HSTP’s mission is to enable policymakers and researchers in the Indian health systems to generate and utilise evidence for improving health outcomes and financial protection. It is done in collaboration with Indian and global expertise through enhancing stakeholders’ capabilities for health systems redesign, validating interventions and fostering policy dialogue.

HSTP activities are primarily funded by Sir Ratan Tata Trusts. HSTP is committed to the highest standards of ethics and professional integrity in all its endeavours and declares no conflict of interest on account of its funding arrangements.

The contents of this report should not be attributed to, and do not represent the views of the funders. All reasonable precautions have been taken by HSTP and its partners to verify the information contained in this publication.

Suggested citation

Nandraj, S., Gupta, P., & Randhawa, S. (2021). Regulation of Health Care Delivery in India - A Landscape Study, Health Systems Transformation Platform, New Delhi.

1) Health Regulation 2) Health Governance 3) Health Care 4) Health Legislation 5) Health Laws

CONTENTS

Foreword

The recent COVID-19 pandemic has exposed the fault lines of health systems in many countries. All the components of the health system such as financing, human resources, supply chains and equity have been put under stress globally. Governance plays a critical role in integrating the building blocks of the health system to provide quality services and to ensure access. Leadership and governance are also critical to ensuring the resilience of the health system to public health emergencies, yet they remain one of the least understood aspects of the health system.

India's diverse and mixed health care system is burdened with issues of quality, accountability, coordination between the public-private health sector, and the difficulty of service provision to large populations. The coronavirus pandemic has exposed these challenges highlighting an underfunded and inadequate public health system and the lack of accountability of the mostly unregulated private sector. Regulatory strategies are a necessary condition to facilitate access to care, protect the interests of the patient and discourage irrational practices that lead to overuse and cost escalation.

Health Systems Transformation Platform (HSTP) works in the areas of health policy, service delivery, financing, and health policy and systems research. As part of our commitment to contribute to generating a body of work for strengthening regulation in the health sector, a study, 'Regulation of Health Care Delivery in India - A Landscape Study', was undertaken. This study aims to understand health legislation with a focus on health care delivery in India and document the strengths, gaps, and challenges. It focuses on health regulations governing the various entities of the health system: practitioners (doctors – allopathy and Indian systems of medicine and homoeopathy, dentists, nurses, pharmacists and allied health care professionals), health facilities (inpatient and outreach services), supportive services (laboratories and diagnostics, ambulances, pharmacies and blood banks), professional actions (abortions and transplantation of organs), illness and diseases (mental health and HIV), and outbreaks, epidemics and pandemics. The study seeks to understand the purpose of regulations with regard to licensing and registration, access, quantity and quality of health care, pricing and cost containment, patient protection, information provision to the patients and grievance redressal mechanisms to regulate the entities.

We hope this report will be useful for researchers, policymakers, implementers, donor agencies and health workers, among others who are interested in understanding and strengthening health regulations in the country.

Rajeev Sadanandan
Chief Executive Officer
Health Systems Transformation Platform

Acknowledgements

This study would not have been possible without the support and contributions from various people, we thank them for this.

The experts Dr. Latha R, Prof. Roy K George, Ms. Evelyn P Kannan, Dr. Ramu K and Mr. Prasanth K S who participated in the expert group meeting and shared their views and inputs.

Dr. Guruprasad Mohanta, Dr. Kumar Rajan, Dr. Latha Jagannathan, Ms. Anagha Khot, Ms. Kavita Narayan, Dr. Rachana Parikh, Prof. Roy K George and Ms. Evelyn P Kannan took time off from their busy schedules to review the drafts and provide their critical comments and suggestions.

Mr. Rajeev Sadanandan, CEO and Dr. N. Devadasan, Technical Advisor, HSTP who were always willing to share their valuable comments and suggestions and provide encouragement.

Our colleagues at HSTP for helping in bringing out this report. Ms. Bharathi Ghanashyam and her team who edited the report and made it more readable.

Sir Ratan Tata Trusts for their continued support and for financial support to undertake this study.

Glossary of Terms

AERB: Atomic Energy Regulatory Board

AHP: Allied Health Care Professional

AIBPE: All India Board of Pharmaceutical Education

AICTE: All India Council for Technical Education

AYUSH: Ayurveda, Yoga, Unani, Siddha, Homeopathy

B. Pharm: Bachelor of Pharmacy

BAMS: Bachelor of Ayurvedic Medicine and Surgery

BDS: Bachelor of Dental Surgery

BHMS: Bachelor of Homoeopathic Medicine and Surgery

BMMP: Biomedical Equipment Maintenance and Management Programme

CCH: Central Council of Homoeopathy

CCIM: Central Council of Indian Medicine

CDE: Continuing Dental Education

CDSCO: Central Drugs Standard Control Organisation

CHCs: Community Health Centres

CME: Continuing Medical Education

CMHA: Central Mental Health Authority

CNE: Continuing Nursing Education

D. Pharm: Diploma in Pharmacy

DCC: Drugs Consultative Committee

DCGI: Drugs Controller General of India

DCI: Dental Council of India

DGHS: Directorate General of Health Services

DoP: Department of Pharmaceuticals

DTAB: Drugs Technical Advisory Board

e-LORA: electronic-Licensing of Radiation Applications

GPAT: Graduate Pharmacy Aptitude Test

HIV/ AIDS: Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome

ILO: International Labour Organization

INC: Indian Nursing Council

IRCS: Indian Red Cross Society

ISCO: International Standard Classification of Occupations

ISM&H: Indian Systems of Medicine and Homoeopathy

M. Pharm: Master of Pharmacy

MCI: Medical Council of India

MoHFW: Ministry of Health and Family Welfare

MTP: Medical Termination of Pregnancy

NACO: National AIDS Control Organization

NBA: National Board of Accreditation

NBTC: National Blood Transfusion Council

NEET: National Eligibility-Cum-Entrance Test

MEITY: Ministry of Electronics and Information Technology

NHM: National Health Mission

NLEM: National list of Essential Medicines

NMC: National Medical Commission

NOTTO: National Organ and Tissue Transplant Organization

NPPA: National Pharmaceutical Pricing Authority

NRA: National Regulatory Authority

OTC: Over the Counter

PCI: Pharmacy Council of India

Pharm D: Doctor of Pharmacy

PIL: Public Interest Litigation

PRTS: Pharmacist Registration and Tracking System

RCI: Rehabilitation Council of India

RDL: Retail Drug Licence

RMP: Registered Medical Practitioner

WDL: Wholesale Drug Licence

WHO: World Health Organisation

ZCC: Zonal Coordination Committees

Executive Summary

Despite its achievements in catering to the needs of a large population, India's diverse and mixed health care system also face a range of challenges, that include limited access to quality health care services, inadequate trained and competent providers, medical negligence, irrational treatment, and practices like over-prescribing of drugs and diagnostic tests, high costs of care leading to impoverishment of households. Such issues get exacerbated in times of emergency, as being witnessed in the present COVID-19 pandemic.

Regulation can be understood as the government exerting control over activities of individuals and organisations to manipulate target variables such as prices, quantities, distribution, and quality of products. The purpose of regulation is to ensure access to health services, maintain quality standards, pricing and cost containment, information collection, protect the rights of patients/consumers from opportunistic behaviour or malpractices, ensure accountability of providers and achieve a non-market goal of equity. Regulation is also often seen as a potential response to address the many problems, which may arise in the production, financing, and delivery of health services. Regulatory roles can have an economic focus, address provider monopolies, combat scarcity of necessary services or curb wasteful service utilisation. The most used instruments for regulation are Acts, Laws, Schedules, Notifications, Ordinances, Rules and Regulations, Resolutions, Orders by the Executive, Judicial Orders, Byelaws, Licensing, Certification, among others. In India, regulatory agencies are government bodies established through legislation passed by the Parliament/Assembly and have statutory authority. Self-regulation by professional groups or peers through accreditation bodies, councils etc. may be voluntary or legally mandated.

In India, regulations related to various aspects of health care like doctors, nurses, health facilities, pharmaceuticals, services such as abortion, sex selective abortion etc., have been reviewed. However, a comprehensive review of regulations related to health care delivery has not been conducted so far as per our knowledge. This study is a step in that direction.

The objective of the study was to review and describe the landscape of health regulation in India, at the Union government level, specifically related to health care delivery[1]. The focus was on legal

[1] Health care delivery is defined as "the provision of health services through an interface between providers and patients/clients/consumers to diagnose health conditions/illnesses/diseases/events, that require medical intervention for the treatment/management of the conditions/illnesses/diseases/events. In other words, health care delivery is the output

provisions, institutional mechanisms including regulatory agencies, and gaps and challenges of the regulatory system. The study was conducted between May 2020 and March 2021.

The study was based on secondary data which included Acts, Rules, Regulations, Notifications and Orders issued by the Union Government and some State governments; judicial orders; documents published by statutory bodies such as the Indian Nursing Council, Pharmacy Council of India, Medical Council of India etc.; proceedings of government meetings and parliamentary committees available in the public domain, papers published in books and peer-reviewed journals; reports on the websites of various government departments and agencies; news media (offline and online) and social media platforms.

A review of the regulatory instruments regarding the entities to be regulated and the purpose of the regulation, in the context of health care delivery, was undertaken using a framework of analysis based on the matrices suggested by Ensor T. et.al., Bloom G. et.al. and Keshri V.R. for low and middle income countries (Ensor T. & Weinzierl, 2006; Bloom et al., 2014; Keshri, 2018). Practitioners, health facilities, supportive services, professional actions, illnesses and diseases, and outbreaks, epidemics and pandemics were among the entities studied. The purposes of regulation studied related to entry/licensing, quality, quantity, pricing, and cost containment, protecting patients and consumers, information provision and grievance redressal. Legislations on other aspects of health and health care, and State level legislations, are beyond the scope of this study. Regulation of public health, research and production of pharmaceuticals, vaccines and medical devices, and health insurance was covered only to the extent they are relevant to the delivery of health care services. The study did not analyse the legislations for their impact. A compilation of the legislations promulgated by the Union Government to safeguard and improve the health of the population is available at https://www.hstp.org.in/health-systems-governance/.

The review of legislations with respect to health care delivery is presented for each of the entities studied. We describe the legislations related to the practitioners of health care, that is, doctors of allopathy (western medicine), doctors of the Indian system of medicine and homoeopathy (AYUSH), dentists, nurses, pharmacists, and allied health care professionals. A notable aspect is that new legislations have been enacted or are in the process of being enacted to regulate the education and profession of the practitioners. Weak regulation by the respective statutory councils, the inherent

---

of the inputs into the health system, that is, the human resource, health infrastructure which would include health facilities, diagnostic and supportive services, pharmaceuticals and medical devices".

conflict of interest and failure of the statutory councils to fulfil their mandated responsibilities are some of the reasons for the change in laws. The National Medical Commission Act, 2019, the National Commission for Indian System of Medicine Act, 2020 and the National Commission for Homoeopathy Act, 2020 replace the respective Councils with Commissions. The National Commission for Allied and Healthcare Professions Act, 2021 is a Union government law to regulate allied health care professionals. Laws such as the Clinical Establishments Act, 2010, Consumer Protection Act, 2019, Drugs and Cosmetics Act (DCA), 1940, were also reviewed in their applicability to the practitioners.

Legislations that regulate in-patient health facilities and outreach services are discussed at length. It is remarkable that until the Clinical Establishments (Registration and Regulation) Act (CEA), 2010 came into being, unlike most other business establishments such as shops, beauty parlours, and dance bars that need a licence to operate, health facilities did not require registration or a licence to operate in many States in India. States' laws in this regard were outdated, inadequate in content and coverage, with no formulation of rules and byelaws, and no prescribed standards. As of March 2021, CEA, 2010 is applicable in 11 States and 6 UT's. Though landmark legislation, the CEA, 2010 prescribes only minimum standards for infrastructure, human resources, supportive services, medical equipment etc. It does not prescribe process and outcome standards. Further, there are no legislative mechanisms for fixing the cost of services, conducting clinical and social audits, and ensuring patients' rights. Laws such as the Drugs and Cosmetics Act, 1940, Atomic Energy Act, 1962 were also reviewed for their applicability to health facilities.

Among outreach services**,** home-based care is the least regulated while medical camps are regulated to a limited extent by government guidelines and court orders but have no specific law. Mobile medical health services are covered under the CEA, 2010 though the minimum standards, are yet to be notified. The fast-growing telemedicine sector has recently been recognised for providing allopathic care and has come under regulation through the Telemedicine Practice Guidelines, 2020 brought via an amendment to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002. Information Technology Act, 2000, and Electronic Health Records Standards 2016, as applicable to telemedicine are discussed.

A detailed review of legislations that regulate services that support diagnosis and treatment, such as laboratories and diagnostics, pharmacies, blood banks, and ambulances is also an important part of the study. The Clinical Establishments (Registration and Regulation) Act, 2010 is the first Act that made it mandatory for laboratory and diagnostic centres to be registered. The licence to open a pharmacy

and sell drugs is granted under the Drugs and Cosmetics Act (DCA), 1940. The Drugs and Cosmetics Rules (DCR), 1945 prescribe the minimum requirements to obtain a drug sale licence, a list of schedules to follow while storing and dispensing drugs, and the role of a pharmacist in operating a pharmacy. Online pharmacies are loosely regulated by certain provisions of DCA, 1940 and DCR, 1945, the draft Drugs and Cosmetics (Amendment) Rules, 2018 that were meant specifically to regulate online pharmacies were not notified as of March 2021. 'Blood' is defined as 'drug' under the DCA, 1940 to regulate the collection, storage, processing and distribution of blood and its components. Drugs and Cosmetics Rules, 1945 prescribe the requirements for infrastructure, licence, equipment, supplies, human resource, etc. to operate a blood bank (blood centre). Road Ambulances are registered as transport vehicles under the Motor Vehicle Act, 1988. The Ministry of Road, Transport and Highways, Government of India, approved the National Ambulance Code and notified the necessary amendments to the Central Motor Vehicles Rules, 1989, in 2016. All the road ambulances that ply after 1 April 2018 are required to comply with the constructional and functional standards specified in the National Ambulance Code.

We reviewed how professional actions such as abortion and transplantation of human organs are regulated in the country. The Medical Termination of Pregnancy Act, 1971 legalised abortion in certain conditions so that women's health and lives could be protected from the dangers of unsafe abortion. Though a progressive piece of legislation, the access to abortion remains conditional even after the amendment of 2021. The Transplantation of Human Organs and Tissues Act, 1994, and Transplantation of Human Organs Rules, 1995 (as amended from time to time) regulate the removal, storage, and transplantation of human organs and tissues for therapeutic purposes and prevention of commercial trafficking of human organs.

The study reviewed laws that regulate access to mental health and HIV/ AIDS related services. The Mental Healthcare Act, 2017 grants the right to access mental health care and addresses the gaps of the previous law, the Mental Health Act, 1987. Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 was enacted in 2018 to prevent and control the spread of HIV/AIDS, provide effective care, support, and treatment, and protect the human rights of persons who are HIV positive, and affected by or vulnerable to the virus and the syndrome.

Lastly, we reviewed the legislations that regulate the management of outbreaks, epidemics, and pandemics. The century-old Epidemic Diseases Act, 1897, is obsolete and wholly inadequate to

address the present-day epidemics and pandemics. The Disaster Management Act, 2005 has a limited role in addressing the challenges posed by public health emergencies.

One common finding across the various entities to be regulated is that there is an absence of regulations for the quantity and distribution of practitioners, health facilities, laboratories, blood banks and pharmacies according to the population, geography or need for health care services. The cost of health care is unregulated because of which ad hoc executive orders to fix prices during the COVID 19 pandemic were issued by different State governments under the Epidemics Diseases Act, 1897 and the Disaster Management Act, 2005. There is a contrasting situation with respect to health legislations in India. On one hand, there exist a plethora of laws and on the other, there is a dearth of legislations in certain vital areas.

BACKGROUND AND INTRODUCTION

Universal Health Care (UHC) is imperative for countries that aim to attain equitable and sustainable health outcomes and improve the well-being of individuals and communities. Strengthening health systems is a means to progress towards UHC (Kieny et al., 2017). Countries worldwide are at various stages of health systems development and differ widely in the health challenges they face.

A health system is defined as a set of six inter-connected building blocks that function together effectively, to achieve the overall goal of equitable and sustained health outcomes (World Health Organization, 2007). They are:

- Service Delivery;
- Health Workforce;
- Health Information System;
- Medical Products, Vaccines and Technologies;
- Health Financing and;
- Leadership and Governance.

Leadership and governance together make up a critical building block as they oversee, guide, and regulate health systems to meet public health goals. While governance is a wider set of control activities related to providing, distributing, and regulating, regulation is conceived as a large subset of governance that steers the flow of events and behaviour. It often involves balancing competing interests and requirements with limited resources, with the larger public good being its guiding light (Dodgson et al., 2002). Both governance and regulation have a unified vision in strengthening accountability and increasing transparency, in both public and private health sectors.

Leadership and governance have received the least attention and remain one of the less understood aspects of health systems (Siddiqi et al., 2009). Regulations are essential to meet health systems objectives of assuring safe and good quality services, improved financial efficiency, the competence of health workers and availability of health information, rational use of medicines and equitable access to health services among others.

The characteristics of health care provide a strong case for government involvement, and regulation is often seen as a potential response to address the many problems which arise in the production, financing, and delivery of health services. The traditional economic rationale for regulation is

attributed to market failure, which leads to inefficient resource allocation. While countries have statutory laws and regulations that define the responsibilities of governments, health organisations and individuals, etc., they still face challenges in health systems development.

The Definitions

The literature on the regulation of the health systems worldwide is not abundant and this is true for India too. Most of the literature has relied upon Selznick's definition of regulation "…sustained and focused control exercised by a public agency over activities that are valued by the community…". Black's definition "…the sustained and focused attempt to alter the behaviour of others according to defined standards and purposes, with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering, and behaviour modification…", is considered one of the prominent and widely used definitions of regulation. Minogue and Carino note, that "…regulation has moved from being rules-based, focused on institutions, and principally about compliance and accountability, towards a view that regulation is equally about broader analyses of political institutions and administrative practices, as well as being a distinctive mode of public policymaking…" (Koop & Lodge, 2017).

In a nutshell, regulation is government control over the activities of individuals or organisations, and more specifically, it can be understood as government action to manipulate target variables such as prices, quantities, distribution, and quality of products. Regulation is a mechanism by which the government limits, steers, or otherwise controls the activities of individuals or organisations. Some regulatory roles can have an economic focus and address provider monopolies, combat scarcity of certain necessary services or curb wasteful service utilisation. Broadly speaking, the government bears responsibility for the achievement of what Saltman and Busse term the "social and economic policy objectives" (of government regulatory activities). Regulation is crucial to encourage universal access to coverage and to discourage [perverse] practices that lead to overuse of services and escalation of costs (Saltman & Busse, 2002). Governments regulate to meet desired goals or outcomes, such as improved health (coverage and equity), social and financial risk protection, assure quality, protect patients, and assure good clinical outcomes. Regulation also helps to inform and educate citizens and ensure patients are free to choose providers and in some cases insurers, within the limits of the other objectives.

Regulatory System

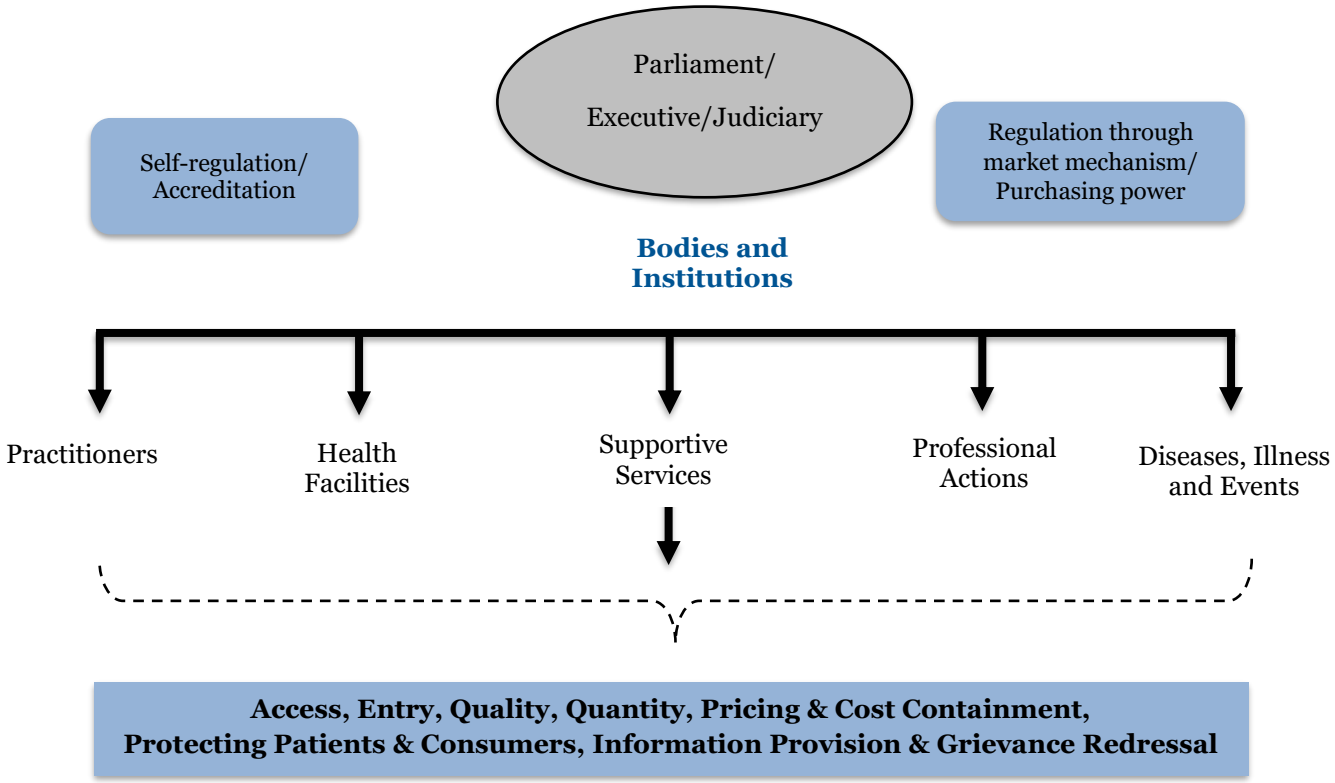
A regulatory system is made up of the institutions, stakeholders and processes involved in designing, making, implementing, and reviewing the regulation. Good regulations define accountability among the target groups and are consistent in action or penalty, irrespective of the position, power, or authority of the person or organisation violating them.

In theory, regulation works through the fear of detection and penalties, which ensures that the targets of regulation follow the rules. If the violations are not detected and penalties not imposed in practice, then there is no deterrence effect among the targets of regulation. While regulation is an important tool, there are challenges associated with developing suitable regulatory mechanisms and implementing them, as regulation is technically complex, resource-intensive and a continuous process, when in fact it must be clear and transparent in its application and the procedure of applying the regulation must be simple and user friendly. Elements of a regulatory process can operate at individual or macro levels, such as organisations or councils. The establishment and application of rules and detection of violations can be achieved through various approaches, that is, continuous monitoring or periodic inspections and imposition of financial penalties or suspension.

Regulatory Structure

A conventional regulatory structure is set within the confines of the three arms of the government, that is, Parliament/Legislature, Executive and a Judiciary. The structure derives legitimacy from the powers conferred by the constitution of a country. The Parliament/Legislature sets the regulatory framework, enacts, and amends laws and exercises oversight, over a regulatory system at various levels - local, regional, and national. The Executive through its regulatory institutions or bodies undertakes the implementation of the regulatory functions. The Judiciary interprets the laws and passes judgements and judicial orders.

Figure 1: Approach to Regulation



Regulatory Bodies

Government agencies are the prime regulatory bodies in a country. The government plays a key role in setting policy and proposing, designing, and implementing regulation. It also assumes responsibility for enforcing, monitoring and adopting accountability strategies to ensure compliance.

Health care regulation has a wide range of supporting instruments, foremost being the laws enacted by the Legislature. The most common instruments (*defined in Annexure I*) used in India are (1) Acts (2) Laws (3) Schedules (4) Notifications (5) Ordinances (6) Rules and Regulations (7) Resolutions (8) Byelaws (9) Licensing (10) Certification (11) Orders by the Executive (12) Judicial Orders etc.

The government enacts and enforces the vertical or horizontal legislation at various levels - local, regional and national, under the purview of the health ministry and/or other ministries of the government, depending on the administrative structure. Legislation usually mentions a set of objectives captured in the preamble to the Act, referring to the mandate under the Constitution, to ensure fundamental rights or to attain social objectives. Additionally, there are notifications and

orders issued by the Ministry of Health and other concerned ministries and urban local bodies (ULBs), as also judicial orders, standards and guidelines released by the government, and codes of conduct suggested by the self-regulatory professional bodies etc. Regulation can also be formulated and implemented by State governments and local bodies, usually under the Constitution or delegated authority from the national or State level.

Additionally, health care involves the discharge of professional duties by the health care practitioners, which may at times lead to acts of medical negligence. The term 'medical negligence' is not defined or referred to in any of the enacted Indian laws. However, it may be understood as wrongful actions or omissions of professionals in the field of medicine, in pursuit of their profession, while dealing with patients. Cases of medical negligence can be brought before the courts, either for criminal liability or for civil liability. Criminal liability can be fixed under the Indian Penal Code, 1860 (IPC), which are general in nature and do not provide specifically for medical negligence. For example, Section 304 A of the IPC, which deals with the death of a person by any rash or negligent act and leads to imprisonment up to two years, is used to deal with medical negligence leading to the death of a patient. Similarly, other general provisions of IPC, such as Section 337 (causing hurt) and 338 (causing grievous hurt), are also often deployed in relation to medical negligence cases. Civil liability for medical negligence is determined under the law of torts, which is meant to safeguard the civil rights of people in India. Law of torts is an uncodified form of law and is still developing in India. Tort is breach of a duty independent of contract, which has caused damage to the plaintiff giving rise to a civil cause of action and for which remedy is available. If there is no remedy, it cannot be called a tort because the essence of tort is to give remedy to the person who has suffered an injury. The law of torts consists of rules recognised and acted on by courts of justice. Tort-based cases can be filed in civil courts. Courts usually determine liability, based on the principles of duty, breach and causation, as presented by the facts and circumstances of the case. Establishing a link between the causation of the injury to the plaintiff and the breach of duty by the defendant is the deciding factor. Certain branches of the law of torts have been codified in India, such as the Bhopal Gas Leak Disaster (Processing of Claims) Act 1985, Motor Vehicles Act 1988, Consumer Protection Act 2019 (repealed the Consumer Protection Act 1986). Apart from the Consumer Protection Act 2019, permanent *lok adalats* constituted under the Legal Services Authorities (Amendment) Act, 2002, can also be approached to seek relief in relation to services "in a hospital or dispensary", which are considered to be "public utility services" as defined in the Act. Under civil laws, patients can sue for the tort of negligence, in case of medical negligence that does not fall within the purview of other Acts, such as the Consumer Protection Act 2019, for example in case of services rendered free of cost (Agrawal, 2016; Deep, 2018; Prakash, 2018).

In India, regulatory agencies are commonly government bodies established on legislations passed through the Parliament/Assembly and have statutory authority. The courts interpret regulations, deal with appeals against regulatory decisions and impose regulatory sanctions.

Instruments for Regulation

India has strategies and supporting instruments for regulating various entities. Some of these are economic incentives, self-regulation, information provision and dissemination, financing and purchasing arrangements such as purchaser-provider, contract-in, contract-out, or pay-for-performance mechanisms. Self-regulation is also enabled through peers, accreditation bodies and councils etc. that may be voluntary or legally mandated. Licensing, accreditation, and certification are the most practised approaches to regulation.

Licensing: Licensing is the process by which legal permission is granted by a competent authority, usually public, to an individual or organisation to engage in a practice, occupation, for example, a license to practice medicine and surgery.

Accreditation: Accreditation is the formal process by which an authorised body assesses and recognises an organisation, programme, or group as complying with requirements, such as standards or criteria.

Certification: Certification is the procedure and action by which a duly authorised body evaluates and recognises (certifies) an individual, as meeting predetermined requirements, such as standards. Certification programmes are generally non-governmental and do not exclude the uncertified from practice, as do licensure programmes. Buyers using the power of purchasing and the threat of non-purchasing or issuing collective rejection by groups play a role. The use of regulatory instruments through incentive-based measures to change behaviours in the delivery, either as monetary rewards or penalties have proved to be an alternative to regulatory measures.

Purpose of Regulation

The primary purpose of regulation in the health sector is to ensure access to health services to the populations, maintaining quality standards and effectiveness, pricing and cost containment, information collection and dissemination, and protecting the rights of patients/consumers. The regulation seeks to ensure accountability of service providers, address information asymmetry between the beneficiary and the provider, maintain the confidentiality of medical information and protect consumers from opportunistic behaviour or malpractice. Further, regulation assists in

controlling distortions created by market forces and establish conditions for the markets to function, with fair competition among providers while ensuring the consumer/patients' best interest. Regulation also assists in controlling financial fraud and other abuses, along with ensuring the non-market goal of equity of access to vulnerable section of the society (Dixon et al., 2011; Nandraj, 2012; Keshri, 2018). Regulation of health care delivery may focus on the following aspects:

Access

- Increase access to patients and consumers for health care services
- Services are not only physically available, but accessible to people who need them when they need them and without barriers of distance and cost
- To ensure those entitled to health services are not denied services, especially the poor and vulnerable
- Health system is equitable and improves technical and allocative efficiency

Entry

- Ensure entry of providers who are qualified and adhere to standards of care
- Issuing licences, approvals, banning activities that are contrary to health system goals
- Continued skill enhancement and in-service capacity building

Quantity and Coverage

- Regulate the number and geographical distribution of providers and facilities to ensure equitable coverage, and based on services exist proportional to the needs of the people
- Ensure that volume and distribution of health care services are appropriate, such as setting the number by population, geography, need etc.

Quality

- Services provided are rational, timely and based on the client's/patient's needs, following standard treatment guidelines provided in a confidential manner, and ensure the safety of patients
- Ensure that standards of quality care in terms of not only physical (for example, facility, medical personnel, equipment and supplies), but also process through which care is provided (for example, organisation of care and clinical performance) and outcome standards are met Setting standards, guidelines, protocols and rules for providing services, for example, waiting time for specified operations and procedures, setting minimum standards for services, staffing ratios or service hours

- Ensure that the pharmaceuticals and medical devices are appropriate for the need and maintain norms
- Ensure that there is continuing medical education and training of providers, both at the individual and institutional level
- Regulating provider behaviour to discourage perverse practices that lead to irrational, unethical, overuse of services and escalation of costs

Pricing and Cost Containment

- Affordable services with no or minimal point-of-care payment/out-of-pocket payment, so that nobody is denied or delayed the required service or provided sub-optimal quality of service for want of money
- To set uniform prices, contain costs and prices so that health care is affordable within financially sustainable boundaries
- Ensure that financial fraud and other abuses do not take place
- Setting profit margins, control monopolies, anti-competitive behaviour and avoid exploitation of monopoly power
- To ensure health services through a financing mechanism of risk protection, that is, social health insurance

Protect Patients and Consumers

- Provide information to patients and consumers about the health care services being provided and health behaviour practices
- Ensure appropriate delivery of services and safety of patients and consumers
- Ban facilities and individuals who provide inappropriate and unacceptable health services and products

Information Provision and Grievance Redressal

- To address the information asymmetry between the provider and the consumer/patient, provide reports and documents related to the services sought
- Collect information from providers for planning, policymaking, meeting public health goals and taking public health measures
- Set up and implement Grievance Redressal System

Others

- Influencing provider behaviour to meet health system goals

- Regulating provider actions in terms of their interactions and referrals, acquisition of technology, use of medicines, irrational and unethical practices
- Setting rules for contracting of services under various aspects, including public-private partnerships

Entities for Regulation

There are various providers involved in delivering health care services. They could be government, for-profit or not-for-profit entities, formal or informal health care services.

Practitioners

- Doctors comprise medical graduates with bachelor or postgraduate specialist diploma or degree in allopathy/western/modern medicine or other/traditional systems of medicine.
- Dentists have a bachelor's or postgraduate degree in dentistry to provide care related to diseases and conditions of the mouth.
- Nurses (including midwives) are people with formal education and training in the care of the sick or the infirm, promoting and maintaining health, and usually, assist or work under the supervision of medical practitioners.
- Pharmacists are involved in storing, preserving, compounding and dispensing medicinal products. They counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical practitioners.
- Allied health professionals, also known as paramedical professionals, are part of the health care team but distinct from doctors, nurses or pharmacists. Allied health professionals may include psychologists, opticians, physiotherapists, laboratory technicians, radiology technicians, emergency medical technicians, Operation Theatre (OT)/Intensive Care Unit (ICU) technicians/attendants, dental hygienists, audiometry technicians, speech therapists, dieticians/nutritionists, occupational therapists, medical/psychiatric social workers, community health workers among others.

Health Facilities

Health facilities are places where health care and related services are provided. They provide out-patient (clinics, polyclinics, health centres, physiotherapy centres, counselling centres etc.) and in-patient services (nursing homes, hospitals, renal dialysis centres, convalesce homes, cardiac cauterisation, Medical Termination of Pregnancy (MTP) centres etc.), and laboratories and imaging centres (pathology laboratories, diagnostic centres, X-ray centres etc.). Additionally, health care services may be offered in a non-facility mode, such as outreach services provided at home or in the community, medical camps, home visits and home-based care, medical mobile units and telemedicine.

Pharmaceuticals, Vaccines and Medical Devices

All substances used for the diagnosis, treatment, mitigation or prevention of any disease or disorder are integral components of health care service delivery. Hence, drugs/medicines, vaccines and medical devices are among the entities to be regulated.

Supportive Services

These refer to services that support diagnosis and treatment, in the delivery of health care. These may comprise pharmacies (including online pharmacies), blood banks and ambulances among others.

Professional Actions

This mainly refers to surgical procedures that are undertaken by providers, such as surgeries, medical intervention, abortions, organ transplants among others.

Illnesses, Diseases and Events

These include communicable diseases, for example, Human Immunodeficiency Virus (HIV), non-communicable diseases (NCDs), for example, mental illness, maternal and child health (MCH) services etc.

Outbreaks, Epidemics and Pandemics

This includes the prevention and management of epidemics, pandemics and disease outbreaks, so that a coordinated and effective response, including emergency measures, may be implemented when required.

Information Systems and Collection

This refers to the collection of health information from individuals, institutions and providers, and analysing and disseminating the same.

Health Regulations in India

The Constitution of India confers upon its citizens, certain fundamental rights that the government is obliged to fulfil. The Directive Principles of State Policy (DPSP) act as guiding principles for the government to enact laws and policies but are not justiciable. Articles 38, 39, 42, 43 and 47 in Part 4 (DPSP) of the Constitution, provide for the promotion of health, nutrition, living standard and health care. Article 47 States, "…The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health, as among its primary duties…". This indicates that health and health care are not fundamental rights in India's Constitution. It is often Article 21, Right to Life, which is a fundamental right, under which the right to health and health care

is subsumed (Duggal, 2007). Further, there are judicial pronouncements based on this principle that provide specific orders and judgements, on matters of right to health and health care.

The Constitution of India lays the foundation of the basic governance structure of the country, delineating specific roles for the Union and State Governments. The Seventh Schedule, Article 246 in part 11 of the Constitution, divides the legislative power into three lists - matters contained in List I or the Union List are those on which the Union Government has the authority to make laws; matters contained in List II, also referred to as the State List are those on which the State Government can legislate; while both Union and State Governments have the power to make laws on matters enlisted in List III or the Concurrent List, with the Union Government enjoying supremacy in case of overlap or conflict. Public health, sanitation, hospitals and dispensaries are part of the State List and therefore health is essentially a State subject. The Concurrent List includes inter alia, matters of population control and family planning, social security and social insurance, medical education, legal and medical professions, prevention of inter-state transmission of communicable diseases, maternity benefits, vital registration of births and deaths. (Jacob, 1974; Government of India, 2006; Centre for Law & Policy Research, 2021).

In addition, there are International Covenants that act as standard setting entities that might set common standards or establish regulatory frameworks for countries. For example, International Health Regulations (2005) (IHR), provide an overarching legal framework that defines the rights and obligations of countries, in handling public health events and emergencies that have the potential to cross borders. They also outline the criteria to determine whether or not a particular event constitutes a “public health emergency of international concern”. India’s international legal commitments have a bearing since India is a signatory to the various International Covenants.

There are a range of Union and State legislations in India that have a bearing on different spheres of people’s personal and professional lives, including their health and health care. A compilation of the existing legislation promulgated by the Union Government identified around 250 such legislations (Nandraj, 2018). These legislations have been put into categories, such as those related to the regulation of (1) Health Facilities, (2) Medical Services, (3) Human Resources, (4) Pharmaceuticals and Vaccines, (5) Medical Devices, (6) Environmental Protection, (7) Social Security, (8) Health Insurance, (9) Occupational Health, (10) Patient Rights and Ethics, (11) Mental Health,(12) Narcotic Drugs and Substance Abuse, (13) Tobacco Control, (13) Health Information, (14) Public Health, (14) Epidemics, (15) Pandemics and Outbreaks amongst others (for a complete list please refer to Annexure II). A compilation of health legislations in India is provided here (Repository of Health Legislations in India, available at https://www.hstp.org.in/health-systems-governance/).

METHODOLOGY

India's diverse and mixed health care system presents a range of challenges, that include issues such as access to quality health care services, inadequate trained and competent providers, high costs of care, irrational treatment and practices like over-prescribing of drugs and diagnostic tests, medical negligence, inadequate information, and lack of quality standards and practice by informal providers. These have been repeatedly highlighted by both government and non-government bodies (Nandraj & Khot, 2003; Mudur, 2004; Prakash, 2015).

In India, while the private health sector is a dominant stakeholder - both in terms of financing and provisioning of health care, it functions in an unregulated and unaccountable manner. This has led to high levels of out-of-pocket spending by households on accessing health care, and in the process has led to large sections of populations getting impoverished. Such issues get exacerbated in times of emergency, as was witnessed during the COVID-19 pandemic.

Media reports and studies have often highlighted the failure of the government in carrying out its stewardship role, such as insufficient governance and regulatory frameworks. There have been serious issues with the implementation of legislations. Parliamentary committee reports on the Medical Council of India (MCI), Central Drugs Standard Control Organisation (CDSCO) etc. have highlighted gaps in health regulation periodically. For instance, in 2012, the 59th report of the Committee on CDSCO observed that drug regulation in the country had largely been weak, because of the higher priority accorded by CDSCO to the interests of the drug industry, than to that of the public. Similarly, the non-performance of the MCI was brought out in the 92nd report in 2016, which observed that the MCI indulges in unethical and corrupt practices, is not accountable and transparent, and had failed to fulfil its mandated responsibilities (Pandya, 2016). Similar concerns have been raised about other self-regulatory bodies, such as the Nursing Councils and the Dental Councils.

Health regulation in India encompasses a variety of actors and issues. The government has promulgated several legislations to safeguard and improve the health of the population. However, there is a contrasting situation with respect to health legislations in India. On one hand, there exist a plethora of laws and on the other, there is a dearth of legislations in certain vital areas of the health care system. Attempts at enacting and implementing appropriate legislations for accountability and transparency of health providers have been opposed by them and their associations.

Regulations related to some aspects of health care like doctors and nurses, health facilities, pharmaceuticals, particular services such as medical termination of pregnancy, sex selective abortions, have been reviewed. However, as per our review and understanding, a comprehensive review of regulations related to health care delivery has not been conducted so far. This study is a step in that direction.

Objectives

The objective of this study is to undertake a review of health regulations in India, specifically related to health care delivery at the national level. The focus is on legal provisions, self-regulation, institutional mechanisms, including agencies/institutions and gaps and challenges of the regulatory system, with a view to describe the landscape of existing regulations.

Desk Review

The study is based on the review of secondary data which includes legislations, orders and notifications, issued by the Health Ministry or any other concerned ministry of the Union Government. The team collected, synthesised and analysed the legislations in India that regulate health care delivery. While doing this, the team referred to the following data sources:

- Acts, Rules, Regulations, Notifications, Orders issued by the Government of India and State Governments
- Judicial orders passed by the courts in India
- Documents published by statutory bodies, like the Indian Nursing Council (INC), Pharmacy Council of India (PCI), Dental Council of India (DCI) and Medical Council of India (MCI)
- Proceedings of government meetings and parliamentary committees available in the public domain
- Papers published in books and peer reviewed journals
- Reports/updates on the websites of various government ministries/departments/agencies
- News media (offline and online) and social media platforms

A review of the regulatory instruments, with respect to the purpose of regulation and entities to be regulated using a framework of analysis, helped in identifying the strengths, gaps and challenges in the regulation of health care delivery in India.

Framework for Analysing Regulations

The team adapted the regulation matrices suggested by Ensor T. et.al., Bloom G. et.al. and Keshri V.R. for low and middle-income countries (LMICs) (Ensor T. & Weinzierl, 2006; Bloom et al., 2014; Keshri, 2018), to develop a framework of analysis. The framework, listed below, enabled an analysis of the existing regulatory instruments of the entities to be regulated and the desired purpose of the regulation, in the context of the delivery of health care services. Practitioners, health facilities, supportive services, professional actions, illness/diseases were among the entities studied and under each category, further sub-categories were studied. The categories and their sub-categories are below:

Practitioners

- Doctors of allopathy (western medicine)
- Doctors of Indian systems of medicine & homoeopathy (AYUSH)
- Dentists, nurses, pharmacists and allied health professionals

Health Facilities

- Inpatient services
- Outreach services

Supportive Services

- Laboratories and diagnostic centres, pharmacies, blood banks and ambulances

Professional Actions

- Abortion and Organ Transplant

Illness/Diseases

- Mental Health and HIV

Outbreaks, Epidemics and Pandemics

Purposes Studied

The purposes of regulation studied related to access, entry, quality, quantity, pricing and cost containment, protecting patients and consumers, information provision and grievance redressal.

Entry/Licensing: Related to the standards of practitioners and facilities - registration, renewal of registration, banning/closing down of facilities, are some of the key instruments used to regulate entry.

Quality: This involved certain standards of care (physical, process and outcome), standard treatment guidelines, standard operating procedures, staffing, clinical and medical audits, adoption of safety measures, use of technology, the establishment of referral protocols, continuing professional education and skill enhancement. Quality of services also included rational, timely, appropriate and need-based services provided in a confidential manner, while ensuring patient safety, maintaining norms, discouraging perverse practices and prohibiting overuse.

Quantity: This referred to regulations about the number of practitioners/facilities required/allowed in a geographical area, by population, by the number of beds, speciality or need.

Pricing and Cost Containment: Referred to regulating fees, charges, pricing of health care services, contracting fees, profit margins, controlling the over provision of services, escalation of costs and monopolies, and anti-competitive behaviour. It also entailed ensuring efficiency in health care costs and preventing financial fraud, other abuses and denial or delay of services due to finance.

Protecting Patients and Consumers: Involved appropriate delivery of services, banning of inappropriate and unacceptable health services and products and maintaining confidentiality.

Information Provision and Grievance Redressal: Included regulation to ensure the provision of appropriate information to patients and consumers, reducing information asymmetry, providing periodic information to the government by practitioners/health facilities, for data compilation and public health measures, data collection and sharing system, and provision of grievance redressal systems for patients/consumers and providers.

Apart from the challenges in implementation, there are additional areas related to health care delivery that remain unregulated. These include:

Quantity and Distribution: There is an absence of legislations that regulate the quantity and distribution of practitioners, health facilities including laboratories and diagnostic centres, or supportive services such as blood banks, ambulance services, pharmacies, according to the population, geography or need for health care services. This has resulted in skewed distribution between urban and rural areas and regional disparities.

Regulation of Fees and Charges: There is an absence of regulations for fees charged by practitioners and health facilities for health care services/procedures. Similarly, there are no regulations for cost

containment by health facilities, laboratories or diagnostic centres etc. In States that have adopted the Clinical Establishments (Registration and Regulation) Act (CEA), 2010, the Clinical Establishments (Central Government) Rules (CER), 2012, require the clinical establishments registered under the CEA, 2010 to display the rates charged for various services/facilities available, and the rates are to be fixed within the range determined by the Union/State government. As per Rule 9 (ii) and (iii) of the CER 2012, the National Council for Clinical Establishment (NCCE) has approved a list of standard procedures and a template for the costing of these procedures. These are shared with the States/UTs who have adopted the Central Act, advising them to use these for determining the standard cost of any procedure, taking into consideration all including pertinent local factors. However, this has not yet been implemented. In some States, the legislation provides information for prices/fees to be disseminated to people who want to use services, for example, West Bengal and Kerala. The prices of drugs that are listed in the country's essential drug list are regulated by the National Pharmaceutical Pricing Authority (NPPA) through the Drug Price Control Order (DPCO), issued from time to time under the Essential Commodities Act, 1955 by the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilisers (MoCF).

Review by External Experts

The above analysis threw up questions regarding challenges of the regulatory mechanism, the varied views of different stakeholder groups, conflicting interests, future opportunities, the need for change in some regulations and recent developments in the field. To better understand such issues, the team conducted meetings with experts, individually and through group consultations. The interactions were held telephonically or through video calls on a virtual platform, like Zoom or in-person due to the ongoing pandemic situation. Further, the chapters of the report were shared with selected experts for review, and their feedback was incorporated into the final report.

Timeline

The study was conducted between May 2020 and March 2021.

Limitations and Scope of the Study

The study is limited to Union government legislations related to the delivery of health care services and based on a desk review of secondary information. Regulations on other aspects of health and health care, as well as State level legislations, are beyond the scope of the current study. Regulation of public health, research and production of pharmaceuticals, vaccines and medical devices, and health insurance is beyond the scope of this study and have been covered only to the extent they are relevant within the context of the delivery of health care services. The study did not analyse the regulations for their impact.

Figure 2: Framework of Analysis for Regulations in the Health Sector

PURPOSE → / ENTITIES ↓	Entry	Quality	Quantity & Distribution	Protect Patients & Consumers	Pricing & Cost Containment	Information Provision & Grievance Redressal
Practitioners (Doctors, Nurses, Dentists, Pharmacists, Allied Health Professionals)	Education & training Registration Continuing skill enhancement and Renewal of registration Banning	Standards of care (Physical, Process & Outcome) Standard Treatment Guidelines/Protocols Clinical & Medical Audits Safety measures Referral protocol Continuing medical education & skill enhancement Rational, timely, need based Provided in a confidential manner Appropriateness of treatment Patient safety Staffing ratios or service hours Maintain norms Discourage perverse practices Prohibit overuse Use of technology	Geographical distribution, population, ratios e.g., to facilities/beds Services proportional to needs	Protect patients & consumers Appropriate delivery of services Information to patients & consumers Banning of inappropriate and unacceptable health services and products Confidentiality of patients' & consumers' information is protected	Fee schedule Pricing health care services Containing costs and prices Escalation of costs Contracting fees Ensuring efficiency in health care costs Control overuse of services Affordable services Denial or delay of services due to finance Uniform prices for services Setting profit margins Prevent financial fraud and other abuses Control monopolies, anti-competitive behaviour	Provision of appropriate information to patients & consumers Periodic information from providers Information from providers for public health measures Data collection & sharing system Beneficiaries' complaint system Provider complaint system Reduce information asymmetry between the provider and patients & consumers
Health Facilities (Outpatient, Inpatient, Outreach Services)	Registration Renewal of registration Banning & closing	Standards of care (Physical, Process & Outcome) Standard Treatment Guidelines/ Protocols Clinical & Medical Audits	Geographical distribution, population, ratios e.g., to facilities/beds Services proportional to needs	Protect patients & consumers Appropriate delivery of services Information to patients & consumers	Fee schedule Pricing health care services Containing costs and prices	Provision of appropriate information to patients & consumers Periodic information from providers

		Safety measures Referral protocol Continuing Training Rational, timely, need based Provided in a confidential manner Appropriateness of treatment Patient safety Staffing ratios or service hours Maintain norms Discourage perverse practices Prohibit overuse Use of technology		Banning of inappropriate and unacceptable health services and products Confidentiality of patients' & consumers' information is protected	Escalation of costs Contracting fees Ensuring efficiency in health care costs Control overuse of services Affordable services Denial or delay of services due to finance Uniform prices for services Setting profit margins Prevent financial fraud and other abuses Control monopolies, anti-competitive behaviour	Information from providers for public health measures Data collection & sharing system Beneficiaries' complaint system Provider complaint system Reduce information asymmetry between the provider and patients & consumers
Diagnostic Laboratory & Imaging Centres	Registration Renewal of registration Banning & closing	Standards of care (Physical, Process & Outcome) Standard Treatment Guidelines/ Protocols Clinical & Medical Audits Safety measures Referral protocol Continuing Training Rational, timely, need based Provided in a confidential manner Appropriateness of service	Geographical distribution, population, ratios e.g. to facilities/beds Services proportional to needs	Protect patients & consumers Appropriate delivery of services Information to patients & consumers Banning of inappropriate and unacceptable health services and products Confidentiality of patients' & consumers' information is protected	Fee schedule Pricing health care services Contracting fees Containing costs and prices Escalation of costs Ensuring efficiency in health care costs Control overuse of services Affordable services	Provision of appropriate information to patients & consumers Periodic information from providers Information from providers for public health measures Data collection & sharing system Beneficiaries' complaint system Provider complaint system

		Patient safety Staffing ratios or Service hours Maintain norms Discourage perverse practices Prohibit overuse Use of technology			Denial or delay of services due to finance Uniform prices for services Setting profit margins Prevent financial fraud and other abuses Control monopolies, anti-competitive behaviour	Reduce information asymmetry between the provider and patients & consumers
Pharmaceuticals, Vaccines & Medical devices	Registration Renewal of registration Banning	Standards of care (Physical, Process & Outcome) Standard Treatment Guidelines/Protocols Clinical & Medical Audits Safety measures Referral protocol Continuing Training Rational, timely, needs Provided in a confidential manner Appropriateness of services/treatment Patient safety Staffing ratios or Service hours Maintain norms Discourage perverse practices Prohibit overuse	Geographical distribution, population, ratios e.g. to facilities/beds Services proportional to needs	Protect patients & consumers Appropriate delivery of services Information to patients & consumers Banning of inappropriate and unacceptable health services and products Confidentiality of patients' & consumers' information is protected	Fee schedule Pricing health care services Contracting fees Containing costs and prices Escalation of costs Ensuring efficiency in health care costs Control overuse of services Affordable services Denial or delay of services due to finance Uniform prices for services Setting profit margins Prevent financial fraud and other abuses	Provision of appropriate information to patients & consumers Periodic information from providers Information from providers for public health measures Data collection & sharing system Beneficiaries' complaint system Provider complaint system Reduce information asymmetry between the provider and patients & consumers

		Use of technology			Control monopolies, anti-competitive behaviour	
Supportive services (Pharmacies, Blood banks, Ambulances etc.)	Registration Renewal of registration Banning & closing	Standards of care (Physical, Process & Outcome) Standard Treatment Guidelines/Protocols Clinical & Medical Audits Safety measures Referral protocol Continuing Training Rational, timely, need based Provided in a confidential manner Appropriateness of services Patient safety Staffing ratios or Service hours Maintain norms Discourage perverse practices Prohibit overuse Use of technology	Geographical distribution, population, ratios e.g. to facilities/beds Services proportional to needs	Protect patients & consumers Appropriate delivery of services Information to patients & consumers Banning of inappropriate and unacceptable health services and products Confidentiality of patients' & consumers' information is protected	Fee schedule Pricing health care services Contracting fees Containing costs and prices Escalation of costs Ensuring efficiency in health care costs Control overuse of services Affordable services Denial or delay of services due to finance Uniform prices for services Setting profit margins Prevent financial fraud and other abuses Control monopolies, anti-competitive behaviour	Provision of appropriate information to patients & consumers Periodic information from providers Information from providers for public health measures Data collection & sharing system Beneficiaries' complaint system Provider complaint system Reduce information asymmetry between the provider and patients & consumers
Professional Actions & Illnesses/Diseases	Registration Renewal of registration Banning procedures & services	Standards of care (Physical, Process & Outcome) Standard Treatment Guidelines/Protocols Clinical & Medical Audits	Geographical distribution, population, ratios e.g. to facilities/beds Services proportional to needs	Protect patients & consumers Appropriate delivery of services	Fee schedule Pricing health care services Contracting fees	Provision of appropriate information to patients & consumers Periodic information from providers

		Safety measures Referral protocol Continuing Training Rational, timely, need based Provided in a confidential manner Appropriateness of treatment Patient safety Staffing ratios or Service hours Maintain norms Discourage perverse practices Prohibit overuse Use of technology		Information to patients & consumers Banning of inappropriate and unacceptable health services and products Confidentiality of patients' & consumers' information is protected	Containing costs and prices Escalation of costs Ensuring efficiency in health care costs Control overuse of services Affordable services Denial or delay of services due to finance Uniform prices for services Setting profit margins Prevent financial fraud and other abuses Control monopolies, anti-competitive behaviour	Information from providers for public health measures Data collection & sharing system Beneficiaries' complaint system Provider complaint system Reduce information asymmetry between the provider and patients & consumers

PRACTITIONERS

NURSES

The word nurse is derived from the Latin word 'nutrire', which means to suckle or to nourish, referring to a wet nurse, that is a woman who breastfeeds the babies of others. A nurse today is defined as a person who has formal education and training in the care of the sick or the infirm. Specifically, a nurse is a licensed health care professional, skilled in promoting and maintaining health and usually assists or works under the supervision of a medical practitioner (Merriam-Webster, 2021). According to WHO, "Nursing encompasses autonomous and collaborative care of individuals of all ages, families, groups and communities, sick or well and in all settings. It includes the promotion of health, the prevention of illness, and the care of ill, disabled and dying people." (World Health Organization, 2020d). Nurses comprise the largest proportion, almost 34 percent of the health workforce in India, as of January 2016 (Karan et al., 2019).

Florence Nightingale, a British nurse, social reformer, and statistician is known as the founder of modern professional nursing. She is recognised for her pioneering work of tending to sick soldiers, during the Crimean war. In India, the foundation of nursing as a distinct profession was laid by the British. Christian missionaries were responsible for introducing systematic and standardised professional training courses for nurses. The foremost training school for nurses was established in Madras in 1871 (Ray & Sen, 2014). The Nurses and Midwives Registration Act was passed in Madras in 1928, and other provinces followed suit (Sharma, 2014). The 'Health Survey and Development Committee' appointed by the Government of India (GoI) in 1943, recommended the formation of an All-India Nursing Council, to ensure that uniform standardised training to be provided at all nurse training institutions in the country (Government of India, 1946). Accordingly, the Indian Parliament passed the Indian Nursing Council (INC) Act (Act No. 48 of 1947) in December 1947, to regulate the curriculum and training programme of nurses (Indian Nursing Council Act, 1947; Ray & Sen, 2014).

The nursing and midwifery workforce in India increased from 1,231,322 in 2000 (World Health Organization, 2020b) to 2,966,375 in 2017. This number includes 8,60,927 Auxiliary Nurse Midwives (ANMs), 2,048,979 Registered Nurses and Registered Midwives (RNs & RMs) and 56,469 Lady Health Visitors (LHVs) (Central Bureau of Health Intelligence, 2019). According to the World Health Statistics report of 2020, India had 17.3 nurses and midwives for every 10,000 people in 2018, a figure much lower than that of developed countries and a global density of 37.6 (World Health Organization, 2020e). Shortage of nurses over a prolonged period of time has adverse consequences for the

population's health outcomes. Like other health professionals, most nurses are employed in urban than rural areas and the private sector employs more nurses than the public sector (Saikia, 2018).

Entry

Some of the commonly used mechanisms to control entry into a profession are a specification of a minimum standard of education and training, registration with a recognised body and requirement of a license to practice. The requirements for persons desirous of entering the health care sector as nurses are similar.

The Indian Nursing Council (INC) Act, 1947, is applicable to all of India. The purpose of the Act is to regulate the education and entry of nursing professionals and ensure the upgradation of their skills, through continuing nursing education (MoHFW, 2005). The Act was brought in to address the difficulties arising due to the varying entry-level qualifications for nursing education, and diverse nursing curriculum and training followed by nursing institutions in different parts of the country. Section 3(1) of the INC Act, 1947, prescribes the Constitution of the Indian Nursing Council (henceforth referred to as Council), as an autonomous body under the MoHFW, Government of India. The main role of the Council is to establish uniform minimum standards of education and training for nurses, midwives, ANMs and health visitors, supervise examinations, and maintain a schedule of nursing qualifications recognised for registration throughout India. It prescribes the syllabus and regulations for the nursing courses, accredits the education/training programmes and specifies minimum quality criteria for educational institutions. The Council was first constituted in 1949 as per the process laid down in the Act (MoHFW, 2005; Khadria, 2007; Tiwari et al., 2013). The Schedule to the Act enlists recognised qualifications and higher qualifications as applicable nationally.

Nurses in India can be divided into the following categories depending on their qualification. Eligibility for ANMs is the completion of the 12th standard, after which a person can enrol for a two-year diploma and work as a Registered Auxiliary Nurse and Midwife (RANM). A General Nurse Midwife (GNM) undergoes a three-year diploma after completing the 12th standard. The B.Sc. Nursing is a four-year degree course that can be pursued after completing 12th standard in science subjects (Physics, Chemistry, Biology). GNM's can earn a degree in nursing by undergoing a two-year post basic B.Sc. course (Khadria, 2007; Tiwari et al., 2013; Sharma, 2014; Gill, 2016). Nurses having a B.Sc. Nursing Degree can pursue M.Sc. Nursing and higher education, such as M.Phil. and PhD Masters courses are offered in different specialisations, such as public health nursing, cardiovascular nursing, oncology nursing, psychiatric/mental health nursing, paediatric nursing, etc. There are several post-graduate diploma and post-graduate certificate programmes, such as in Public Health Nursing (PHN), Paediatric

Nursing (PN), etc. A newly added M.Sc. level course is the Nurse Practitioner in Critical Care (NPCC) (Indian Nursing Council, 2016).

The MoHFW, GoI, entrusted the Council with the responsibility to draft a bill to amend the INC Act, 1947, to grant greater autonomy to trained nurse practitioners to provide certain services independently. A licentiate examination to issue licenses to newly graduated nurses has also been under discussion. However, neither of these have seen any progress so far (Chandna, 2018). MoHFW, GoI and the Council introduced a specialised Nurse Practitioners in Midwifery (NPM) training in 2018. GNMs/B.Sc. level staff nurses (RN & RM), with two years of experience in maternity care, are eligible for the post-basic 18 months NPM training, after which they are eligible to manage midwife-led care units at public health care facilities. However, the NPM nomenclature and course has not been incorporated into the legislation and is therefore not recognised. Similar initiatives were tried out in different States from the early 2000s, but could not be sustained and scaled up for similar reasons (MoHFW, 2018). Nursing schools provide diplomas in ANM and GNM training, while nursing colleges (that are affiliated to universities) provide Bachelor's, Master's and Doctoral degrees (Tiwari et al., 2013).

At the State level, State Nursing Councils (SNCs)/State nurses and midwife councils are constituted under legislations of the respective States, to grant recognition to nursing education institutions, organise examinations, prescribe rules of conduct and regulate the registration, licensing and renewal of licenses of nurses, midwives, ANMs, multipurpose workers and health visitors in the State. If any State nursing council wants to offer a new qualification that is not included in the Schedule of the INC Act, 1947, it needs to apply to the Indian Nursing Council to get such a qualification recognised. (Khadria, 2007; Gill, 2016).

Sections 13 and 14 of the INC Act, 1947, grant the Executive Committee (EC) of the Council the authority to inspect nursing institutions, to assess their suitability to offer nursing courses/training, quality of the training and sufficiency of the examinations. The INC Regulations specify the powers, roles and functioning of the EC, and the procedure for the inspection of examinations and training institutions, by inspectors appointed for the purpose by the EC. If the courses, examinations, proficiency of students or conditions for admission at institutions recognised by State council are not found to conform with the regulations made under the Act or the requirements of the Council, the Council may de-recognise the said qualification offered by the institution, after following the due process (Indian Nursing Council Regulations, n.d.).

The State nursing councils maintain a register of nurses, midwives and health visitors. After completing their nursing course, nurses need to register with the council in the State where they have studied, in order to obtain a license to work. The Indian Nursing Council (Amendment) Act, 1957 (Act No. 45 of 1957), prescribes the Council to maintain an updated Indian Nurses Register that contains the names of nurses, midwives, auxiliary nurse-midwives and health visitors who are enrolled in any State register (Indian Nursing Council (Amendment) Act, 1957). The Indian Nursing Council (Conduct of Business) Regulations, 2009, require the Council to maintain a register with names of each Registered Nurse and Registered Midwife (RNRM)/Registered Auxiliary Nurse and Midwife (RARM)/Registered Lady Health Visitor (RLHV), along with their qualifications and other details (Indian Nursing Council (Conduct of Business) Regulations, 2009). The INC (Amendment) Act, 1957, also provides for the registration of Indian citizens who gain nursing education in other countries, as well as for temporary registration of foreign nurses working in India. As per the INC (Conduct of Business) Regulations, 2009, the State councils need to renew the registration of nurses every five years, provided the nurse completes 150 hours of continuing nursing education (CNE) during the five-year period. The Indian Nursing Council (Continuing Nursing Education) Regulations, 2019, provide detailed guidelines on the process of CNE. The State councils need to update the qualifications of nurses registered with them, as and when applicable. An online Nurses Registration & Tracking System (NRTS) has been established, according to the provisions of the Indian Nursing Council (Nurses Registration & Tracking System) Regulations, 2019, that supersede Clause 59 (Part X, Indian Nurses Register) of the Indian Nursing Council (Conduct of Business) Regulations, 2009. NRTS has standardised data collection forms for RNs & RMs, RANMs and RLHVs upon Aadhar based biometric authentication. After due verifications and approval by the State council and on being enrolled in the Indian Nurses Register, the concerned nurses are provided with a Nurse Unique Identity Card (NUID), and Nurse and Midwife Register Passbook.

The Indian Nursing Council (Nurses Registration & Tracking System) Regulations, 2019, specify the procedure for reciprocal/transfer of registration if a registered nurse wishes to transfer her/his registration from one State to the other. Through the NRTS, the nurse can apply online and pay a uniform reciprocal registration fee. The SNCs are authorised to levy a penalty if an applicant does not apply for reciprocal registration within three months of moving out of the earlier SNC jurisdiction. However, neither the INC Act, 1947 nor the INC Regulations, 2009, make reciprocal/transfer registration mandatory.

Quantity

There is an absence of legislations to regulate the number of nurses produced or educational institutions that can be established in the country, or their distribution in different parts of the country. As a result, more than half of the nursing institutes are situated in the four southern States

of India - Andhra Pradesh, Karnataka, Kerala and Tamil Nadu (Saikia, 2017). Nurse-to-patient ratio and nurse staffing norms in hospitals have been recommended by the Indian Nursing Council, INC (1985), Medical Council of India, MCI (1990), Staff Inspection Unit, SIU (1991-92) and the National Accreditation Board for Hospitals & Healthcare Providers, NABH (2005) (Sharma & Rani, 2020). These need to be revised according to the changing disease burden and nature of health care services.

Quality

There is no defined scope of practice for different levels and qualification of nurses (Sharma, 2017). Although there are no explicit legislations that prohibit nurses from practising independently, they hardly do so except to provide specific reproductive and child health services as outlined in the Government of India guidelines (National Rural Health Mission, 2010). Nurses in India essentially practice in an institutional setting as part of a medical team, usually headed by a doctor. The Clinical Establishments Act, 2010, does not mention nurses as independent practitioners and barring this, there is no legal restriction on independent practice by nurses. They cannot perform complicated deliveries because they are not trained for it and they are not authorised to prescribe medicines under the Drugs and Cosmetics Act, 1940. However, a nurse is a licensed health care worker trained to provide preventive and promotive services, and education and counselling. The INC and GoI have taken measures to increase the scope of practice of RN & RM, by introducing two nurse practitioner courses, that is, midwifery and critical care. These courses authorise the nurses to administer/prescribe certain approved drugs, medical equipment and therapies in the institutional setting (Indian Nursing Council, 2016) (MoHFW, 2018). However, the necessary amendments to the INC Act, 1947, have not been affected to include these courses in the list of recognised qualifications.

Gaps and Challenges

The discrepancy and confusion in the roles of the Council and the State Nursing Councils, has led to several ill-equipped nursing training institutions functioning in the country (Gill, 2016). In 2004, about 61 percent of the nursing schools/colleges were found unsuitable for teaching, but the Council could not take any action against them as they were granted permission by the State Nursing Councils (MoHFW, 2005). For example, though the Council withheld the recognition of government nursing schools in Uttar Pradesh (UP) because their teaching staff did not have the required training, the UP State council continued to recognise those schools (Raha, Berman, & Bhatnagar, 2009).

The Karnataka State Association of the Managements of Nursing and Allied Health Sciences Institutions, and some nursing colleges filed a petition in the Karnataka High Court after the Council removed the nursing colleges of the State, from the list of recognised institutions of nursing. The High Court of Karnataka and the Supreme Court ruled in the favour of the State nursing council. The ruling

clarified that the recognition and approval of colleges imparting nursing training and fixing the student intake, are to be regulated by the State enactments and the State authorities including the State nursing council, and not the Council (Chhapia, 2017; High Court of Karnataka, 2017; Special Correpondent, 2017). The High Court of Karnataka in its judgement dated 24 July 2017, ruled that the Council has no authority to grant recognition to institutions imparting nursing courses. It directed the Council not to publish any such material on its website that indicates that the institutions must obtain recognition from it, as it may be inferred that the colleges that are not listed on the Council website are not recognised. The Court observed that the Council under section 10 of the INC Act, 1947, has the power to recognise qualifications and syllabus, and not institutions. Citing 1993 and 2014 Patna High Court orders, 2005 Supreme Court order, and 2002 and 2005 orders of the Karnataka High Court, the ruling clarified that the recognition and approval of colleges, imparting nursing training and fixing the student intake, are to be regulated by the State enactments and the State authorities including the State nursing council, and not the Council (High Court of Karnataka, 2017; Special Correspondent, 2017). The above ruling was upheld by the Supreme Court in its order dated September 2017 (Chhapia, 2017). Despite the above rulings, the Council issued a letter in February 2019, stating that it still enjoyed the power to inspect all nursing colleges for the purpose of granting them recognition. The private nursing schools' and colleges' management associations across the country objected to the letter terming it contempt of court (Shrivastav, 2019). There have been allegations of corruption against the Council with some State nursing councils, alleging that it charged a high amount of money for recognising nursing colleges and for putting their names on its website (Chhapia, 2017).

Some other contentious issues are related to the working conditions, pay scales, non-payment of salaries, confiscating the degrees and various forms of exploitation of the nurses in private health facilities. Nurses are reported to have faced several problems, particularly when employed in the private sector. These include low salary, poor nurse to patient ratio leading to long working hours and excessive workload, non-nursing duties, and exploitative terms and conditions of employment. There have been calls for enacting a Nursing Act and forming national-State level observation boards, to lay down standard working conditions and security measures for the welfare of nurses (Mathrubhumi, 2011; Walton-Roberts et al., 2017). Further, there are issues of nurses' right to work across the country. The private nursing schools and colleges management association filed a petition in the Supreme Court (SC) of India, against an order passed by the Aurangabad Bench of the High Court of Bombay dated 9 October 2017, that a person holding a nursing degree or diploma recognised by the nursing council of a State could work only in that State (Bombay High Court, 2017). The SC in its order dated 22 January 2019, reversed the above ruling. It observed that Article 19(1)(g) of the Constitution of India granted the nurses the fundamental right to practice their occupation throughout the territory

of India and that the Indian Nursing Council Act, 1947, does not restrict their practice of nursing only to the State where they receive their qualification from (Manorma Online,2019; Supreme Court of India, 2019).

The National Health Policy 2017 envisages the phasing out of GNM training by 2022. The Council has issued a notification to phase out the GNM course from 2021, with the last batch to the course to be admitted in 2020 (Indian Nursing Council, 2019b). Annually almost 0.12 million nurses pass out as GNMs. From 2021, only the B.Sc. course will be offered. In some States, there are concerns about the procedure of transition from GNM schools to B.Sc. Nursing colleges, as there are no clear guidelines yet from the Council in this regard. Phasing out of the GNM course will pave the way for a single entry into the nursing profession, which will add uniformity and standardisation at the point of entry into the profession and also add value to the profession.

The INC Act, 1947, as well as the State council acts have not changed with the changing times and needs of the nursing profession and the health care system. Amendments to the INC Act, 1947, were proposed in 2014 to widen the scope of the Council and reform its functioning, but they could not be pursued. In the early 2000s, the Government of India took a policy decision to permit ANMs, LHVs and staff nurses to undertake certain interventions as skilled birth attendants. These include administering specific drugs, providing basic obstetric care and managing complications, including essential newborn care and resuscitation services (National Rural Health Mission, 2010). Similar is the case of mid-level health care providers being integrated into the Ayushman Bharat Initiative and the midwife led units, associated with labour rooms of medical colleges and district hospitals (MoHFW, 2018; Indian Nursing Council, 2019a). Such policy decisions that give greater autonomy to nurses/nurse-midwives need to be considered while laying down the scope of practice for the profession. A National Nursing and Midwifery Commission (NMMC) Bill is under consideration (Nursing Section, 2020), which gives an opportunity to bring about changes in nursing education, as well as practice (Gupta, 2020).

There is a lack of representation of nurses in decision-making positions in the State and national level bodies and councils, that are usually filled by non-nursing persons. In the absence of a Nursing Cell/Directorate of Nursing or the post of Director Nursing in the Centre and the States, decisions for the nursing sector are taken mainly by non-nursing administrators, such as the senior State health administrators and medical directors. This has a direct impact on the development of and reforms in nursing education, as well as nursing services in the country. The High Power Committee (HPC) formed by the GoI in 1989, had recommended the formation of directorates of nursing in the States for better governance of the nursing sector. To date, the recommendation has not been put into action in all the States (Bagga et al., 2015). In 2013, Odisha was the first State to have a directorate of nursing

(Government of Odisha, 2020). At the Union government level, a separate directorate of nursing is recommended (Bagga et al., 2015).

The expansion of the private nursing educational institutions helped in meeting the need for a higher number of nursing professionals. Up to 95 percent of the nursing and midwifery institutions in the country are operated by private entities. At the same time, numerous concerns have been raised about the quality of education and training imparted at private institutions. Observations have been made about the private institutions being operated solely with a profit motive and inadequate infrastructure, faculty and quality education (Saikia, 2017).

There are no uniform standards applicable across the States for nursing cadres, nomenclature and job descriptions, which have restricted the growth and professional development of the sector. Senior positions that enjoy decision-making powers need to be created at both the State and national levels.

PHARMACISTS

The word pharmacy is derived from the Greek word “pharmakon”, meaning medicine or drug. A pharmacist is a “medicine or drug man”. The International Labour Organization’s (ILO) International Standard for Classification of Occupation (ISCO) defines pharmacists as “…health professionals who are involved in storing, preserving, compounding, and dispensing medicinal products...” They also counsel patients on the proper use and adverse effects of drugs and medicines. ILO recognises pharmacists through various definitions, such as hospital pharmacist, industrial pharmacist, retail pharmacist and dispensing chemist (Pearson, 2007; World Health Organization 2020a). In 2016, the Board of Pharmaceutical Practice (BPP) adopted the following definition “…a pharmacist, is a scientifically trained graduate healthcare professional who is an expert in all aspects of the supply and use of medicines. Pharmacists assure access to safe, cost-effective and quality medicines and their responsible use by individual patients and healthcare systems…” (Board of Pharmaceutical Practice, 2021). Pharmacists are authorised to provide drugs to patients (with or without prescription under specified conditions), next in line with the doctors. They play a significant role around the world in manufacturing and delivering safe, effective drugs and promoting rational use of medicines (Pharmapproach, 2020).

In India, the earliest known compilation of medicinal substances is credited to Sushruta, who is attributed as a physician of the 6th century BC. Charaka and Sushruta are known physicians and pharmacists of ancient India, who studied more than 1000 herbs. In the medieval period (130 - 200 CE), the father of pharmacy, Galen, emerged as an important pharmacist of his time. His medications and procedures were the mainstay for about 1500 years and still inspire modern pharma industries and laboratories (Khakurel et al., 2019). Advances were made between 400 to 900 AD centuries with the independent calling of Apothecary, a historical name for a professional who formulates and dispenses medicines to physicians and patients, a role now served by a pharmacist. During the first decade of the 19th century, the most important breakthrough occurred when the pharmacist, Friedrich Sertürner, extracted morphine from crude opium, opening the era of alkaloidal chemistry. Retail pharmacies started opening in The United States of America in 1729. In the 1800s, modern national pharmacopoeias (book describing drugs, their effects, dosage and directions for use) came out in Britain and The United States of America. The production of the poliomyelitis vaccine and the discovery of penicillin revolutionised the modern pharmacology techniques of drug discovery in the 1900s. Pharmacies became retail outlets of pharmaceutical industries and simultaneously the rise in clinical pharmacy or hospital pharmacy emerged (Pearson, 2007; Urick & Meggs, 2019). The British

period played a key role in bringing the profession of pharmacy to India. The practice of the pharmacy profession in India began in 1811, with the opening up of a chemist shop in Calcutta (now Kolkata). Pharmacy education started in Goa in 1842. The regular university-level programme, B. Pharma, was started in 1937 at the Banaras Hindu University, Varanasi, under the leadership of Prof. M L Shroff, father of Indian pharmacy. By 1979, many organisations merged to form the All-India Organization of Chemists and Druggists (Hardas, 2012; Yenepoya University, 2020).

By 1920, provincial level establishments were started in Bengal, Punjab and United Provinces (now Uttar Pradesh) etc., and legislations enacted to regulate the import, export, transport, manufacture and sale of intoxicating drugs and substances. The Drugs Enquiry Committee (DEC) under the chairmanship of Late Col R N Chopra was appointed in 1930 by the Government of India, realising the absence of a systematic profession like pharmacy in India. The committee reported that compounders and untrained people were managing the profession of pharmacy and recommended that there should be a law to control the sale of drugs, and another law to ensure that drugs are managed by qualified persons trained in pharmacy (Hardas, 2012; Yenepoya University, 2020).

The Bhore Committee in 1946 recommended a three-tier system of pharmacy education in India, that is, diploma, degree and technologists in pharmacy. Before 1948, there were no restrictions or legislative controls over the minimum education required to practice the pharmacy profession in India. It was being handled by compounders and dispensers (Government of India, 1946).

Entry

In 1948, the Union Government enacted the Pharmacy Act (Act No. 8 of 1948) applicable throughout India, to regulate the profession of pharmacy and maintain the standards of pharmacy education (Pharmacy Act, 1948). As per the provisions of the Pharmacy Act, 1948, the Pharmacy Council of India (PCI) was established. PCI is responsible for prescribing the minimum standard of education required for qualifying as a pharmacist and the minimum conditions for the institutions imparting education in pharmacy, ensuring uniform implementation of the educational standards throughout the country, inspection of pharmacy institutions, and withdrawing approval if the courses or colleges do not follow prescribed educational standards. PCI also maintains a Central register of pharmacists (Pharmacy Council of India, 2018a). State Pharmacy Councils (SPCs) are constituted under section 19 of the Pharmacy Act, 1948, by the respective State government. SPC is responsible to register and renew the registration of the qualified persons, maintain State registers, remove or suspend a pharmacist's registration, hold elections to elect State council members and regular meetings, ensure coordination with the State government, PCI and other concerned departments, and check for unethical practices as per the Act (Pharmacy Council of India, 2018b).

In 1945, a national level council, the All India Council for Technical Education (AICTE) was set up to ensure coordinated development of technical education, including pharmacy. AICTE became statutory in 1987, with the enactment of the All India Council for Technical Education (AICTE) Act, 1987 (All India Council for Technical Education, 2016). Till recently, the AICTE regulated advanced pharmacy education and gave approvals to educational institutes offering courses like B. Pharm. and M. Pharm, while PCI was responsible for granting approval to colleges offering D. Pharm. The Supreme Court of India on 5 March 2020, gave direction for a single regulatory body at the national level for pharmacy education in India, and since then Pharmacy Council of India is the only responsible body granting recognition to institutions offering pharmacy courses, either diploma, bachelors or advanced courses (Pharmaceutical Jurisprudence, 2018; Supreme Court of India, 2020).

As per the Drug Act of 1940 (now called the Drugs and Cosmetics Act (DCA), 1940) and Drugs and Cosmetics Rules (DCR), 1945, a pharmacist must adhere to and maintain standards while providing the services (Drugs and Cosmetics Act, 1940). Central Drugs Standard Control Organisation (CDSCO) is the National Regulatory Authority (NRA) of India and various responsibilities have been entrusted to the State Drug Controllers, who is primarily responsible for granting a licence for the wholesale and retail sale of drugs and regular inspection of the premises licensed for manufacturing, storing or dispensing of drugs (Drugs and Cosmetics Rules, 1945; MoHFW, 2020a).

In India, there are more than one million registered pharmacists who work in a variety of health care settings, in the pharmaceutical industry (research and development, manufacturing, quality, sales, etc.), in practice settings (hospital, community and clinical), in academics and research. Currently, more than 5,000 pharmacy educational institutions produce around 3,00,000 pharmacists per annum in India.

A diploma in pharmacy (D Pharm) is the minimum educational qualification required to register as a pharmacist and practice the pharmacy profession, as per Education Regulations 1991, promulgated under the Pharmacy Act, 1948. The minimum eligibility criteria to study D Pharm is that the candidate must have passed the 10+2 examination. The diploma course is a minimum of two years of study, besides practical training of 500 hours in a hospital, dispensary or pharmacy. The Education Regulations 1991 prescribe minimum requirement for admission, course content, syllabus and other criteria, to receive the certificate in D Pharm (Education Regulations, 1991).

The Bachelor of Pharmacy (B Pharm) Course Regulations, 2014, specifies the minimum requirement for admission, course content, syllabus and other criteria, to receive the certificate in B Pharm (four years course) (The Bachelor of Pharmacy (B.Pharm) Course Regulations, 2014).

The Master of Pharmacy (M Pharm) Course Regulations, 2014, prescribe the minimum requirement to receive the certificate in M Pharm (two years course) (Master of Pharmacy (M.Pharm) Course Regulations, 2014). Each State conducts its examination for admission into D. Pharm. and B. Pharm. courses, as per the admission requirement prescribed by the Pharmacy Council of India. For admission in the M. Pharm. course, an all-India examination - Graduate Pharmacy Aptitude Test (GPAT) is conducted by the National Testing Agency since 2019, prior to which it was conducted by the All India Council for Technical Education (Ministry of Education, 2019).

Other Advanced Courses: Bachelor of Pharmacy (Practice) Regulations, 2014, specifies minimum educational requirement and other criteria to receive the certificate in Bachelor of Pharmacy (Practice) (two years course). This course was introduced as an additional qualification for a registered pharmacist, who has a minimum experience of four years practising either in a community or hospital pharmacy. Pharm.D. Regulations, 2008, prescribes the minimum requirement for admission process, curricula, syllabus and other criteria, to receive the certificate in Pharm D (Doctor of Pharmacy, that is, doctorate level degree).

The State Pharmacy Council is responsible for the preparation and maintenance of the State register of pharmacists, as per Section 29 of Pharmacy Act 1948. A person is registered as a pharmacist in the State register by the State Pharmacy Council (SPC), after passing D Pharm. Pharmacy (Amendment) Act, 1976, provided for registration of persons who qualified as compounders or dispensers as per the Drugs and Cosmetics Act, 1940, but were not registered under the Pharmacy Act, 1948, in the State pharmacists' register. The SPC also has the provision to grant registration to persons (citizens of India only) under the Pharmacy Act, 1948, to enter and practise the profession of pharmacy, provided they have obtained a qualification in pharmacy from any institution outside India, which is recognised by the PCI. Those pharmacists working in the industrial sector are not considered practising pharmacists and hence do not need registration.

The SPC is also responsible for the renewal of the registration of pharmacists. A pharmacist is required to pay a renewal fee as prescribed by the State council, upon payment of which, the registrar would renew his/her name in the State register. Pharmacy Practice Regulations, 2015, recommends that the pharmacist should attend a minimum of two refresher courses in pharmacy of a minimum of one-day duration, each over a span of five years, organised either by PCI or SPC or any other recognised professional body, for renewal of their registration (Pharmacy Practice Regulations, 2015).

PCI launched a national digital platform for registration and tracking of pharmacists at the Union government level, through the Pharmacist Registration and Tracking System (PRTS) in 2018. PRTS intended to help PCI collect data on gender, age, education level and State-wise information, as well

as on the employment status of pharmacists. It is also expected to address issues of malpractice in the pharmacy profession, by registering only qualified pharmacists (Yadav, 2018).

Quantity

Taking into consideration the availability of a sufficient qualified pharmacist workforce in the country, PCI passed a notification in 2019, to put a moratorium on the opening of new pharmacy colleges for diploma and degree courses in pharmacy, for a period of five years, beginning from the academic year 2020-2021. This moratorium is not applicable in the north-eastern region of the country, where there is a shortage of pharmacy colleges (Pharmacy Council of India, 2019).

Quality

To improve the quality of health care, ensure pharmacists maintain high standards in duty, reduce the cost of health care and to inhibit criminal abuse of medicines under the Pharmacy Practice Regulations, which were introduced in January 2015. Under the provision of Pharmacy Practice Regulations, 2015, a pharmacist can work either as a community pharmacist, hospital pharmacist, drug information pharmacist or clinical pharmacist. Apart from dispensing drugs, pharmacists are also required to provide oral communication to the patient or caregiver, to ensure proper use of drugs and devices.

Part VI of the Drugs and Cosmetics Rules (DCR), 1945, Sale of Drugs Other than Homoeopathic Medicines gives guidelines and standards on how, when, where and who can obtain a licence or renew it from the State government to store, sell, display, or distribute drugs. A pharmacist or an owner of the pharmacy store (with a full-time registered pharmacist employed for dispensing of drugs), can obtain a licence for drug sale. The State licencing authorities issue two types of licences for drug sale, that is, for retail sale and wholesale. The sale of drugs by retail must be conducted by a registered pharmacist possessing a degree or diploma in pharmacy, and registered under the Pharmacy Act, 1948. Wholesale licences are issued to people or firms who want to set up the wholesale business for drugs and medicines. A registered pharmacist is not mandatory to obtain the wholesale licence, but the sale of drugs must be conducted in the presence of registered pharmacists or in the presence of a competent person with experience in dealing with drugs.

Schedule N under the Drugs and Cosmetics Rules, 1945, mentions that a pharmacy should always operate/function under the supervision of a registered pharmacist, who is wearing clean white overalls and whose name should be displayed conspicuously on the premises (Schedule N: Drugs and Cosmetics Rules, 1945).

Prescription Guidelines

Pharmacy Practice Regulations, 2015, specifies minimum criteria for the provision of pharmaceutical care. It specifies that a registered pharmacist should compound, prepare, mix, dispense or supply any drug or medicines on the prescription of a Registered Medical Practitioner (RMP), who is registered either with the State medical register or State dentist register or is engaged in the practice of veterinary medicine. A registered pharmacist is not allowed to substitute the prescription but is supposed to review the patient record and conduct a pharmaceutical assessment of each prescription, for identifying overutilisation or underutilisation, therapeutic duplication, drug-disease interactions, drug-allergy interactions and clinical abuse/misuse. The other activities of dispensing (prescription assembly) like removal of drugs from the packing, filling the prescription etc., may be performed by someone who has been trained for these activities but under the supervision of a registered pharmacist. However, the actual dispensing of drugs to patients should always be performed by the pharmacist.

Approximately 1,600 medicines are routinely prescribed in India and 656 of them are covered under schedule H, H1, G or X mentioned in the DCR, 1945. Many of the commonly prescribed medicines lack clear prescription guidelines, and this has resulted in a scenario where the drug classification of these medicines is open to interpretation for RMPs, pharmacists, manufacturers, and regulators. The current drug classification system primarily focuses on five drug classes, that is, Schedule G, H, H1, K, and X drugs as mentioned below (Kamboj, 2020).

Figure 3: Drug Classification System

Drug Schedule	Definition	Prescription Guidance
Schedule G	Schedule G consists of drugs that can be administered only under the supervision of an RMP	'Caution: It is dangerous to take this preparation except under medical supervision'
Schedule H	Schedule H consists of drugs that are required to be dispensed on the prescription of an RMP	Medicines to be sold by retailer only on RMP prescription The prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once No person dispensing a prescription containing substance specified in Schedule H and Schedule H1 or X may supply any other preparation, whether containing the same substance or not, in lieu thereof At the time of drug dispensing, the name and address of the seller and the date on which the prescription is dispensed must be noted on the prescription above the signature of the prescriber.
Schedule H1	Schedule H1 consists of drugs including antibiotics, habit forming drugs and a few anti TB drugs which were abused under Schedule H, and now have a regulation on their sales and additional warning to the patient	Medicines shall not be sold in retail except on and in accordance with the prescription of an RMP Supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied, prescription copy, and such record shall be maintained for three years and be open for inspection
Schedule K	One of the aspects of this schedule is the list of drugs that can be sold without a license	None
Schedule X	Schedule X consists of drugs that are required to be dispensed on the prescription of RMP.	It requires special retail & license for selling these medicines. Medicines to be sold only on RMP prescription. Copy of the prescription to be preserved for two years and records of all schedule X drugs (available and dispensed) to be kept in a separate register.

Section 5 of Schedule K allows an RMP to stock and dispense medicines to his patients from his premises, without obtaining a drug selling licence, or employing the services of a registered pharmacist and without having an open shop or selling across the counter. As per DCR 1945, there is no separate category of drugs called Over-the-Counter (OTC) drugs. Drugs not included in Schedule H, H1, and X and household remedies under Schedule K such as paracetamol, liquid paraffin, eucalyptus oil, tincture iodine, etc., which can be sold by a pharmacist without the prescription of RMP are considered OTC drugs (Schedule K: Drugs and Cosmetics Rules, 1945).

Indian Medical Council Code of Medical Ethics (Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002), states that a pharmacist should check the legality of every prescription while dispensing a medicine, such as details of the prescribing doctor. A pharmacist should be aware that a doctor cannot affix his/her signboard at a pharmacy shop (IMA, 2020).

Pricing and Cost Containment

The personal financial interests of a registered pharmacist engaged in the practice of the pharmacy profession should not conflict with the medical interests of patients. A registered pharmacist can charge for his services, but he must specifically announce his fees to the patient before rendering service and not after, as specified in the Pharmacy Practice Regulations, 2015. The State Drugs Standard Control Organization/Food and Drugs Administration (FDA) of the States and Union territories, keep a check over the retail sale of drugs and ensure that drugs are not sold at rates higher than the maximum retail price (MRP).

Protect Patients and Consumers

Pharmacy Practice Regulations, 2015, recommends that a registered pharmacist should have regard for the laws of the country that regulate the practice of pharmacy, such as Drugs and Cosmetics Act, 1940; Indian Medical Council Act, 1956 (now National Medical Commission Act, 2019); Narcotic Drugs and Psychotropic Substances Act, 1985; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954. A registered pharmacist should not employ any attendant who is neither registered nor enlisted under the Pharmacy Act, 1948, and should not permit such persons to attend patients wherever professional discretion or skill is required, as per the Pharmacy Practice Regulations, 2015. Pharmacists must always ensure confidentiality of the information entrusted by the patients with them. They should never reveal or judge the character of the patient during medical attendance unless ordered by the laws of the State.

Pharmacy Practice Regulations, 2015, prescribes proper display of the name of the owner of the pharmacy store at or near the main entrance of each premise. A registered pharmacist should be appointed where pharmacy business is conducted otherwise, it would be a violation of section 42 of the Pharmacy Act. The Regulations 2015 have a provision, which prescribes that every registered pharmacist should maintain the medical/prescription records pertaining to his/ her patients for a period of five years, from the date of commencement of the treatment. They are also required to computerize medical/prescription records for quick retrieval. If any request is made for medical records, either by the patients/authorised attendant or legal authorities involved, a registered pharmacist should duly acknowledge and provide documents within a period of 72 hours.

Pharmacy Practice Regulations, 2015, prescribes that a registered pharmacist should not aid, abet or commit any unethical acts, such as soliciting of patients directly or indirectly, make use of him (or his name) for advertising to invite attention to him or to his professional position, or dispensing of secret remedial agents of which he does not know the composition. They should not offer or accept any rebates or commission or bonus, in consideration of referring any patient for sale/dispensing of medicines.

Information Provision

The registered pharmacist, especially those engaged in public health work, should notify the public health authorities of every case of communicable disease under his care, in accordance with the laws, rules and regulations of the health authorities, as per the Pharmacy Practice Regulations, 2015.

Grievance Redressal

Any complaint of professional misconduct by a pharmacist can be brought before the PCI/concerned State Pharmacy Council for disciplinary action. If the registered pharmacist is found to be guilty of committing professional misconduct as judged by the peer group, the PCI/concerned SPC may award punishment as deemed necessary. Pharmacy Practice Regulations, 2015, also provides an opportunity for the pharmacist to be heard in person in case of a complaint against them.

Gaps and Challenges

Before 1980, there were only 11 universities and 26 colleges in India which offered pharmacy education at the bachelor's and master's levels. In the year 2007, 854 institutions enrolled around 52,000 students in the B Pharm degree programme and 583 institutions enrolled around 34,000 students in the D Pharm. In the 1980s, the private institutes accounted for only 10% of the total admitted students, which rose to 91% of the total admitted pharmacy students in 2010 (Basak & Sathyanarayana, 2010; Mandal, 2012). Recent data from the AICTE States that the annual intake capacity of pharmacy seats in colleges have soared up to 2.77 lakh for the academic year 2019-20. However, with the increase in the number of colleges and seats, the enrolment has not kept pace. As many as 52,223 in 2017-18 and 50,106 in 2018-19 seats were left vacant (Sharma & Chandna, 2019). In the academic year 2019, there were 1985 D. Pharm. and 1439 B. Pharm. colleges providing pharmacy education in the country (Kunnathoor, 2019).

The debate to upgrade minimum qualification for registration of pharmacists from diploma to degree, and incorporation of need-based pharmacy curriculum to include clinical pharmacy, community pharmacy, patient counselling, etc. are pending with the regulatory bodies of pharmacy in India.

Role of PCI vs AICTE

B. Pharm. and M. Pharm. qualifications were earlier regulated by the AICTE and all institutions offering these courses were approved by the AICTE, while the establishment of a new institution, introduction of a new course or increase in intake capacity, had to adhere to the course regulations provided by the PCI, under the Pharmacy Act 1948. However, in some instances, AICTE increased the intake capacity in the institutions, despite the PCI's refusal. The dual regulations of pharmacy education under PCI and AICTE was creating considerable confusion. The Supreme Court of India decided in a case - Pharmacy Council of India vs Dr SK Toshniwal Educational Trusts Vidarbha Institute of Pharmacy on 5 March 2020, that the dual regulation should be ended forthwith and the AICTE Act, 1987, governing the general technical education would be amended, deleting 'pharmacy' from its mandate. In the field of pharmacy education, and recognition of degree and diploma courses of pharmacy, the Pharmacy Act, 1948, and rules framed therein would prevail. It also directed that the concerned institutions, who increased their intake capacity as approved by AICTE but was not approved by PCI, should apply afresh within four weeks period, from the date of the decision of the Supreme Court (Supreme Court of India, 2020).

There are more than a half million retail pharmacies in the country. Drug dispensing is the primary duty of community pharmacists. Their potential role in providing pharmaceutical services beyond drug dispensing has been recently recognised, resulting in an all-around focus on community pharmacy practice (Basak et al., 2009). The Pharmacy Practice Regulations, 2015, have briefly defined the role of community pharmacists but finds a limited execution in practice.

Pharmacists are against the practice of dispensing drugs by anyone other than their peer group. However, Schedule K (serial 23) of DCR 1945, permits certain cadres of health workers to dispense drugs, under specific conditions. These include (i) multipurpose workers attached to Primary Health Centres (PHC) or Sub Centres (SC), (ii) community health volunteers under the Rural Health Scheme, (iii) nurses, auxiliary nurses, midwives and lady health visitors attached to Urban Family Welfare Centres or PHC/SC and (iv) anganwadi workers, and (v) community health officers at Ayushman Bharat Health and Wellness Centres, provided the drugs are supplied under the Health or Family Welfare Programme of the Union or State Governments. Accordingly, ASHAs, ANMs and nurses administer drugs under the GoI's reproductive and child health programme, as outlined in GoI guidelines (National Rural Health Mission, 2010).

Various studies have brought out that inappropriate dispensing (sale-practice) is common among pharmacists; all types of drugs are easily available over the counter and the selling and storage of medicines is often not according to the prescribed regulations (Basak & Sathyanarayana, 2011).

Maharashtra's Food and Drug Administration received complaints of professional misconduct by pharmacists in the State and found that 543 retail pharmacies across the State were dispensing medicines, without a registered pharmacist. It also observed that the pharmacists were renting out their registration certificate and themselves were engaged in other employment, violating the laws (Nautiyal, 2020). Strict vigil and actions are required by the State licensing authorities (both State drugs authority and State pharmacy council), against those flouting and violating drugs and pharmacy laws.

ALLIED HEALTH CARE PROFESSIONALS

Allied Health Care Professionals (AHPs) are part of the health care system, providing a range of patient care services, such as curative, preventive, diagnostic and rehabilitative, in clinical or non-clinical environments. They work in various areas of public health and social care. However, their precise nomenclature and responsibilities vary across countries. Historically, these professionals have been known as paramedics or paraprofessionals or health technicians. Paramedical professionals are also variously referred to as substitute health workers, auxiliaries, non-physician clinicians or mid-level health providers.

WHO defined Allied Health Care Professionals as "…participants who have specific connections with the art and science of healthcare and are recognized as members of the health team in the national health systems. They are educated at professional levels in a recognised, accredited health or health related institute..." (WHO Regional Office for South-East Asia, 2000). The organization of International Chief Health Professions Officers (ICHPO) defined allied health care professionals in 2012 as "…a distinct group of health professionals who apply their expertise to prevent disease transmission, diagnose, treat, and rehabilitate people of all ages and all specialties. Together with a range of technical and support staff, they may deliver direct patient care, rehabilitation, treatment, diagnostics and health improvement interventions to restore and maintain optimal physical, sensory, psychological, cognitive and social functions..." (Mangine, 2017). According to the ILO's ISCO, paramedical professionals work autonomously or with limited supervision, to provide medical services with a more limited scope and complexity than those provided by doctors (World Health Organization 2020a). The Association of Schools Advancing Health Professions, United States of America, divided AHPs into two categories: technicians (assistants) and therapists/technologists.

Role of Allied Health Care Professionals

India's human resources for health are multifarious, ranging from trained biomedical specialists to community health volunteers. AHPs play an open-ended role as a part of a multidisciplinary team in health systems. Services of AHPs are available at various levels of primary, secondary or tertiary care in institutions, both in urban and rural areas. AHPs mostly perform roles like assisting, facilitating and supplementing the work of doctors, dentists, pharmacists and specialists. They may also provide care independently as behavioural health sciences professionals, community health promoters, ecologists, etc. Their scope of work encompasses human development from neonate to old age; health promotion and injury prevention; assessment, management, and evaluation of interventions. Their

work settings range from hospitals to the homes of patients, to provide services for acute care illness or care of individuals with multi-system illnesses (Public Health Foundation of India, 2012; Health Sector Skill Council, 2013). AHPs providing diagnostic services may include cardiovascular technologist and technician, medical and clinical laboratory technician, radiological technician and technologist. AHPs like anaesthesiologist assistants, blood bank technicians, chiropractors, dental assistants, dental hygienists, dialysis technicians, emergency and medical technicians, mental health counsellors, opticians, optometrists, or operation theatre (OT) technicians, may provide curative services. AHPs like dieticians and nutritionists, home health aides, medical equipment technician, medical records and health information technicians, medical transcriptionists, pharmacy technicians, nursing or physician's assistants, may also provide non-direct care. AHPs providing rehabilitative care include audiologists, clinical psychologists, occupational therapists, orthotists and prosthetists, physiotherapists and speech-language pathologists. AHPs providing community related services include diabetes educators, health educators or sanitary inspectors.

Medical laboratory technicians form the backbone of the diagnostic services and research and are responsible for supporting and assisting doctors and scientists in their day-to-day health care work. They perform complex tests for diagnosis, treatment, and prevention of diseases. They are responsible for preparing patients and operating equipment for the tests, besides maintaining patient records and equipment. They prepare work schedules, evaluate the purchase of equipment, or manage a radiology department, playing an important role in hospitals, laboratories and clinics. Physical therapists or physiotherapists treat patients with movement disorders or functional impairments due to health-related problems, congenital defects, illnesses, or injuries, such as arthritis, low back pain, fractures, head injury, cerebral palsy and paraplegia. Dental hygienists specialise in preventive oral health. In India, they work within a dental practice in a clinical or hospital setting and do not have their independent set-ups (Health Sector Skill Council, 2013). Audiologists or speech language pathologists (SLPs) specialise in the evaluation, diagnosis and treatment of communication disorders, cognitive-communication disorders, voice disorders and swallowing disorders etc (Kumari, 2019). Clinical psychologists work generally in disability rehabilitation centres in hospitals. They provide services for persons with intellectual disability and mental illness in areas of mental health, learning disability, emotional problems, positive health and addiction (Singh, 2015). Optometrists or optometric physicians are vision care experts. They conduct eye tests, diagnose visual problems, prescribe orthoptics and vision training, designing and fitting of spectacles, contact lenses and low-vision aids, and also provide optometric counselling (Health Sector Skill Council, 2013).

The exact number of AHPs is difficult to estimate because of various categories of AHPs delivering services, and the lack of single registration or a council in India. Several studies have estimated the size and composition of AHPs in the country. Census 2001 estimated 3,587 dieticians, 13,678 optometrists, 16,240 medical equipment operators, 99,010 medical assistants, 2,658 dental assistants, 7,265 physiotherapists and 15,396 health associates in India. An analysis indicated 0.81 million AHPs as of January 2016, which included health assistants, sanitarians, dieticians and nutritionists, optometrists and opticians, dental assistants, physiotherapy associates, pharmacist assistants (Karan et al., 2019). Many committees have highlighted the importance of producing more paramedical professionals, to address the shortage of human resources for health care service delivery in India.

Rehabilitation Council of India Act, 1992

The Rehabilitation Council of India (RCI) Act was enacted in 1992 (Act No. 32 of 1992), as a Union government legislation. The key objective of the RCI Act, 1992, is to regulate and standardise the training of rehabilitation professionals in the disability sector, on the lines of professional bodies such as the MCI. This Act provides for the constitution of the RCI, an apex body to further the professional development of those in the field of disability rehabilitation. The RCI provides training policies, programmes and minimum standards of education for professionals working in the field of rehabilitation and special education, recognise institutions/universities running degree/diploma/certificate courses in the field of rehabilitation in India, and also the courses awarded by foreign universities/institutions, maintain a Central rehabilitation register of all qualified professionals and institutions possessing the recognised rehabilitation qualification (Rehabilitation Council of India Act, 1992). It recognises vocational rehabilitation centres, and national or apex institutions on disability as manpower development centres. Rehabilitation Council of India Regulations, 1997, define the role and responsibilities of the national regulator RCI (Rehabilitation Council of India Regulations, 1997). RCI has set up 14 Zonal Coordination Committees (ZCC), based on the geographical coverage of States. ZCC of RCI is responsible to monitor the functioning of RCI approved training institutions, monitor the contact programmes, term-end examinations, entrance exam and improve the quality of training programme, being conducted in the State (Rehabilitation Council of India, 2000).

The RCI Act, 1992, regulates the entry and registration of 16 categories of rehabilitation professionals, that is, (1) audiologists and speech therapists, (2) clinical psychologists, (3) hearing and ear mould technicians, (4) rehabilitation engineers and technicians, (5) special teachers for educating and

training the handicapped, (6) vocational counsellors, employment officers and placement officers, (7) multi-purpose rehabilitation therapists, technicians, (8) speech pathologists, (9) rehabilitation psychologists, (10) rehabilitation social workers, (11) rehabilitation practitioners in mental retardation, (12) orientation and mobility specialists, (13) community based rehabilitation professionals, (14) rehabilitation counsellors, administrators, (15) prosthetists and orthotists, and (16) rehabilitation workshop managers. The renewal of registration is conducted by the RCI under the RCI Act, 1992 (Rehabilitation Council of India, 2020). Continuing Rehabilitation Education (CRE) Programmes, 2018, prescribe that all registered rehabilitation professionals should renew their registration with the RCI once in five years and must attend 100 hours of CRE for renewal of certification. CRE is intended to update the professional knowledge and skills of master trainers, working in the field of disability rehabilitation and special education (Rehabilitation Council of India, 2018.

The RCI Act 1992, prescribes punitive action against unqualified or non-RCI registered professionals delivering services to persons with disability. ZCC has the provision to inform RCI about malpractice/quackery in the field of special education and disability rehabilitation. Before taking any legal action, the Zonal Committee should first seek RCI's approval.

National Commission for Allied and Healthcare Professions Act, 2021

A few States such as Madhya Pradesh, Maharashtra and Himachal Pradesh had established State councils, supported by their respective State legislations to govern paramedical education.[2] The key functions of the State councils were to register paramedics and maintain State registers, prescribe standards of paramedical education, course and curriculum, and recognise educational institutions (Public Health Foundation of India, 2012).

The importance of AHPs in the Indian health care system was highlighted as early as 1962, in the Mudaliar Committee's report and later a working group of the Planning Commission in 1984, underlined the roles of auxiliary and paramedical personnel in public health and health management.

[2] Madhya Pradesh Sah Chikitsiy Parishad Adhiniyam, 2000 introduced M.P. Paramedical Council (Maintenance, Publication and Revision of Register and Appeal) Rules, 2001: It covered provision for registration and licensing, renewal registration, provisions to deal with malpractice and other punishment provisions. It regulated the training and curriculum by prescribing infrastructure standards, provision for certificate/diploma/degree/PG affiliation and university. The Maharashtra Paramedical Council Act, 2011, M.P. Sah Chikitsiy Parishad Adhiniyam, 2000 and Himachal Pradesh Paramedical Council Act, 2003 provided establishment of the state paramedic council with the responsibility to maintain state registers, laying down norms for courses, curricula, staff pattern, physical and instructional facilities, assessment and examination pattern, guidelines for admission, prescribing standards for establishing of the institutes. Andhra Pradesh Para Medical Board Act, 2006 covers provision for registration and licensing, renewal of registration and provisions to deal with malpractice.

The efforts to regulate the AHPs began in the early 1990s. The first Union government Bill on AHPs was introduced in 2007 by the MoHFW in Lok Sabha, the Paramedical and Physiotherapy Central Councils Bill, 2007, however, it was not passed. In 2012, a report commissioned by the Government of India highlighted that India's mandate for universal health coverage depends on the availability of qualified and adequate Allied Healthcare Professionals, at primary, secondary and tertiary levels. The report stressed the need to regulate and standardise the diverse group of AHPs in India, and the plethora of existing courses and curricula (Public Health Foundation of India, 2012).

The Allied and Healthcare Professions Bill was reintroduced by the MoHFW in 2018. The Bill proposed to regulate and standardise the education and practice of allied and healthcare professionals. It defined 'allied health professionals' and 'health care professionals' separately, based on their course and scope of work. It mentioned 15 recognised categories in the Schedule and proposed to set up a separate council for all the 15 categories at the Union government level. However, the Bill was withdrawn in 2020, based on the report of the Standing Committee on the Allied and Healthcare Professions Bill, 2018 (Allied and Healthcare Professions Bill, 2018; Mann, 2019).

A new Bill, the National Commission for Allied and Healthcare Professions Bill, 2020, was introduced in the Rajya Sabha in September 2020, incorporating the recommendations of the 117th report of the department related Parliamentary Standing Committee of Health and Family Welfare on "The Allied and Healthcare Professionals Bill, 2018" (Department-related Parliamentary Standing Committee on Health and Family Welfare, 2020). The Bill was subsequently passed in both the houses of the Parliament and received the President of India's assent on 28 March 2021 (National Commission for Allied and Healthcare Professions Act, 2021).

The National Commission for Allied and Healthcare Professions (NCAHP) Act, 2021 (Act No. 14 of 2021) broadly defines two categories of Allied Healthcare Professionals:

(i) 'Allied health professional' as an associate, technician, or technologist, trained to support the diagnosis and treatment of any illness, disease, injury, or impairment; and implementation of any health care treatment recommended by a medical, nursing or any other health care professional; and should obtain a diploma or degree, with a duration of at least 2,000 hours.

(ii) 'Health care professional' includes a scientist, therapist, or any other professional who studies, advises, researches, or provides preventive, curative, rehabilitative, therapeutic, or promotional health services; and should obtain a degree, with a duration of at least 3,600 hours.

The Act prescribes for the setting up of the National Commission for Allied and Health Care Profession (NCAHP) at the Union government level. The functions of the Commission are to develop the policy, standards and guidelines for education, professional conduct and maintain an online and live Central register. National Commission will decide about registration of existing professionals and procedure for provisional registration of such professionals. It will also determine the procedure for the common entry and exit licensing examinations, for AHPs and National Teachers Eligibility Test (NTET). The National Commission can withdraw the recognition granted to the allied and health care institutions, as per Section 43, of the NCAHP Act, 2021, if so required.

It mandates that the Union Government shall constitute the National Allied and Healthcare Advisory Council (NAHAC), with representation from all the States to advise the National Commission on the issues relating to allied and health care professionals. The State Allied and Healthcare Council would be established by every State government, within six months from the date of commencement of the Act. The State councils are responsible for the implementation of the Regulations provided under the Act. They would ensure registration of AHPs and enforcement of ethics, approve and inspect allied and health care institutions, impose penalties, ensure uniform entry and exit examinations. Further, as there are no statutory bodies in States, which holistically cover the entire gamut of AHPs, existing councils at the State level pertaining to the recognised categories covered under the NCAHP Act, 2021, would be subsumed and their mandate would be expanded, to cover all the professions. The State councils will constitute the following autonomous boards:

- The Under-Graduate Allied and Health Care Profession Board and the Post-Graduate Allied and Healthcare Profession Board, would determine standards of allied education at the graduate, postgraduate level and super-speciality level, develop competency based on dynamic curriculum content, review institutional standards, faculty development, approval of courses of recognised qualification, and other functions as entrusted by the State council.
- The Allied and Healthcare Profession Assessment and Rating Board would determine the procedure for the assessment and rating of allied and health care institutions, by providing for inspection of institutions, grant permission for establishment of new allied and health care institutions and seat capacity, recommend for withdrawal of recognition of institutions and any other function, as entrusted by the State council.
- The Allied and Healthcare Professionals Ethics and Registration Board would maintain online and live State registers of all licensed allied practitioners in the State, regulate the professional conduct and promotion of ethics and undertake any other function, as entrusted by the State council.

A registered Allied Healthcare Professional is permitted to discharge any duty or treatment or perform any function, within the defined scope of practice as an allied and health care professional under the Act. Only those who are enrolled in a State or the national register can practice as a qualified allied and healthcare practitioner. The categories of professions can be added or amended within the Schedule as per Section 70, NCAHP Act 2021.

Conclusion

The existing Central RCI Act, 1992, prescribes minimum standards of education and training of only 16 categories of rehabilitation professionals but does not cover the quantity parameter, in terms of regulating the number of professionals or educational institutions registered in a year, treatment guidelines or referral protocols, patient safety and confidentiality standards. With the enactment of the NCAHP Act, 2021, as many as 56 categories of AHP groups would be regulated under the Union government legislation in terms of education, professional conduct, and scope of services. Currently, training for allied health services is conducted by institutions, ranging from government-affiliated universities, distance-learning universities to public and corporate hospitals, and even pharmaceutical companies. Several private institutions provide allied health education and function as self-regulators of the profession. Many of these institutions function without any supervision and control over the quality and standard of education. The NCAHP Act, 2021, would regulate and standardise the education and training of AHPs across the country. It will determine the scope of practice of AHPs and help in creating coordination between the medical and allied health care professionals. The NCAHP Act, 2021, is expected to make a significant contribution to health sector reform and prove to be a landmark step. The difference between the various AHP groups and their current roles across the States would need to be considered, while standardising the practice guidelines for them.

In India, there is a conspicuous lack of recognition in the form of accreditation, quality control, career plan and respectable pay scales for AHPs. Their status highlights the doctor-centred nature of medical services, as they work mostly under the shadow of doctors. The NCAHP Act, 2021, could assist in recognising and raising the professional status of AHPs, as well as enable high quality, multi-disciplinary health care service to all.

DENTISTS

The term Dentistry comes from French 'dentiste', for a tooth. It is a branch of medicine that consists of the study, diagnosis, prevention and treatment of diseases, disorders and conditions of the oral cavity, commonly in the dentition, oral mucosa, adjacent structures and tissues, particularly in the maxillofacial (jaw and facial) area. A dentist, also known as a dental surgeon, is a person who practices dentistry. They are skilled and licenced to practice the diagnosis, prevention and treatment of diseases and conditions of the oral cavity.

Greek scholars, Hippocrates and Aristotle gave the first written documents on dentistry in 500-300 BC and then in 100 BC, Roman scholars added details on oral hygiene and common dental problems (Hussain & Khan, 2014; GoDental, 2020). In the 13th century, the blacksmith, wigmaker, jeweller and apothecary extracted teeth as a side job. By the 15th century, barbers started tooth extraction as their main occupation, and by the 16th century, barbers and surgeons were called tooth drawers, specialising in dentistry (British Dental Association, 2020a). By the 1700s, dentistry evolved from a trade to a profession. The term *'dentist'* first appeared in 1728 when the French dental surgeon, Pierre Fauchard, Father of Modern Dentistry, published his treatise Le Chirurgien Dentiste (BBC History Magazine, 2018; British Dental Association, 2020b). This book was the first complete scientific description of dentistry, and comprehensively included basic oral anatomy and function, operative and restorative techniques and denture construction.

Dentistry developed during the British period in India. In 1920, the Government introduced a course in dentistry, as one of the subjects for medical students at Calcutta Medical College. In the same year, dental education was organised as a separate branch, and the first dental college was founded in India in Calcutta by Dr. Rafiuddin Ahmed. In 1939, Dr. Ahmed laid out the first dental regulation in India, namely, the Bengal Dentists Act of 1937. In 1947, India had only three dental colleges, namely, Sir. C.E.M. Dental College, Bombay, the Nair Hospital Dental College, Bombay, and the Calcutta Dental College, Calcutta (Dental Council of India, 2017b).

In India, a person must undergo a five-year course, Bachelor of Dental Surgery (BDS) from a university recognised by the Dental Council of India (DCI) to qualify as a dentist. One can specialise in 10 subjects as Master of Dental Surgery (MDS) or through Post Graduate Diploma (PG-Dip). Currently, there are 313 BDS, 268 MDS and 9 PG-Dip colleges, with a total of 26,949 and 6,511 seats permitted for the BDS and MDS courses respectively. The dental auxiliary is a generic term used for personnel assisting a dentist in treating a patient. In India, a dental auxiliary may be a dental hygienist, who scales, cleans

or polishes teeth, or gives instruction in dental hygiene, or a dental mechanic, who makes or repairs dentures and dental appliances. There are 110 colleges for Diploma in Dental Hygienist and Dental Mechanic, as recognised by the DCI (Dental Council of India, 2017a).

A dentist must comply with regulations, which range from who can enter the profession to the compliance in dental clinics. Several legislations have been enacted by the Union and State governments in India.

Entry

The Dentists Act, 1948 (Act No. 16 of 1948) was enacted on 29 March 1948 by the Union Government, to regulate dental education and profession throughout India. The Act governs the entry of a person into the dental profession and registration of institutions imparting dental education (both undergraduate and postgraduate colleges).

The Dentists Act, 1948, provided for the establishment of the Dental Council of India (DCI) and State Dental Councils (SDCs), to regulate the profession. The Dental Council of India, a statutory body, was constituted in 1949. As per this Act, dentists possessing recognised dental qualifications are registered as dentists under Part A of the State register. The Dentists Act, 1948 has been amended several times in 1955, 1972, 1993, 2016 and 2019. DCI has laid down objectives and rules for maintenance of a uniform standard of dental education (BDS and MDS), standard curricula and examination pattern, inspections of dental colleges or for permission to start new dental colleges, minimum physical and staffing requirements, increase in admissions, starting of new postgraduate courses and overall supervision of dental institutions of India. DCI is responsible for the recognition of dental qualifications granted by an institution or university located outside India (Part II of the schedule). DCI maintains a database of the dentists, dental faculty and students through State dentists' registers, and guides the ethical and professional conduct of the dentists while providing dental services. SDCs are constituted under section 21 of the Dentists Act, 1948. The State council has members from amongst the dentists registered under Part A and Part B, professors or heads of departments of dental colleges recognised under the Act and members from the State government. The SDCs are responsible for the preparation and annual update of the State dentist registers and for sharing them with the DCI. They are also responsible for renewing the registration of dentists and conducting annual examinations in State dental institutions (Dentists Act, 1948).

The Dentists (Amendment) Act, 2016, introduced a uniform system of entrance examinations for all dental institutions, applicable at undergraduate and postgraduate levels, from the academic year 2017. The amendment was applicable to all State government seats in government and private dental

institutions and provided the DCI with the power to frame regulations, concerning the conduct of the exams (Dentists (Amendment) Act, 2016). According to the Revised BDS Course Regulations (10th Amendment), 2019, a candidate is not eligible for admission into the Bachelor of Dental Surgery (BDS) course, until s/he clears the National Eligibility-Cum-Entrance Test (NEET). The Regulations also provide minimum eligibility criteria to appear for the NEET exam. Similarly, for admission in the Master of Dental Surgery (MDS) course, NEET-MDS is mandatory, and no other entrance examination is valid, according to the Dental Council of India, Master of Dental Surgery Course Regulations, 2017.

According to the DCI Screening Test (2nd Amendment) Regulations, 2018, anyone (Indian Citizen or Person of Indian Origin or Overseas Citizen of India) possessing any dental qualification from a dental institution outside India and wanting to get registered with a State dental council, needs to clear NEET.

Before 1993, BDS Course Regulations, 1983 and MDS Course Regulations, 1983, made it mandatory for colleges to seek recognition from DCI, with approval from the Union Government before functioning. However, due to lacunae in those regulations, the DCI noticed that many dental colleges were established without adequate academic and training facilities. To exercise better control over new dental colleges, the Dentists (Amendment) Act, 1993, mandated permission from the DCI before establishing new dental colleges, increasing the admission capacity and introducing new or higher courses. The amendment also gave DCI the power to withdraw recognition of colleges, in case of non-fulfilment of the minimum requirements (Dentists (Amendment) Act, 1993). The DCI (Establishment of New Dental Colleges, Opening of Higher Courses of Study or Training and Increase of Admission Capacity in Dental Colleges) Regulations, 2006 prescribed the procedure, formats, and requirements for anyone seeking to establish new dental colleges or a course from the academic year 2006-07. These Regulations were last amended in 2017.

Each State dental council is responsible for the preparation and maintenance of dentists' register, as per Section 31 - Part A (possessing recognised dental qualifications) and Part B (not possessing recognised qualifications but have been practising as dentists for at least five years before registration). However, since 1972, there has been no new registration in Part B and currently, only 979 dentists across India are registered under Part B in a few States, such as West Bengal, Kerala, Jammu and Kashmir, Puducherry, Punjab and Delhi. A registrar is appointed in each State dental council, whose responsibility is to prepare and maintain the State register of dentists, renew registration and remove the name of the defaulter from the State register upon failure to pay renewal fees. Some State dental councils mandate minimum continuing dental education score for registration renewal, as per Continuing Dental Education Regulations, 2018 (Dentists Act, 1948).

Quantity

There are no legislations to regulate the distribution of dentists or dental colleges or clinics geographically in the country. There are no legislations that regulate the number of dentists who can be registered annually in India. Similarly, there is no limit on how many dental colleges/universities or clinics can be registered in a year.

Quality

To maintain uniform standards in dental institutions of India, DCI framed Revised BDS Course Regulations, 2007 and Revised MDS Course Regulations, 2007, recommending the minimum standards for BDS and MDS colleges, curricula, examination pattern, minimum infrastructure and staffing pattern.

Standards of Care

The Clinical Establishments (Registration and Regulation) Act (CEA), 2010, prescribe the minimum standards of facilities and services by a clinical establishment, including dental clinics. The CEA, 2010, defines 'dental clinics' as places where dentists provide dental care with no inpatient facilities, and 'dental hospitals' as places where dentists provide dental services with inpatient facilities. Dental clinics include single practitioner or poly dental clinics providing services as listed in the Dentists Act, 1948. Minimum standards are given by MoHFW, GoI, for dental clinical establishments mention minimum requirements, in terms of space, infrastructure, equipment, instruments and drugs, including emergency drugs, consumables and a list of legal requirements as per the size of the dental hospital/single dental chair clinic and workload, to provide a safe and secure patient care environment. They specify minimum requirements for human resources, maintenance of records and mandatory registration of dental clinic/dental hospital with the local/district authority, in accordance with the provisions of the CEA, 2010 (MoHFW, 2010a). The dental clinics are also governed by the Atomic Energy Act, 1962, and the Atomic Energy (Radiation Protection) Rules, 2004 (superseding the Radiation Protection Rules, 1971), for safe handling of radiation generating equipment, such as dental X-ray equipment. The Atomic Energy (Radiation Protection) Rules, 2004, mandate the registration of dental clinics or hospitals that have any radiation generating equipment installed. The regulatory requirement of dental X-ray facilities and hospitals/clinics with diagnostic X-ray equipment, in terms of design, construction, commissioning of a room and handling of radiological units are stipulated in the Rules (Atomic Energy Act, 1962; Atomic Energy (Radiation Protection) Rules, 2004). The Atomic Energy Regulatory Board (AERB) is responsible for the registration and issuance of a licence, which is a mandatory legal requirement for the procurement and use of radiation appliances/devices in dental hospitals or clinics. An electronic licensing platform called the electronic-Licensing of Radiation

Applications (e-LORA) System has been developed for easy registration of radiation generating equipment (AERB, 2020).

The safety code 'Radiation Safety in Manufacture, Supply and Use of Medical Diagnostic X-Ray Equipment' (March 2016) was approved by the AERB in November 2015 and supersede the earlier versions of the AERB safety code. It stipulates the regulatory requirements for medical diagnostic X-ray equipment to be followed by the manufacturer (to ensure safety by design), supplier (to ensure safe commissioning of equipment including imported equipment) and in its use (to ensure proper utilisation of safety features of the X-ray equipment on a routine basis). The AERB formed the Directorate of Radiation Safety (DRS), to conduct regulatory inspections of X-ray facilities in the States and support the facilities in obtaining licence/registration from AERB. Some of the States where DRS are established and functioning are Kerala, Mizoram, Chhattisgarh, Tripura, Arunachal Pradesh and Punjab, while the process is underway in some others (NHSRC, 2017). In August 2016, the AERB issued a letter to the Dental Council of India to highlight non-compliance in a majority of the dental hospitals and clinics operating diagnostic X-ray equipment in India (AERB, 2016). Guidelines issued by the GoI in 2018 lay down the procedure for obtaining a new licence and renewing the old licence, and safety and quality measures that need to be followed, along with other requirements, for providing X-ray services. Periodic safety status reports as per prescribed format on the AERB website need to be maintained, and quality assurance should be conducted once in two years on every X-ray equipment (AERB, 2018).

The Government of India issued Bio-medical Waste (Management and Handling) Rules 1998, amended in 2016, under the Environment (Protection) Act, 1986. The Rules lay down methods for disposal of bio-medical waste (BMW) applicable to all health facilities and health care providers, including dentists who generate, collect, dispose or handle bio-medical waste in any form. The rules for the handling of BMW including its generation, sorting and segregation in colour-coded waste disposal bags, storage and collection by authorised agencies, packaging, loading, transportation, unloading, processing, treatment, destruction, conversion, or offering for sale or transfer, disposal have been laid down. It is the social and legal responsibility of every dentist to ensure that biomedical waste is handled and disposed of safely, as directed by the Revised Dentists (Code of Ethics) Regulations, 2014 (Revised Dentists (Code of Ethics) Regulations, 2014; Benakatti & Kanathila, 2018).

Standard Treatment Guidelines

Regulation 8.3.3 of the Revised Dentists (Code of Ethics) Regulations, 2014, prescribe that a dentist can practice all branches of dentistry provided s/he shows adequate qualification, competence and training in the concerned branch or branches. However, s/he should not claim to be a specialist unless s/he has a speciality qualification recognised by the dental council. The Clinical Establishments (Central Government) Rules, 2012, recognise a list of standard treatment guidelines issued by the Union Government. Currently, it recognises two oral disease guidelines issued under National Health Programmes, namely, dental caries and periodontitis and guidelines for prevention and control of fluorosis (MoHFW, 2010b).

As per schedule K of the Drugs and Cosmetics Rules, 1945 dentists cannot sell drugs across the counter or engage in the import, manufacture, distribution or sale of drugs. Revised Dentists (Code of Ethics) Regulations, 2014, mandates that dentists prescribe drugs by their generic name and ensure safe and rational use of drugs. It also prescribes that a dentist should write his/her name and designation in full, along with the recognised degrees and the registration particulars on their prescription letterhead.

The Revised Dentists (Code of Ethics) Regulations, 2014, prescribe the consultation etiquettes for a dentist while providing treatment to a patient. In case the patient needs expert care of a specialist or if the dentist is not equipped to treat, appropriate references to dental or medical specialists should be made according to the nature of the problem. All referrals for investigation or treatment should be judicious, justifiable and done in the best interests of the patient to arrive at a diagnosis.

Pricing and Cost Containment

The Revised Dentists (Code of Ethics) Regulations, 2014, has a section on payment for professional services. A dentist engaged in the practice shall give priority to the interests of patients, which should not conflict with his/her personal and financial interests. S/he should announce the fee before rendering service, and remuneration received after services should be in the form as announced to the patient. It is unethical to enter into a contract of "no cure - no payment". A dentist or the clinic should indicate the cost of treatment for a dental procedure and provide an estimated cost likely to be incurred by the patient. The prescription should also make it clear if the dental surgeon himself has dispensed any medicine.

Protect Patients and Consumers

The Revised Dentists (Code of Ethics) Regulations, 2014, mention the responsibilities of dentists. As per Regulation 3.9, a dentist should observe the provisions of the other Acts, such as the Drugs and Cosmetics Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic Substances Act, 1985; Environmental Protection Act, 1986; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; Persons with Disabilities (Equal Opportunities and Full Participation) Act, 1995 and Bio-Medical Waste (Management and Handling) Rules, 1998 (as amended from time to time), and such other Acts, Rules and Regulations made by the Union Government or State governments or local administrative bodies, or any other relevant Act relating to the protection and promotion of public health. The Regulations of 2014 guide a dentist to ensure the highest quality treatment that does not compromise the outcome of treatment, maintain confidentially of patient's information and never reveal such information unless required by the laws of the State.

Dental quacks can be penalised under section 49 of the Dentists Act, 1948, leading to imprisonment and penalty by the State dental councils. A dentist should be aware of unethical practices and practices by unqualified persons and should not aid or abet or commit any acts as specified by the Revised Dentists (Code of Ethics) Regulations, 2014, which shall be construed as unethical. They should not employ someone within their professional practice, who is neither registered nor enlisted under the Dentists Act, 1948, and not permit such persons to attend, treat or perform operations upon patients wherever professional discretion or skill is required. A dentist should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession. It is the responsibility of the dentist to report to the competent authorities, instances of quackery and any kind of abuse including doctor-patient sexual misconduct, misuse of a fiduciary relationship, child abuse and other social evils that may come to their attention.

Information Provision

Every dentist is required to maintain relevant records pertaining to his/her out-patients and in-patients (wherever applicable), as prescribed by the Revised Dentists (Code of Ethics) Regulations, 2014. These records must be preserved for a minimum period of three years from the date of commencement of the treatment, in a format determined by the DCI or accepted as a standard mode of documentation. A dentist should also maintain a register of medical certificates giving full details of certificates issued. Further, efforts should be made to digitalise dental/medical records for quick retrieval. The Clinical Establishments (Central Government) Rules, 2012, specify maintenance of records of patients seeking treatment in a dental clinic and dental hospital, registered with the local/district authority in accordance with the provisions of the CEA, 2010.

Grievance Redressal

Revised Dentists (Code of Ethics) Regulations, 2014, provide scope for registration of complaints by a patient against a dentist about professional misconduct before DCI or the State dental council, as appropriate, for disciplinary action. If the dentist is found guilty of professional misconduct, the concerned council may award punishment, as deemed necessary. Professional incompetence is to be judged by a peer group, as per guidelines prescribed by the State dental council. Dentists, as well as dental clinics or hospitals, are liable if there is any infringement of statutes. Any dental malpractice can be challenged under the Consumer Protection Act, 2019, to protect the interests of the patients in India. This Act was designed to protect the interest of consumers, as well as to provide simple, easily accessible solutions to redress consumer grievances. In legal terminology, "Negligence" refers to the failure to exercise due professional care that is expected of a doctor. A patient can file a complaint against a dentist or dental clinic or hospital in consumer disputes redressal commissions, present at different administrative levels (district, State and national level) (Thavarajah et al., 2019).

Gaps and Challenges

The Dentists Act, 1948 and its amendments (Amendment of 1972 and 1993), thereafter, permit DCI to grant recognition to new colleges, permit new dental courses or increased number of seats in existing colleges, and withdrawal of recognition of dental colleges or qualifications offered by them. The situation is different on the ground because of continuous jurisdictional disagreements between States and the Union government administrative bodies. State(s) have been known to give permission to private institutions or admit students without permission, jeopardising the professional future of students as their qualification might not be recognised, or would only be recognised within the geographical boundaries of the State.

Dentists may migrate from one State to the other for higher education, better professional opportunities or other personal reasons. However, dentists' registers may not be updated regularly to maintain live registers. As a result, a single dentist may be simultaneously registered in different State registers, which inflates the number of dentists in DCI records at the national level, much beyond the actual number of dentists in the country.

Various studies have highlighted the poor status of implementation of radiation safety practices, provided under the Atomic Energy (Radiation Protection) Rules, 2004, among dental practitioners. A study from Kerala and one from Punjab and Haryana found that as many as 80 percent of the dental clinics had a separate operating room for the radiography unit and to perform radiographic procedures, however, their overall compliance and adherence to radiation safety practices were low. The study highlighted that 90 percent of the dentists did not provide any radiation protection

measures to their patients, and only 26 percent of dentists reportedly had their X-ray equipment serviced routinely (Sheikh et al., 2014; Aravind et al., 2016).

In recent years, an increase in dispute between patients and dentists has been observed in the field of dentistry under the Consumer Protection Act, 2019. The cases range from inadequate and inappropriate treatment to problems of medical malpractice and negligence. A review of judgments on dental negligence claims in Indian Consumer Redressal Forums highlighted that in 40 percent of the dental negligence cases, dentists were found guilty and compensation of approximately Rs. 100,000 was awarded to the patients (Vashist, 2014; Thavarajah et al., 2019). This could be attributed to rising patient awareness about the Consumer Protection Act, 2019, inferior or substandard quality of dental services or professional misconduct.

Lack of accessible dental services is an issue of concern. Reasons such as geographic imbalance of dentists, minimal dental services in public health facilities with only 3% of the registered dentists being employed in the public sector, and unaffordable cost of dental services in the private sector are some of the reasons for this. One of the key areas which the existing legislations have neglected is pricing and cost containment of dental services in the private sector. Such a state of affairs has driven a large number of people to seek services from dental quacks who practice dentistry without due qualification, thereby compromising on the quality of care. (Kumari et al., 2018).

Given the developments in the dental profession since 1948, the Ministry of Health and Family Welfare, Government of India, proposed the draft National Dental Commission Bill in January 2020, to bring about changes in dentistry. The Bill proposes the formation of a regulatory body, the National Dental Commission (NDC), to lay down policies and maintain high-quality standards in dental education and profession, and the dissolution of the existing Dental Council of India. The draft Bill has introduced major changes, such as, the introduction of the National Exit Test (Dental) for final year undergraduate students, to obtain a licence to practice dentistry and for admission to MDS, among other issues. The draft Bill has been sent to States for their inputs. It proposes four Autonomous Boards to be set up under NDC: UG Dental Education (BDS), PG Dental Education (MDS), Dental Assessment & Rating Board to grant permission to establish a new dental college or increase seats and Ethics & Dental Registration Board to maintain a national register of all dentists in India (National Dental Commission Bill, 2020). However, some of the key challenges which the draft Bill has missed to address are geographical inequalities in the distribution of dental education, as well as its professionals, quality and cost of dental services, a private sector limited to urban geographies and patient safety (Randhawa, 2021).

DOCTORS - INDIAN SYSTEMS OF MEDICINE AND HOMOEOPATHY

The Indian Systems of Medicine and Homoeopathy (ISM & H) comprise Ayurveda, Unani, Siddha and Homoeopathy, and therapies such as yoga and naturopathy. Some of these systems are indigenous, and others such as homoeopathy came to India from outside and have become a part of Indian tradition over the years (Planning Commission, n.d.; Ravishankar & Shukla, 2007). The Government of India created the Department of Indian Systems of Medicine and Homoeopathy in the MoHFW at the Union government level in 1995, to ensure the development of these different systems of medicine. In 2003, the department was renamed as the Department of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, Homoeopathy). For more focussed attention, the Department of AYUSH was converted into a separate ministry, known as the Ministry of AYUSH in 2014. This Ministry is now responsible for the promotion of the ISM&H (Ministry of AYUSH, 2021). At the State level, department of AYUSH is part of the State's MoHFW.

Ayurveda is believed to have originated out of the Vedas (particularly Rigveda and Atharvaveda). The knowledge of Ayurveda was first comprehensively documented in compendia, such as *Brahma Samhita, Agnivesha Tantra, Bhela Samhita*, etc. Around 5000 years ago, Charaka, one of the principal contributors to Ayurveda, documented it in the *Charaka Samhita*, which was edited by the later scholars and translated into several languages globally. Another significant ancient text is the *Sushruta Samhita* that mainly deals with the surgical aspect of diseases (Ministry of AYUSH, 2020b). The Siddha system of medicine is practised in some parts of South India, especially in the State of Tamil Nadu. The term 'Siddha' originates from the word 'Siddhi', which means achievement, and the Siddha system of medicine depends largely on drugs of metal and mineral origin, while Ayurveda mainly involves the use of products/drugs derived from plants (Ravishankar & Shukla, 2007; Ministry of AYUSH, 2020b).

Unani medicine is a Greek system of medicine, based on the humoral theory developed by Hippocrates (460-370 BC), and further refined by Aristotle (384-322 BC) and Galen (131-201 AD). Arabian scholars and physicians played a great role in the development of Unani medicine and were instrumental in introducing it in India around 1350 AD. The practitioner of Unani in India is called a hakim. The drugs employed in the Unani system of medicine are mainly derived from plants, some are obtained from animals and some are of mineral origin. Both single and compound preparations are used for treatment (Alavi, 2005; Ravishankar & Shukla, 2007; Ministry of AYUSH, 2020b).

Homoeopathy was introduced as a system of medicine by a German Physician, Dr. Christian Frederick Samuel Hahnemann (1755-1843), in the early 1800s. Hahnemann coined the term 'Homoeopathy'-

'Homoios' in Greek means 'similar' and 'pathos' means 'suffering'. It is based on the 'principle of similars' or 'like cures like', that is, an illness can be cured by administering a medicine which, if given to a healthy person, would produce similar symptoms of that illness, but to a lesser degree. Homoeopathy was introduced in India in the early 19th century in Bengal and then spread all over the country. In 1973, the Government of India recognised homoeopathy as one of the systems of medicine and set up the Central Council of Homeopathy (CCH), to regulate its education and practice (Loudon, 2006; Ghosh, 2010).

Regulations for Practitioners of ISM&H

The Indian Medicine Central Council (IMCC) Act, 1970 (Act No. 48 of 1970) and the Homoeopathy Central Council (HCC) Act, 1973 (Act No. 59 of 1973) are Central Acts, passed by the Parliament of India, and applicable to the whole country. They provide for the constitution of the Central Council of Indian Medicine (CCIM) and Central Council of Homoeopathy (CCH) as regulatory bodies, respectively. Both the Acts detail the composition, procedure of formation and functioning modalities of the respective councils. The IMCC Act, 1970, provides for the Central Council of Indian Medicine to constitute from amongst its members, a committee each for the three disciplines, that is, Ayurveda, Siddha and Unani (Indian Medicine Central Council Act, 1970; Homoeopathy Central Council Act, 1973).

The IMCC Act, 1970 was amended in 2002, 2003, 2010 and 2020. The Sowa Rigpa system of medicine was included when the Act was amended in 2010. The 2020 amendment provides for supersession of the Central Council by the Board of Governors for a period of one year, during which a new Central Council is to be reconstituted. In the interim period, the Board of Governors would exercise the powers and perform the functions of the Central Council.

The Homoeopathy Central Council (HCC) Act, 1973 was amended in 2002, 2018, 2019 and 2020. The 2018 amendment provided for supersession of the Central Council by the Board of Governors for a period of one year, during which a new Central Council was to be reconstituted. In the interim period, the Board of Governors could exercise the powers and perform the functions of the Central Council. The period of reconstitution of the Central Council was increased to three years from its date of supersession, by the 2019 and 2020 amendments to the HCC Act, 1973.

Over the years, many issues emerged with regard to the functioning of both the Central Councils. Both, the Councils and the IMCC Act, 1970 and the HCC Act, 1973, were found to be inadequate in regulating the respective medical institutions, providing a transparent system of inspection and recognition/de-recognition of educational institutions, standardising curricula and education standards, and ensuring

ethics in the practice of different systems of medicine. As a result, the quality of medical education, as well as health care services was adversely affected (NITI Aayog, 2017; Department Related Parliamentary Standing Committee on Health and Family Welfare, 2019). The status of the IMCC Act, 1970, maybe gauged from the reply given by the Ministry of AYUSH to the Parliamentary Standing Committee's query on the reasons for the ineffective implementation of the Act: "Absence of effective provisions in IMCC Act relating to the constitution of the council, membership to have a transparent selection of members and their tenure; no provision in the Act for taking action against the college for non-compliance of standards, non–conduction of fair inspections and recommendation by the Council; no conditions for removal of members from the Council or for superseding the Council on account of any untoward incident or act." pg. 3, 115th Report on the National Commission for Indian System of Medicine Bill, 2019 (Department Related Parliamentary Standing Committee on Health and Family Welfare, 2019).

Hence, two new Acts were passed by the Parliament of India in September 2020 to replace these Acts, that is, the National Commission for Indian System of Medicine (NCISM) Act, 2020 and the National Commission for Homoeopathy Act, 2020, both drafted on the lines of the National Medical Commission Act, 2019. Since the transition to the new Acts has not yet taken place, the IMCC Act, 1970 and HCC Act, 1973, continue to be in force.

The National Commission for Indian System of Medicine (NCISM) Act, 2020 (Act No. 14 of 2020), is an Act passed by the Parliament of India and extends to the whole country. According to the Act, the Indian System of Medicine (ISM) comprises Ashtang Ayurveda, Unani, Siddha and Sowa Rigpa systems of medicine. The Act seeks to put in place an education system that improves access to quality and affordable medical education, so that adequate and quality medical professionals of ISM may be available in all parts of the country. It provides for medical professionals to adopt the latest medical research in their work and to contribute to research, facilitates maintenance of a medical register of ISM for the entire country, enforces ethical standards in all aspects of medical services and provides for a grievance redressal mechanism, to promote equitable and universal health care (National Commission for Indian System of Medicine Act, 2020).

The Act provides for the Union Government to constitute the NCISM (Commission), an Advisory Council for ISM and four autonomous boards, for regulating all aspects relating to the standard of medical education, professionals and institutions in the ISM. Apart from its advisory role to the Commission, the Advisory Council is to provide the States and Union territories a platform to engage with the Commission and help in shaping the overall agenda, policy and action relating to medical education, training, research and development in the ISM. The NCISM Act, 2020, allows the

Commission to frame guidelines for determining fees for fifty per cent of seats in private medical institutions and deemed to be Universities, governed under its provisions. The Union Government is responsible for making rules and the Commission for making regulations, to implement the various provisions of the Act. The National Commission for Homoeopathy (NCH Act No. 15 of 2020) has the same provisions as the National Commission for Indian System of Medicine Act, 2020, applicable to the field of homoeopathy. The Act provides for the formation of the National Commission for Homoeopathy, the Advisory Council for Homoeopathy and three autonomous boards, namely the Homoeopathy Education Board, the Medical Assessment and Rating Board for Homoeopathy, and the Board of Ethics and Registration for Homoeopathy (National Commission for Homoeopathy Act, 2020).

The other legislations that regulate different aspects of service delivery by the practitioners of ISM&H are the Clinical Establishments Act, 2010, Consumer Protection Act, 2019, Drugs and Cosmetics Act, 1940, Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

Entry

Under the IMCC Act, 1970 and the HCC Act, 1973, the two national-level statutory regulatory bodies, namely the Central Council of Indian Medicine (CCIM) and Central Council of Homoeopathy (CCH) respectively, are responsible for framing and implementing the various regulations, curricula and syllabi for under-graduates and post-graduates, in their respective systems of medicine. They lay down minimum standards of education, recommend recognition of medical qualifications, register the practitioners and lay down ethical codes. At the State level, each State has a Board or Council of Indian Medicine/Homoeopathy that processes applications for the establishment/recognition of new medical institutions and forwards them with its recommendation to the State government for approval, recommend courses for inclusion/exclusion in the curricula, conduct examinations, award degrees, etc. (Government of Tamil Nadu, 2015; Government of Rajasthan, 2019; Ministry of AYUSH, 2020c).

Different disciplines offer graduate and postgraduate degrees. Bachelor of Ayurvedic Medicine and Surgery (BAMS) is a four-and-a-half-year course in India, followed by a one-year internship that results in an undergraduate degree in Ayurveda. Similarly, some courses offer graduate degrees in Siddha, Unani and Homoeopathy systems of medicine (Ministry of AYUSH, 2020b). The total number of registered AYUSH doctors in India as of 1 January 2018 was 799,879. Of these, the highest number was Ayurvedic doctors (55.47%), followed by Homoeopathy doctors (36.69%) (Central Bureau of Health Intelligence, 2019).

Under the National Commission for Indian System of Medicine (NCISM) Act, 2020 and the National Commission for Homoeopathy Act, 2020, the National Commissions for Indian Systems of Medicine and Homoeopathy respectively are supposed to conduct uniform national eligibility-cum-entrance tests and post-graduate national entrance tests, for admission to the under-graduate and post-graduate courses respectively, in each of the disciplines of ISM&H in all medical institutions. To ensure the quality of teaching, the Commissions are required to conduct national teachers' eligibility tests separately for the postgraduates of each discipline of ISM&H, desirous of taking up teaching professions in those disciplines.

To ensure standardisation of education and training, the Boards of Unani, Siddha and Sowa Rigpa, Ayurveda and Homoeopathy education, are given the responsibility to determine the standards of education. They are also expected to frame guidelines for setting up medical institutions at the undergraduate, postgraduate and super-speciality levels in respective disciplines, as well as grant recognition to medical qualifications at all levels. The Medical Assessment and Rating Boards for ISM&H are responsible for the assessment and rating of medical institutions, on the basis of their compliance with the standards laid down by the respective Boards. They may accordingly grant permission for the establishment of new medical institutions, introduce new courses, increase the number of seats or take appropriate disciplinary action, in accordance with the Regulations under the Act, including recommending withdrawal of recognition to the Commission.

Under the National Commission for Indian System of Medicine Act, 2020 and the National Commission for Homoeopathy Act, 2020, the National Commissions for Indian System of Medicine and Homoeopathy respectively, are supposed to conduct common final year undergraduate national exit tests for granting licences to practice as medical practitioners of respective disciplines of ISM&H, and for enrolment in the respective State/national registers. Persons with foreign medical qualifications too will have to qualify through the national exit test for obtaining a licence to practice, and for enrolment in the respective State or national registers. The Boards of Ethics and Registration for ISM&H are responsible for maintaining the national registers of all licensed practitioners. Anyone who practices without the required registration as per the respective Act may result in imprisonment for up to one year or fines up to Rs. 500,000, or both.

At the State level, each State has a Board or Council of Indian Medicine/Homoeopathy to register/renew the registration of medical practitioners qualified in respective systems of medicine, and to maintain the register of practitioners in the State (Government of Tamil Nadu, 2015; Government of Rajasthan, 2019; Ministry of AYUSH, 2020c). Respective State boards/councils are

responsible for renewing the registration of practitioners every five years and share the information with the respective Central Councils (now Commissions), for updating the national registers.

There is an absence of legislations to regulate the number of ISM&H doctors produced, educational institutions that can be established or their distribution across the country.

Quality

The Clinical Establishments (Central Government) Rules, 2012, promulgated under the Clinical Establishments (Registration and Regulation) Act, 2010, require clinical establishments registered under the Act (and by extension the medical personnel serving in those establishments) to ensure compliance with standard treatment guidelines, issued by the Union/State government. Standard treatment guidelines for 18 medical conditions in Ayurveda have been formulated and are available (MoHFW, 2010b). In States/UTs where CEA, 2010 is applicable, health facilities need to meet the prescribed minimum standards of facilities and services, the requirement of personnel, maintenance of records and reporting, and be registered with the respective district authority, in accordance with the provisions of the Act. The registration is to be renewed every five years.

Minimum standards for AYUSH facilities have been developed and are available (MoHFW, 2010a). These include minimum clinical out-patient services to be provided by a single or group of practitioners with or without a daycare facility, and in-patient services to be provided at different levels of health facilities. Minimum standards are prescribed for support services like diagnostics and imaging, pharmacy, ambulance etc., physical facilities in terms of space required for different functional areas, that is, consultation room, waiting area, nursing station, pharmacy etc., furniture and fixtures, public utilities, equipment/instruments, human resource requirements, licenses to be attained, records to be maintained, reporting, and basic process to be followed by the facilities in providing services. The district registering authority has the power to grant, renew, enforce, or cancel the registration of any clinical establishment, in accordance with the provisions and Rules of the CEA, 2010. The authority may restrain a clinical establishment from carrying on its services if the inspection of the establishment reveals imminent danger to the health and safety of patients. Any violation of the provisions of the CEA, 2010, may lead to a monetary penalty being levied upon the concerned party (Nandraj, 2019).

The Drugs and Cosmetics Act, 1940 (amended from time to time), regulates the import, manufacture, distribution and sale of drugs and cosmetics. Chapter IVA of the Act, “Provisions Relating to Ayurvedic Siddha and Unani Drugs” lays down regulation of Ayurvedic, Siddha and Unani drugs. It specifies that the Union Government must constitute the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, to advise the Union Government and State governments on technical matters related to the

concerned provisions of the Act. It also requires that the Union Government must constitute the Ayurvedic, Siddha and Unani Drugs Consultative Committee, to advise the Union Government, State governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, on uniform implementation of the related provisions of the Act throughout India.

Chapter IVA of the Act defines what constitutes misbranded, adulterated and spurious Ayurvedic, Siddha and Unani drugs. It specifies the conditions for the manufacture and sale of Ayurvedic, Siddha and Unani drugs with the caveat that those conditions do not apply to vaidyas and hakims, who manufacture such drugs for the use of their own patients. Practitioners of ISM&H are liable to disciplinary action if they sell a drug or poison prohibited by the Drugs and Cosmetic Act, 1940. As per the Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, practitioners of homoeopathy have a right to prepare and dispense their own prescription.

Pricing and Cost Containment

Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 and Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, prescribe that the practitioners will not publicly exhibit their fees but may put it up in their consulting or waiting room. They will neither take nor offer commission (in cash or kind) for referral, not use touts or agents for procuring patients and will not enter into a contract of 'no cure no payment'. Practitioners of Homoeopathy may reduce their fees depending on the patients' economic situation (Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982; Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982).

According to the Clinical Establishments (Central Government) Rules, 2012, the health facilities registered under the CEA, 2010, need to display the rates charged for the various services/facilities available and the rates are to be fixed within the range determined by the Union Government or State government. As per Rule 9 (ii) and (iii) of the Clinical Establishments (Central Government) Rules, 2012, the National Council for Clinical Establishment has approved a list of standard procedures and a template for costing of these procedures. These are shared with the States/UTs who have adopted the Union government Act, advising them to use these for determining the standard cost of any procedure, taking into consideration all including pertinent local factors.

Protect Patients and Consumers

Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 and Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, prescribe the code of medical ethics to be practised by the practitioners of ISM&H. These include guidance on consulting another practitioner in cases of serious illness, especially in doubtful or difficult conditions. In every such consultation/referral, the patient's benefit is to be of utmost importance and should not involve any insincerity, rivalry or envy, amongst the concerned practitioners. If there is an irreconcilable difference of opinion between two doctors, the same shall be clearly explained to the patient/family who would be free to seek further advice, if they so desire. When a patient is referred to a specialist by the attending practitioner, a Statement of the case is to be given to the specialist, who shall communicate his/her opinion in writing directly to the attending practitioner in a closed cover.

The regulations specify that while the practitioners are free to decide who to provide their services to, in case of an emergency they are duty-bound to attend to the patient. The practitioners of ISM&H are not to neglect patients under their treatment, nor withdraw from a case without informing the patient/family in advance. No registered medical practitioner of ISM&H shall wilfully commit an act of negligence that may deprive the patient of necessary medical care.

Disclosing the secrets of a patient that have been learnt in the exercise of the profession, except in a court of law under orders of the presiding judge, is listed as an offence under the regulations, which constitutes professional misconduct and may warrant disciplinary action against the practitioner. The practitioners may not publish the photographs or case reports of patients in medical or other journals, without the patients' consent.

The Boards of Ethics and Registration for ISM&H established under the NCISM Act, 2020 and the NCH Act, 2020 respectively, are responsible for regulating professional conduct and promoting medical ethics through SMCs of ISM&H, existing under the respective State Acts. In States where SMCs do not exist, the State government has the responsibility of establishing the SMC for ISM&H, within three years of the commencement of the Acts.

Information Provision

Under the Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 and Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, practitioners have to notify the public health authorities of every case of

communicable disease under their care, in accordance with the applicable Laws, Rules and Regulations. The practitioners are to neither exaggerate nor minimise the gravity of patients' condition and are expected to provide such information to the patients and/or their relatives/friends, that will serve the best interests of the patients and their families. They are expected to keep the patients and their families informed about the treatment being provided. As per the Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Amendment Regulations, 2018, the homoeopathic practitioner has to provide the prescription to the patient/authorised attendant/legal authority within 72 hours of such a request being made. Other than this, the regulations do not have a provision for giving patients' documents or reports to the patients or their families.

In States where CEA, 2010 is applicable, the health facilities registered under the Act need to maintain and provide electronic health/medical records of patients, and information and statistics as required by other laws applicable at the time, in accordance with the provisions of the Clinical Establishments (Central Government) Rules, 2012. As of January 2021, the CEA, 2010, is applicable in 18 States and UTs. The facilities are required to maintain and share information and statistics, with regard to national programmes, notifiable diseases and emergencies/disasters/epidemics with the district authorities.

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, is a Union government Act passed by the Parliament of India. It is an Act to control the advertisement of drugs in certain cases. The Act prohibits the advertisement of certain drugs/magic remedies for the treatment of certain diseases and disorders, misleading advertisements of drugs, and import into and export from India, of documents containing such advertisements. The Act recommends consultation with the Drugs Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940, and with experts in the field of Ayurveda or Unani systems of medicines while framing its Rules.

Grievance Redressal

According to the Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 and Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982, in case of any professional misconduct, a complaint may be made to the respective State council/board who may take appropriate disciplinary action, including deleting the practitioner's name from the register permanently or for a specified period. The State board will communicate the decision to the concerned Central Council and the practitioner too may appeal to the Central Council, against the State council's/board's decision.

Under the NCISM Act, 2020 and the NCH Act, 2020, the State medical councils for ISM&H, and in their absence the Boards of Ethics and Registration for ISM&H are the designated authorities, to receive any complaints/grievances against registered practitioners of ISM&H respectively at the State level, according to the procedure as may be specified by the Regulations. In case of a complaint filed against a practitioner of ISM under the NCISM Act, 2020, if s/he is aggrieved by the decision of the SMC, s/he may appeal to the Board of Ethics and Registration for ISM against it. If the medical practitioner is aggrieved by the decision of the Board of Ethics and Registration for ISM, s/he can further appeal to the Commission.

The Consumer Protection Act, 2019, is meant to protect the interests of consumers and to establish authorities for timely and effective administration, and settlement of consumers' disputes. It repeals the Consumer Protection Act, 1986 and extends to the whole of India. The Act applies to all goods and services that are paid for. It is applicable if services hired or availed of or agreed to be hired or availed of suffer from any deficiency, and deficiency in health care services falls within the purview of the Act. Under the Act, the Central Consumer Protection Council, State Consumer Protection Councils and District Consumer Protection Councils are established, to offer advice on promotion and protection of consumer rights. National, State and district consumer disputes redressal commissions are formed to entertain the consumers' complaints. Penalties under the Act include both monetary fines and imprisonment, as well as suspension or cancellation of licenses, if applicable. Consumer mediation cells are to be formed at the district, State and national level for settling cases through mediation if the parties so desire.

In States/UTs where CEA, 2010 is applicable, if the doctors have any grievances with the District Registering Authority, regarding the registration of their health facility, such as refusal to grant or renew a certificate of registration or revoking a certificate of registration of their health facility, they may appeal to the State Council of Clinical Establishments, established under the CEA, 2010.

Gaps and Challenges

There is no regulation on the cost of care that doctors provide, neither their own fees nor charges related to the treatment they may provide. Apart from complaining to the provider specific professional councils, such as the State Councils/Boards or the Boards of Ethics and Registration of ISM&H, and the Consumer Protection Act, 2019, which have their own limitations, there is no legal provision for grievance redressal for patients and consumers. Also, there is no provision for the articulation of patients' rights (Nandraj, 2018). The CEA, 2010, too is deficient in these aspects.

Practitioners qualified in the ISM have been demanding that they be recognised at par with their MBBS counterparts and be provided equal status in government services. They have also demanded that ISM services be covered by insurance, and adequate financial allocation and other measures to be taken to facilitate the practice.

One of the ISM practitioners' demands has been that they could be allowed to practice allopathy, along with their own system. The argument is that ISM practitioners have been providing services in rural areas and filling the void arising due to the shortage of allopathy doctors, and their reluctance to work in rural areas. The appointment of ISM practitioners as medical officers in government health facilities in rural areas by various State governments has long been a contentious issue. Since these practitioners also prescribe allopathic drugs, the State allopathy medical councils have raised objections, that such a practice is illegal, as only allopathy doctors can prescribe allopathic drugs (Noha, 2016). Erstwhile MCI and the IMA have also been opposing this demand, on the grounds that it would be detrimental to the practice of modern medicine (Government of India, 2017). However, some leeway has been granted by the new NMC, NCISM and NCH Acts, all of which provide for an annual joint sitting of the three Commissions, greater engagement between the various systems of medicine and promotion of medical pluralism.

DOCTORS - ALLOPATHIC

The word 'doctor' comes from the Latin word 'docere', which means 'to teach' and was used in the early 14th century, to refer to theologians who had approval from the Church to speak on religious matters. The term gradually started being used for those attaining the highest degree of learning in a particular field, medicine being one of them. By the end of the century, it was used for both qualified academic and medical professionals (Word History, 2020a). WHO defines medical doctors as practitioners of modern medicine who diagnose, treat and prevent illness, disease, injury, and other physical and mental impairments and maintain general health in humans. They may be specialists in certain disease categories, types of patients or methods of treatment, or they may be generalists who provide continuing and comprehensive medical care to individuals, families and communities. Specialists may conduct medical education and research activities in their particular fields of specialisation (World Health Organization, 2010).

The Greek physician, Hippocrates (460-370 BC) is known as the father of western medicine. One of his greatest contributions, which has guided the practice of medicine for more than 2000 years is the ethical code of conduct, popularly known as the 'Hippocratic oath' adopted by medical practitioners across the world. Western medicine reached India under colonial rule. The Portuguese first introduced it in India in the 16th century. This was followed by the setting up of medical departments to provide medical relief to the members of the East India Company. During the 1800s, the British established the 'Indian Medical Services' and teaching hospitals in Madras, Bombay and Calcutta (Singh et al., 2012; Anshu & Supe, 2016; Saini, 2016).

Presently in India, the Bachelor of Medicine and Bachelor of Surgery (M.B.B.S.) is awarded at the under-graduate level, while post-graduate qualifications include the degrees of Doctor of Medicine (M.D.) and Master of Surgery (M.S.) besides Diplomas in various specialities. The post-graduate qualifications may be in different specialisations like orthopaedics, paediatrics, obstetrics and gynaecology, ear, nose and throat (E.N.T.), anaesthesiology etc. The super specialisation degree is called the Doctorate in Medicine (D.M.). The total number of registered allopathic doctors in India (up to 2018) is 1,154,686. The average population served by one government allopathic doctor is 10,926 persons. According to the World Health Statistics Report of 2020, India had 8.6 medical doctors for every 10,000 people as of 2018, which is much lower than the developed countries and global density of 15.6) (World Health Organization, 2020e). The country has 529 medical colleges. The total number

of admissions for the academic year 2018-19 in medical colleges was 58,756 (Central Bureau of Health Intelligence, 2019).

Regulations Governing Allopathic Doctors

The National Medical Commission (NMC) Act, 2019 (Act 30 of 2019), is a Union government Act passed by the Parliament of India, whose objectives include providing for a medical education system that improves access to quality and affordable medical education and makes the services of high-quality medical professionals accessible to all the citizens. It also promotes national health goals, encouraging medical professionals to adopt the latest medical research, and facilitates maintenance of a medical register for India and enforces high ethical standards in all aspects of medical services. Notified vide gazette notification dated August 8, 2019, all the provisions of the Act came into force on 25 September 2020. The Act repealed the Indian Medical Council (IMC) Act, 1956.

The NMC Act, 2019, requires the Union Government to constitute a 33-member National Medical Commission (NMC/Commission), comprising a Chairperson, 10 ex-officio members and 22 part-time members. The Act specifies the tenure of different members of the NMC, their conduct in terms of declaring assets, holding certain posts after demitting office, outlines rules for meetings of the NMC and decision-making processes in the meetings. It also spells out the powers and functions of the Commission, redressal of grievances against the Commission, and the constitution and composition of an advisory body called the Medical Advisory Council. This Council provides a platform for the States and Union territories to put forth their views and concerns before the Commission. As provided for in the NMC Act, 2019, the Union Government has constituted four autonomous boards, namely the Under-Graduate Medical Education Board, the Post-Graduate Medical Education Board, the Medical Assessment and Rating Board, and the Ethics and Medical Registration Board. Each of the four boards has its distinct regulatory roles (National Medical Commission Act, 2019).

Prior to the NMC Act 2019, doctors were regulated by the Indian Medical Council (IMC) Act, 1956 (Act 102 of 1956), which was a Union government Act passed by the Parliament of India (Indian Medical Council Act, 1956). IMC Act, 1956, repealed Act 27 of 1933, to provide for the reconstitution of the Medical Council of India (MCI/Council), and the maintenance of a medical register for India and related matters. The IMC Act, 1956, conferred upon the Union Government the responsibility to constitute the MCI comprising members of each State, medical university, representatives of persons enrolled in the State medical registers of all States and members nominated by the Union Government. The Act provided for the Council to constitute from amongst its members an Executive Committee (EC) and other such committees as the Council may deem necessary, to conduct the purposes of the Act. Rules

were formulated that described the procedure for the election of members to the Council (Indian Medical Council Rules, 1957 and Indian Medical Council (Election of Licentiate) Rules, 1965); specified the modalities of the functioning of the Post Graduate Medical Education Committee constituted under Section 20 of the IMC Act, 1956. These Rules were amended from time to time. There were Regulations, such as those that laid down the procedures and modalities of imparting graduate medical education (Regulations on Graduate Medical Education, 1997); prescribed the minimum qualification and experience and procedure for the appointment of medical teachers in medical colleges, imparting graduate and post-graduate medical education (Minimum Qualifications for Teachers in Medical Institutions Regulations, 1998); laid down the requirements and procedure for obtaining permission of the Union Government, to establish a medical college both by the government and private entities (Establishment of Medical College Regulations, 1999) etc. The Regulations were amended from time to time. The IMC Act, 1956 was amended in 1964, 1993, 2001, 2010, 2011, 2012, 2016 and 2019, before being repealed in 2020.

While the MCI was primarily an elected body for self-regulation of the medical professionals and functioned with a high degree of autonomy, the constitution and functioning of the NMC is more centralised. The MoHFW has the authority and oversight over the NMC. Within the MoHFW, the administrative responsibility lies with different units of the technical arm of MoHFW, the Directorate General of Health Services, such as the medical education division and the medical hospital's division (Sriram et al., 2018). At the State level, the directorates of medical education and health services are responsible for regulating medical education and services, along with the respective State medical councils.

IMC Act, 1956 and Rules – The Concerns

Reported irregularities in functioning and allegations of fraudulent practices and corruption against the elected members marred the functioning of the Council for several years. Some of the contentious issues that parliamentary committees over the years (1987, 2005, 2013) have deliberated upon, include restricting the term of the elected posts such as the President and Vice President of the MCI to no more than two terms, reduction in the term of office of President, Vice President and members of the Council from five to four years and the extent of government control on the functioning of the MCI. Concerns were also raised about granting recognition to colleges that did not meet minimum standards, thereby affecting the quality of doctors produced by such colleges (Department Related Parliamentary Standing Committee on Health and Family Welfare, 2013; Niti Aayog, 2016). The 73rd report of the Parliamentary Standing Committee (PSC) on the IMC (Amendment) Bill, 2013, noted with concern the increasing incidents of negligence by doctors while treating patients in health facilities. It

observed biases in addressing such complaints, with the Council (that is constituted only of medical professionals), taking a very lenient view towards fellow colleagues. Since nobody investigating complaints was willing to testify against their peers, the percentage of prosecution by the Council was almost negligible. The Council did not inspire the doctors to practice the professional standards of conduct as laid down in the IMC (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (Jain et al., 2014).

The 92nd report of the PSC on the functioning of the MCI observed that the MCI did not have any mechanism to filter out from the Indian Medical Register names of such doctors who may have retired, migrated or not be alive any longer. As a result, the MCI did not have a live database of currently active doctors in the country, which was one of its primary functions according to the IMC Act, 1956. The report concluded that as the regulator of medical education in the country, the MCI had failed in all its mandates and been unresponsive to the changing needs of the health system in the country (Department Related Parliamentary Standing Committee on Health and Family Welfare, 2016). Consequently, the MCI was dissolved with the repealing of the IMC Act, 1956.

Since the enactment of the NMC Act, 2019, Rules have been notified for some aspects. For the Rules and Regulations that have not been formulated, the existing ones continue to be in force. While new Rules and Regulations are in the process of being framed, the Rules and Regulations of IMC Act, 1956, will prevail as per Section 61(2) of the NMC Act, 2019 (National Medical Commission, 2019).

The other legislations that regulate different aspects of service delivery by Allopathic doctors are the Clinical Establishments Act, 2010, Consumer Protection Act, 2019, Drugs and Cosmetics Act, 1940, Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

Entry

Entry of doctors into the health care system is regulated by prescribing minimum standards of education and training, registration with a recognised body and obtaining a license to practice.

The NMC Act, 2019, prescribes the minimum requirements for annual admissions and minimum standards for granting recognition to under-graduate and post-graduate medical colleges. It also specifies procedures for recognition and de-recognition of medical qualifications, if institutes do not meet prescribed standards, for both under-graduate and post-graduate medical education.

The Commission maintains an updated register of medical practitioners, called the National Register that contains the names of all the medical practitioners enrolled with any State medical council. Persons whose names are entered are entitled to practise as medical practitioners, according to their qualification in any part of India and charge fees for their services. The National Register is treated as

a public document within the meaning of section 74 of the Indian Evidence Act, 1872, and is to be made available to the public by putting it on their website. The manner in which a name or qualification may be added to, or removed from the National Register, and the grounds for removal are to be specified by the Regulations.

The amendment to the IMC Act, 1956 in 2001 prescribed that a person seeking admission into a foreign medical institution, needs to get an eligibility certificate issued by the Council, without which upon return, the person would not be eligible to appear for the screening test and thereby enrolment, under the IMC Act, 1956 (now NMC Act, 2019). Accordingly, Eligibility Requirement for Taking Admission in an Undergraduate Medical Course in a Foreign Medical Institution Regulations, 2002 and Screening Test Regulations, 2002, were prescribed to standardise the entry-level qualification and training of doctors who study abroad.

To ensure uniform minimum standards for admission into undergraduate and postgraduate courses, a common entrance examination was introduced through the IMC (Amendment) Act, 2016. In continuation, the NMC Act, 2019, provides for a uniform National Eligibility-cum-Entrance Test (NEET), to be conducted for admission to the undergraduate and postgraduate super-speciality medical education respectively. A common final year undergraduate medical examination called the National Exit Test (NET), is to be conducted to gain a licence to practice medicine and for enrolment in the State/national register, as well as for admission to the postgraduate broad-speciality medical education.

The NMC Act, 2019, introduces the cadre of Community Health Provider (CHP), a person connected with modern scientific medical profession, who meets the criteria that may be specified by the Regulations. The Commission may grant the CHPs limited licence to practice medicine at mid-level, as may be specified by the Regulations.

Registration/Licensing

The NMC Act, 2019, provides for a uniform final year undergraduate medical examination, called the National Exit Test (NET). An undergraduate medical student needs to clear this test to be enrolled in any of the State or national registers and obtain a licence to practice medicine in the country. Anyone with foreign medical qualification also needs to qualify through the NET, to obtain a licence to enrol in the State register or the national register and practice as a medical practitioner.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, prescribe the code of medical ethics to be followed by doctors[3]. The Regulations specify that only doctors having recognised qualification and who are registered with the State Medical Council (s)/NMC are allowed to practice modern systems of medicine or surgery. Any person practising modern medicine in violation of the NMC Act, 2019 may be punished with imprisonment up to one year, or a monetary penalty up to Rs. 0.5 million or both.

Quality

The Clinical Establishments (Central Government) Rules, 2012, promulgated under the Clinical Establishments (Registration and Regulation) Act, 2010, require the clinical establishments registered under the CEA, 2010 (and by extension the medical personnel serving in those establishments), to ensure compliance with standard treatment guidelines issued by the Union/State governments. Regulations related to standards of care are applicable only in States/UTs where CEA, 2010 is applicable. In these States/UTs, the health facilities need to meet the prescribed minimum standards of facilities and services, requirement of personnel, maintenance of records, reporting and be registered with the district authority, in accordance with the provisions of the Act. The registration is required to be renewed every five years. Minimum standards for different levels of facilities have been developed and are available (MoHFW, 2010a). Minimum standards for facilities are prescribed for infrastructure, medical equipment and instruments, drugs, medical devices and consumables. Additionally, standards are in place for human resource requirements, support services, legal/statutory requirements, record maintenance and reporting, and basic process to be followed by the facilities in providing services. Standard treatment guidelines for 227 medical conditions in allopathy have been formulated and are available (MoHFW, 2010b).

Standards for Doctors Providing Out-Patient Care

Minimum standards have been framed under the CEA 2010, for single practitioner/more than one doctor clinic manned by a general physician/specialist doctor/super-specialist, or a group of doctors who provide patient care services such as examination, consultation, prescription to outpatients, dispensing of medicines, injection and dressing with/without observation/short stay facility. The standards specify the minimum space requirement for carrying out the basic functions of the clinic. It is required to be well illuminated, ventilated and clean with adequate water supply, have a board/signage displaying the name of the clinic at the gate or on the building of the clinic, name of

[3] The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 were amended in 2003, 2004, 2009 and 2016.

the doctors with registration number, the fee structure of the various doctors/specialists, timings of the clinics and services provided within the facility in the local language. At least one support staff should be available to meet the care, treatment and service needs of the patients, though there may be more depending upon the workload and scope of the services provided.

The availability, maintenance and storage of equipment and drugs, as per the scope of service is to be ensured. Every patient visiting the clinic is to be registered, and a record of their assessment (diagnosis, medications and investigations) is to be documented legibly in the prescription, with the signature of the consultant/specialist/ super-specialist, with date and time. The clinic is required to take all precautions to control infections like practice hand hygiene, store needles and sharp waste in puncture proof container, segregate clinic waste at source, keep the premises pest and termite free etc. Standards related to clean water for handwashing, sanitation and hygiene of the toilets, patient safety aspects like preventing patient fall, management of biomedical waste (BMW), in accordance with the BMW Management and Handling Rules, 1998 are also given (MoHFW, 2010a).

The district registering authority is the registering authority, which has the power to grant, renew, enforce, or cancel the registration of any clinical establishment, in accordance with the provisions and Rules of this Act. The district registering authority may restrain a clinical establishment from carrying on its services if the inspection of the establishment reveals imminent danger to the health and safety of patients. Any violation of the provisions of the CEA, 2010, may lead to a monetary penalty being levied upon the concerned party (Nandraj, 2019).

Dispensing of Drugs

According to the provisions of the Drugs and Cosmetics Rules (DCR), 1945, drafted in accordance with the Drugs and Cosmetics Act (DCA), 1940, drugs can be dispensed only on the prescription of a registered medical practitioner and the practitioner cannot directly sell drugs to the patient, except in specified circumstances as laid down in the Rules. Substances specified in Schedule H, Schedule H1 or Schedule X cannot be sold by retail, except on and in accordance with the prescription of a registered medical practitioner (Rule 65(9), DCR, 1945). In the case of substances specified in Schedule X of the Drugs and Cosmetics Act, 1940, the practitioner is required to produce the prescription in duplicate, one copy of which would be retained by the dispensing chemist for a period of two years.

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, prescribe that all physicians must write their name and designation in full, along with registration particulars on the prescription letterhead. They must use generic names of drugs, ensure rational prescription and use of drugs and mention on the prescription if the physician dispensed any medicine.

In government hospitals where the patient load is heavy, the name of the prescribing doctor must be written below his/her signature. Further, the regulations specify the physician's behaviour with respect to referral and confidentiality. A physician is neither supposed to give, solicit, or receive nor offer to give, solicit or receive, any gift, gratuity, commission or bonus in consideration of or return for the referring, recommending or procuring of any patient for medical, surgical or other treatment. A physician cannot directly or indirectly, participate in or be a party to act of division, transference, assignment, subordination, rebating, splitting or refunding of any fee for medical, surgical or other treatment or with regard to specimen or material for diagnostic purposes or other study/work. A physician may refuse treatment to a patient and refer to another physician when a patient is suffering from an ailment, which is not within the range of experience of the treating physician. However, in case of an emergency, a physician must treat the patient and not arbitrarily refuse treatment.

To upgrade their skills, the registered medical practitioners are required to participate in professional meetings organised by reputed professional academic bodies or any other authorised organisations, as part of Continuing Medical Education (CME), for at least 30 hours every five years. They have to communicate the compliance of CME to their respective State medical council/MCI or NMC.

Pricing and Cost Containment

According to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, a physician shall clearly display the fees and other charges on the board of the chamber and/or the hospital's s/he visits. It is unethical to enter into a contract of "no cure no payment" and physicians working in the public sector are not to accept any fees for their services. The Clinical Establishments (Central Government) Rules, 2012, require the clinical establishments registered under the CEA, 2010, to display the rates charged for the various services/facilities available and the rates are to be fixed within the range determined by the Union/State government.

As per Rule 9 (ii) and (iii) of the Clinical Establishments (Central Government) Rules, 2012, the National Council for Clinical Establishment has approved a list of standard procedures and a template for costing of these procedures. These are shared with the States/UTs who have adopted the Union government Act, advising them to use these for determining the standard cost of any procedure, taking into consideration all including pertinent local factors.

Protection of Patients and Consumers

According to the 'Global Burden of Unsafe Medical Care' study, 2013, India records approximately 5.2 million cases a year of adverse events during treatment, ranging from incorrect prescription, wrong dose, wrong patient, wrong surgery, and wrong time to wrong drug. With greater awareness amongst

people, litigation against health care providers has been rising. A review of the cases of alleged medical negligence brought before the Delhi District Consumer Dispute Redressal Commission between 2009 to 2014 found that out of 48 cases, 43 cases involved private providers and five involved government providers. Medical negligence or deficiency in service could be proved only in 15 (31%) of the 48 cases (Yadav & Rastogi, 2015).

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, specify the physician's behaviour with respect to referral, confidentiality, information sharing with patients, not committing an act of negligence wilfully, not engaging in unethical acts like advertising or soliciting patients and charging commission. The Regulations also specify the acceptable relationship with pharmaceutical and allied health sector industry including punishment for violation, and acts of commission or omission that constitute professional misconduct leading to disciplinary action. SMCs can take action against a registered practitioner who does not practice ethically and rationally. Upon receipt of a complaint, the SMC may conduct an enquiry and if found guilty, may award suitable punishment including temporary or permanent removal of the practitioner's name from the State medical register, thereby disallowing the practitioner the right to practice in future.

Further, the physicians are required to disclose incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession. While following the laws of the country, physicians should specifically observe the provisions of laws that have a bearing on people's health. These include Acts like the Drugs and Cosmetics Act, 1940; Pharmacy Act, 1948; Narcotic Drugs and Psychotropic Substances Act, 1985; Medical Termination of Pregnancy Act, 1971; Transplantation of Human Organ Act, 1994; Mental Health Act, 1987; Environmental Protection Act, 1986; Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; Persons with Disabilities (Equal Opportunities and Full Participation) Act, 1995 and BMW (Management and Handling) Rules, 1998 (as amended from time to time).

The common minimum standards framed under the CEA, 2010, require the facility to provide a safe and secure environment for patients, their families, staff and visitors. It has to be situated in clean surroundings and comply with the local byelaws. Floor needs to have an even surface and be non-slippery, with no seepage in walls or any blockage of drains. Availability of mosquito netting on windows shall be ensured by the clinician.

Information Provision

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, prescribe the code of medical ethics to be practised by doctors. The Regulations prescribe the procedure for physicians to maintain patient records, display their registration number and fees for professional

services/other charges, use generic names of drugs, ensure rational prescription and use of drugs, as well as mention on the prescription if the physician dispensed any medicine. If the patients/authorised attendants or legal authorities request medical records, the practitioner has to issue them within a period of 72 hours.

In the States where CEA, 2010 is applicable, the Clinical Establishments (Central Government) Rules, 2012 require the clinical establishments registered under the CEA, 2010, to maintain and provide electronic health/medical records of patients, and information and statistics as required by other laws applicable at the time. The facilities are required to maintain and share information and statistics with regard to national programmes, notifiable diseases and emergencies/disasters/epidemics, with the district authorities. The common minimum standards framed under the CEA, 2010, require that medical records of patients and health information and statistics with respect to national programmes, be maintained and shared with district authorities in the form of quarterly reports. A copy of out-patient records, procedure records and referral/emergency records must be maintained as per the MCI guidelines.

Grievance Redressal

A patient/consumer can complain to the respective State Medical Council in case of grievance against a medical practitioner under the NMC Act, 2019. If the medical practitioner is aggrieved by the decision of the State Medical Council in the case, s/he may appeal to the Ethics and Medical Registration Board against it. If the medical practitioner is aggrieved by the decision of the Ethics and Medical Registration Board, s/he can further appeal to the Commission.

The Consumer Protection Act, 2019, is meant to protect the interests of consumers and to establish authority for timely and effective administration and settlement of consumer disputes. It repeals the Consumer Protection Act, 1986 and extends to the whole of India. The Act applies to all goods and services that are paid for. 'Consumer' is defined in the Act as a person who buys any goods or avails any service for a consideration, which has been paid or promised or partly paid and partly promised, or under any system of deferred payment that does not have any commercial purpose for that person. The Act is applicable if services hired or availed of or agreed to be hired or availed of suffer from any deficiency. Deficiency is defined as "(i) any act of negligence or omission or commission by such person which causes loss or injury to the consumer; and (ii) deliberate withholding of relevant information by such person to the consumer". Hence, deficiency in health care services falls within the purview of the Act (Consumer Protection Act, 2019).

Under the Consumer Protection Act, 2019, Central Consumer Protection Council, State Consumer Protection Councils and District Consumer Protection Councils are established to offer advice on promotion and protection of consumer rights. National, State and district consumer disputes redressal commissions are formed to entertain the consumers' complaints. The Act specifies the authority of each body, the process of filing complaints, method of proceedings before the redressal commissions, time period for disposal of complaints, penalties, appeal in case of grievance and punishment for non-compliance with the redressal commission's order. Penalty under the Act includes both monetary fines and imprisonment, as well as suspension or cancellation of license, if applicable. Consumer mediation cells are formed at district, State and national levels for settling cases through mediation if the parties so desire. In States/UTs where CEA, 2010 is applicable, if the doctors have any grievance with the district registering authority regarding the registration of their health facility, such as refusal to grant or renew a certificate of registration or revoking a certificate of registration of their health facility, they may appeal to the State Council of Clinical Establishments established under the CEA, 2010.

The Epidemic Diseases (Amendment) Act, 2020, was mainly brought about for the protection of health care service providers and health facilities, considering the incidents of violence reported in the initial period of the COVID-19 pandemic in April 2020. The amendment prohibits violence against health care service personnel and damage or loss to property related to health facilities, during an epidemic. Violation may be punished with imprisonment for three months to five years, and with fines of Rs. 50,000 to Rs. 200,000. In case of grievous injury caused to health care service personnel, the Court shall presume the accused to have committed the offence, unless proved otherwise, and the punishment constitutes six months to seven years imprisonment and a fine of Rs. 100,000 to Rs. 500,000. In addition, any person convicted under the Act is also liable to pay monetary compensation, for causing hurt or grievous hurt to any health care service personnel, as well as in lieu of damage or loss to any property (Epidemic Diseases (Amendment) Act, 2020).

Gaps and Challenges

There is an absence of regulations on the cost of care that practitioners provide, or the fees or charges related to the treatment they may provide. Apart from complaining to the provider specific professional councils such as the State medical council or the Ethics and Registration Board, and the Consumer Protection Act, 2019, which have their own limitations, there are insufficient legal provisions for grievance redressal for patients and consumers. The CEA, 2010, too is deficient on the grievance redressal aspects for the patients/consumers.

The Consumer Protection Act, 2019, is for consumers of all types of goods and services, ranging from home appliances to patients suffering due to medical negligence. Innumerable cases involving technical issues are pending in the consumer courts, resulting in delayed justice. Thus, establishing appropriate authorities that are capable of dealing with such specialised cases and can deliver speedy and proper justice to both the parties, may be more appropriate instead (Datta, 2014; Lalchandani, 2020; Verma, N., 2020).

While the CEA, 2010, prescribes input level standards for infrastructure, human resources, supportive services, medical equipment, it does not prescribe any process and outcome standards. There are no legislative mechanisms for clinical and medical audits to monitor inappropriate treatment, unnecessary surgeries, mandatory investigations and over prescriptions (Nandraj, 2019).

HEALTH FACILITIES

IN-PATIENT FACILITIES

Health facilities are places that provide either inpatient or outpatient facilities for health care services. Outpatient facilities provide only consultation without admitting patients, though they may have observation beds for short stay and/or diagnostic services. Inpatient facilities provide consultation, as well as treatment under admission. They include (1) smaller nursing homes, (2) larger hospitals and (3) teaching hospitals. They offer services categorised as general practice, single speciality, multi-speciality (including palliative care centre, trauma centre, maternity home) and/or super-speciality. These facilities also provide outpatient care, specialised treatment by organised medical and other professional staff, and inpatient facilities round the clock.

Hospitals offer a varying range of acute, convalescent and terminal care using diagnostic and curative services, in response to acute and chronic conditions arising from diseases, as well as injuries and genetic anomalies. A nursing home is defined as any premises used or intended to be used for the reception of persons suffering from any sickness, injury or infirmity, and provision of treatment and nursing for them. This definition also includes maternity homes, which are defined as any premises used or intended to be used for the reception of pregnant women or of women in labour, or immediately after childbirth (Clinical Establishments (Registration and Regulation) Act, 2010).

There are health facilities that provide services such as (1) physiotherapy, (2) counselling, (3) dietetics, (4) occupational therapy, (5) speech therapy, (6) optometry etc., as stand-alone outpatient facilities, or part of other outpatient or inpatient facilities like polyclinics and hospitals. Further in the recent past, certain inpatient facilities have come up that provide medical surgical services, for example, abortion, cataract etc., however, the patient is discharged on the same day. Health facilities also include laboratories and diagnostic centres that provide investigative and diagnostic services. These may be independent entities or part of a larger health facility, such as a hospital. In this document, laboratories and diagnostic services are covered separately under supportive services.

Regulations Related to In-Patient Health Facilities

In India, unlike most other business establishments, such as shops, beauty parlours and dance bars that need a licence to operate, health facilities providing care such as hospitals, clinics and nursing homes, do not require registration or a licence to operate in many States. A review of the legislations that were in existence, such as Delhi, Jammu & Kashmir, Karnataka, Madhya Pradesh, Maharashtra, Orissa and West Bengal, showed that many of them were outdated, inadequate in content and coverage, with no formulation of rules and byelaws, and no prescribed standards. For example, some

of the States Acts, such as the Bombay Nursing Home Registration Act of 1949, West Bengal Clinical Establishment Act of 1950 and Delhi Nursing Homes Registration Act of 1953, are not equipped to address the concerns of present-day health care service delivery. Their clauses, rules and byelaws have not been updated to meet the growing burden of diseases, and the change in treatment and service delivery patterns of the variety of health care models that exist. Another lacuna in some of the existing State legislations is that their scope is limited to the hospitals and nursing homes providing allopathy care. Laboratories, diagnostic centres, clinics run by single doctors and dentists, clinical establishments from other recognised systems of medicine and government establishments, are not included. Furthermore, minimum standards related to infrastructure, human resources, patient safety, display of information have not been developed, nor have issues relating to accountability of quality and price been addressed in the State legislations. In some cases, penalties for non-compliance are minimal, to the extent of being ineffective (Nandraj, 2018).

In this context, the Union Government enacted the Clinical Establishments (Registration and Regulation) Act (CEA), 2010 (Act No. 23 of 2010), to provide for the registration and regulation of clinical establishments in the country, with the purpose of prescribing minimum standards for facilities and services provided by them. The Act is applicable to all kinds of public and private clinical establishments of all recognised systems of medicine, except the establishments run by the Indian Armed Forces. According to the Seventh Schedule of the Constitution of India, public health, sanitation, hospitals and dispensaries are part of the State List and therefore regulation of health facilities falls under the States' responsibility. Though the parliament generally has no power to legislate on items from the state list, two or more States may ask the parliament to legislate on an issue that is otherwise reserved for the State. Other States may then choose to adopt the resulting legislation. Since majority of the States in India had failed in their obligation to enact appropriate legislation for registering and regulating private healthcare providers, the Central Government wrote to all the State governments that the Centre would be keen to enact a Central Act. Four states i.e. Arunachal Pradesh, Sikkim, Mizoram, and Himachal Pradesh gave their concurrence, which enabled the Central Government to enact the central CEA, 2010. Other States that wish to adopt the Central Act, do so by passing a resolution under Clause (1) of Article 252 of the Constitution of India in their respective State assemblies (Nandraj, 2018). The Act applies to 11 States and 6 Union territories (UTs) as of March 2021.

The CEA, 2010, provides for the constitution of a national council for clinical establishments, whose functions include developing minimum standards for ensuring proper health care by different specialities/levels of clinical establishments and their periodic review, classification of the clinical establishments into different categories, and compiling and publishing a national register of clinical

establishments. Every State/UT is required to constitute a State/UT council for clinical establishments, whose functions include compiling and updating the State registers of clinical establishment and sharing such information with the national council, acting as an appellate body to hear appeals against the orders of the district registering authority, and publishing an annual report on the state of implementation of standards in their respective States/UTs. The State governments are also required to set up an authority called the district registering authority in each district, for the registration of clinical establishments. The district registration authority has the power to grant, renew, enforce or cancel the registration of any clinical establishment, in accordance with the provisions and Rules of the Act. In case of non-compliance, the CEA 2010, provides for stiffer penalties than some of the State Acts. These include fines of up to Rs. 10,000 for the first offence, Rs. 50,000 for the second offence and Rs. 500,000 for subsequent offences (Nandraj, 2018). At the national level, the DGHS, MoHFW is responsible for the implementation of the CEA, 2010, and at the State level, the Directorate of Health Services (DHS) is responsible.

Figure 4. Regulation of Clinical Establishments in the States and UT's (as on March 2021)

States and UTs where the CEA, 2010 is applicable from its date of notification, that is, 1 March 2012	Arunachal Pradesh, Himachal Pradesh, Sikkim, Mizoram and (UTs) Andaman & Nicobar Islands, Dadra and Nagar Haveli and Daman and Diu, Lakshadweep, Chandigarh, Puducherry, Jammu & Kashmir
States which have adopted the CEA, 2010	Assam, Bihar, Haryana, Jharkhand, Rajasthan, Uttarakhand, Uttar Pradesh
States/UTs having their own legislations	Andhra Pradesh, Chhattisgarh, Goa, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Manipur, Meghalaya, Nagaland, Odisha, Punjab, Tamil Nadu, Tripura, West Bengal, Telangana. 1 UT: Delhi

There has been considerable opposition from the medical associations to the legislations for regulating the clinical establishments. Amongst the States that have enacted their own Acts, the Government of Punjab enacted the Punjab Clinical Establishments (Registration and Regulation) Act, 2020, which the State IMA opposed on the grounds that the Act would lead to harassment of doctors, as well as an increase in treatment costs for the patients. They argued that doctors in the State are already regulated by the Punjab Medical Council and NMC/MCI, while buildings are regulated by the building regulations and norms, and additionally, several of them are getting National Accreditation Board for Hospitals & Health care Providers (NABH) accreditation, and thus CEA is not required for the State. The State government relented to the demands of the agitating doctors and is considering exempting

individual doctor-owned small and medium health centres (less than 50 bedded), from the ambit of the regulation (TNN, 2020; Kumar, 2020). In Goa, the private sector has been opposing the implementation of the Act as it would need them to change the manner in which their establishments function (TNN, 2019). In Tamil Nadu, doctors' associations are demanding that the rules for consultation rooms where no injections or instruments are used, be relaxed (Narayan, 2019). In Odisha, when the High Court sought a status report in 2019, on the implementation of the Orissa Clinical Establishment (Control & Regulation) Act and Rules, 1990, from the State government, the Secretary, Department of Health and Family Welfare responded that the State had data for registration of clinical establishments for only 9 of the 30 districts in the State. It was also reported that steps were being taken to collect information from the district level task force committees, for the remaining 21 districts (Patnaik, 2019). In Rajasthan, the IMA and private hospital and nursing home society have been demanding that smaller hospitals with less than 50 beds and clinics should be kept out of the purview of the CEA, 2010 (Ali, 2019).

Apart from the CEA, 2010, where applicable, health facilities need to comply with the Drugs and Cosmetics Act, 1940, Consumer Protection Act, 2019, Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, and standard regulatory requirements under the respective State Shops and Establishments Act (relating to hours of work, cleanliness, holidays, etc.), Bio-Medical Waste Management Rules, 2016, Atomic Energy (Radiation Protection) Rules, 2004, pollution control, fire safety, food safety etc.

Registration and Licensing

In States where the CEA, 2010 is applicable, health facilities have to meet the prescribed minimum standards of facilities and services, the requirement of personnel, maintenance of records/reporting and be registered with the district registering authority, in accordance with the provisions of the Act. The registration is to be renewed every five years. The Clinical Establishments (Central Government) Rules, 2012, lay out the procedure for the grant of provisional registration/renewal of registration of clinical establishments, by the district health officer (Clinical Establishments (Central Government) Rules, 2012).

Additionally, health facilities need to comply with the standard regulatory requirements, under the respective State Shops and Establishments Act (relating to hours of work, cleanliness, holidays, etc.) and obtain registration under the provisions of the Bio-Medical Waste Management Rules, 2016, pollution control, fire safety, food safety etc. As per the Atomic Energy (Radiation Protection) Rules, 2004, the facilities must be granted licence within a period of 180 days from the date of receipt of the

application, subject to the condition that all the requirements for issuance of the licence are duly fulfilled.

Quality

MoHFW, GoI has provided minimum standards for health facilities under the CEA, 2010, for different levels of hospitals, categorised on the basis of complexity of care provided. Thus, there are separate standards given for hospitals providing general medical services, specialist medical services, services of one or more of the super specialities, and teaching/training institutions. Minimum standards for (1) infrastructure, (2) medical equipment and instruments, (3) drugs, (4) medical devices and consumables, (5) human resource requirements, (6) support services, (7) legal/statutory requirements, (8) record maintenance and reporting, and (9) basic process to be followed by the facilities in providing services are available (MoHFW, 2010a). However, while input level standards for infrastructure, human resources, supportive services, medical equipment are given, no process and outcome standards are available.

According to Section 9 (iii) of the Clinical Establishments (Central Government) Rules, 2012, health facilities registered under the CEA, 2010, need to ensure compliance with the standard treatment guidelines, issued by the Union/State governments. Standard treatment guidelines for 227 medical conditions in allopathy and 18 medical conditions in Ayurveda have been formulated (21 clinical specialities) (MoHFW, 2010b).

In states/UTs where CEA, 2010 is applicable, the minimum standards for hospitals drafted under the CEA, 2010, mandate registered medical practitioners to manage patients on the basis of findings of initial assessment, including the need for referral, and the hospitals to have provision for transporting patients for transfer/referral/investigations etc. in a safe manner, if required. The patient shall be referred to another facility, along with the required clinical information or notes. If the hospital does not have emergency services, it has to provide first aid to the patients and arrange for their appropriate transfer/referral.

In order to strengthen the public health system in rural areas, Indian Public Health Standards (IPHS) were published in 2007, under the National Rural Health Mission (NRHM). IPHS are a set of uniform standards to improve the quality of health care delivered through public health facilities, primarily in the rural parts of the country. The standards are available for SCs, PHCs, CHCs, and sub-district and district hospitals, to guide public health care infrastructure planning and up-gradation. The standards were revised in 2012, in the context of the changing protocols of the existing programmes and the introduction of new programmes, such as for non-communicable diseases. Though aimed to achieve

high quality of health care across the country, the IPHS are recommendatory in nature and not enforceable by law (DGHS, 2012).

Apart from the legislative measures, there is a voluntary mechanism for self-regulation by the National Accreditation Board for Hospitals & Healthcare Providers (NABH). NABH is a constituent board of the Quality Council of India (QCI), set up to establish and operate accreditation programme for health care organisations. The mission of NABH is "…to operate accreditation and allied programs in collaboration with stakeholders, focusing on patient safety and quality of health care based upon national/international standards, through process of self and external evaluation..." The accreditation is voluntary and both government and private health facilities can apply for it. The standards cover the entire range of hospital operations and services, such as registration of patients, their (1) initial assessment, (2) laboratory services (both in-house and outsourced), (3) display of patient rights and education, (4) policies and procedures on the care of patients, (5) management of medication, (6) hospital infection control process, (7) facility management and safety, (8) human resources management, and (9) patient information management systems. NABH currently offers accreditation programmes for allopathic hospitals, small health care organisations/nursing homes, blood banks and transfusion services, oral substitution therapy (OST) centres and primary and secondary health centres, dental hospitals/clinics, and medical imaging services. It also offers AYUSH hospital accreditation programme, in association with the Ministry of AYUSH, GoI for Ayurveda, Yoga and Naturopathy, Unani, Siddha, Homoeopathy hospitals and Panchkarma clinics, with separate accreditation standards as per the individual system of medicine and its requirements (National Accreditation Board for Hospitals & Healthcare Providers, n.d.).

Pricing and Cost Containment

The Clinical Establishments (Central Government) Rules, 2012, prescribe that the clinical establishments registered under the CEA, 2010, display the rates charged for various services/facilities available, and the rates are to be fixed within the range determined by the Union/State government. As per Rule 9 (ii) and (iii) of the Clinical Establishments (Central Government) Rules, 2012, the National Council for Clinical Establishment, has approved a list of standard procedures and a template for costing of these procedures. These are shared with the States /UTs who have adopted the Union government Act, advising them to use these for determining the standard cost of any procedure, taking into consideration all including pertinent local factors.

The West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017, provides for the constitution of a West Bengal Clinical Establishment Regulatory Commission, which will fix the charges for different kinds of treatment and services provided by the health facilities

registered under the Act. According to clause 3 (o) and (p) of section 7 of the Act, the clinical establishments are required to "…strictly follow the fixed rates and charges, including the Package Rates for investigation, bed charges, operation theatre procedures, intensive care, ventilation, implants, consultation and similar tests and procedures, and any additional treatment or procedure shall not attract additional charges, over and above such fixed rates and charges including the Package Rates…", and have to provide estimates for treatments not covered in fixed rates and charges, while ensuring that final bills do not exceed the estimates by a certain percentage, as may be prescribed by the Government (West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017).

The Kerala Clinical Establishments (Registration and Regulation) Act, 2018, mandates all health facilities to display, in a conspicuous place in the clinical establishment in Malayalam as well as in English, the fee rate and package rate charged for each type of service provided, facilities available and for specific procedures. No clinical establishment can charge fees or package rates more than what is displayed (Kerala Clinical Establishments (Registration and Regulation) Act, 2018).

Protect Patients and Consumers

In States/UTs where CEA, 2010 is applicable, the minimum standards for hospitals drafted under the CEA, 2010, mandate that patients and/or family members be informed about the disease condition, and proposed care including the risks, alternatives and benefits. They need to be informed about the expected cost of the treatment and have to be also kept informed about the progress and any change of condition. Patients and/or their families are expected to be educated about the safe and effective use of medication, food-drug interaction, diet and disease prevention strategies. They have also to be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials. The discharge summary is required to provide information in an understandable language and format about the clinical history, investigations, treatment provided, discharge advice and any other follow-up/care, in case of emergency. The security and safety of patients, staff, visitors and relatives are to be ensured by the provision of appropriate safety installations and the adoption of appropriate safety measures. For instance, the safety and security of neonates in the labour room needs to be ensured. Safety signages are to be appropriately placed within the hospital premises, for example, fire exit, hazardous radiation, inflammable material, no smoking etc. Appropriate backup and safety measures with regard to the use of medical gases need to be in place, to ensure patient safety at all times. All the relevant documents pertaining to any invasive procedures performed shall be maintained in the record, including the procedure safety checklist. The District Registering Authority constituted under the CEA, 2010, may restrain a health

facility from carrying on its services, if the inspection of the facility reveals imminent danger to the health and safety of patients. Any violation of the provisions of the Act may lead to a monetary penalty being levied upon the concerned party.

The Atomic Energy Act, 1962, a Union Government legislation provides for the development, control and use of atomic energy for the welfare of the people of India, and for other peaceful purposes and for matters connected therewith. The Act confers upon the GoI powers and responsibilities, including those for (i) production, development, use and disposal of atomic energy/radioactive substances; (ii) control over radioactive substances or radiation generating plants, in order to prevent radiation hazards, secure public safety and safety of persons handling radioactive substances or radiation generating plant and (iii) ensure safe disposal of radioactive wastes. The Atomic Energy Act, 1962, gives the Union Government powers to enter and inspect the premises and to take penal actions against any party contravening the provisions of the Act. Further, the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987, and the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012, lay down the policy and regulatory framework for control of, and ensuring safety in activities relating to the use of atomic energy. The Union Government has established the Atomic Energy Regulatory Board (AERB) to carry out certain regulatory and safety functions envisaged in the Act, and as the competent authority to enforce the safety related Rules under the Act. The AERB regulates the nuclear and radiation facilities and activities by adopting the following processes (AERB, 2014):

- Development of safety requirements and guidance for utilities and users.
- Licensing process for various facilities and activities based on safety requirements and guidance.
- Regulatory inspections for checking compliance with license conditions as well as safety requirement.

The Atomic Energy (Radiation Protection) Rules, 2004, promulgated under the Atomic Energy Act, 1962, provide the legal framework for the safe handling of radiation generating equipment, including X-ray equipment (NHSRC, 2017). It is mandatory for all users of medical diagnostic X-ray equipment to obtain a licence for operation from AERB, as per Atomic Energy (Radiation Protection) Rules 2004. The Rules mandate the display of radiation symbol or warning sign conspicuously and prominently on externally visible surfaces of radiation equipment and containers for storage of radioactive materials; packages for radioactive materials and vehicles carrying such packages; at the entrance to the room housing the radiation generating equipment; and at the entrance of the controlled area and supervised area. The license is valid for a period of five years.

To prevent the misuse of certain habit-forming drugs (narcotic drugs) listed in Schedule X, Rule 65[12] of the Drugs and Cosmetics Rules, 1945, recommends] that substances specified in Schedule X should be kept under lock and key in a cupboard or drawer reserved solely for the storage of these substances, or in a part of the premises separated from the remainder of the premises and to which only responsible persons have access (Schedule X: Drugs and Cosmetics Rules, 1945).

Under the Consumer Protection Act, 2019, Central Consumer Protection Council, State Consumer Protection Councils and District Consumer Protection Councils are established, to offer advice on promotion and protection of consumer rights (including the rights of the patients/consumers of health services). National, State and district consumer disputes redressal commissions are formed to entertain the consumers' complaints. The Act specifies the authority of each body, the process of filing complaints, method of proceedings before the commission, time period for disposal of complaints, penalties, appeal in case of grievance and punishment for non-compliance with the commission's order. Penalty under the Act includes both monetary fine and imprisonment, as well as suspension or cancellation of license, if applicable. Consumer mediation cells are to be formed at the district, State and national level, for settling cases through mediation if the parties so desire.

Information Provision and Grievance Redressal

The Clinical Establishments (Central Government) Rules, 2012, prescribe that the health facilities maintain and provide electronic health/medical records of patients, and information and statistics as required by other laws applicable at the time. Every registered health facility has to furnish such returns, statistics and other information to the district authority/State council/national council, as may be prescribed by them from time to time. The minimum standards laid down under the CEA, 2010, mandate the facilities to maintain and share information and statistics with regard to national programmes, notifiable diseases and emergencies/disasters/epidemics, with the district authorities. The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, prescribe that if the patients/authorised attendant or legal authorities involved, request for medical records, the practitioner has to issue them within a period of 72 hours.

All health facilities - government hospitals, private hospitals, laboratories and clinics are required to report cases of diseases classified as 'notifiable' by the government, to district/State government authorities. Any failure to report a notifiable disease is a criminal offence and the State government can take necessary action against defaulters (Saxena, 2019a; Saxena, 2019b).

In case of a grievance, patients can complain to the provider specific professional councils, such as the State medical council/board or the ethics and registration board, and/or can file a complaint under the Consumer Protection Act, 2019. In States/UTs where CEA, 2010 is applicable, in case of any

grievance with the district registering authority regarding the registration of the health facility, such as refusal to grant or renew a certificate of registration or revoking a certificate of registration, the aggrieved party may appeal to the State Council of Clinical Establishments established under the CEA, 2010.

The Epidemics Diseases (Amendment) Act, 2020, was mainly brought about for the protection of health care service providers and health facilities, considering the incidents of violence reported in the initial period of the COVID-19 pandemic in April 2020. The amendment prohibits violence against health care service personnel and damage or loss to property related to health facilities, during an epidemic. Violations may be punished with imprisonment for three months to five years, along with fines of Rs. 50,000 to 200,000. In case of grievous injury caused to health care service personnel, the Court shall presume the accused to have committed the offence unless proved otherwise, and the punishment constitutes six months to seven years imprisonment and a fine of Rs. 100,000 to 500,000. In addition, any person convicted under the Act is also liable to pay monetary compensation for causing hurt or grievous hurt to any health care service personnel, as well as in lieu of damage or loss to any property (Epidemics Diseases (Amendment) Act, 2020).

Gaps and Challenges

In the existing legislations including the CEA, 2010, there is an absence of regulation of fees and charges by private health facilities. Issues related to differential rates, overcharging and excessive billing, commissions for referrals, demanding money before operation procedures and forcing patients to purchase from specific vendors are not touched upon. There are no legislative mechanisms for clinical and medical audits to monitor Inappropriate treatment, unnecessary surgeries, mandatory investigations and over prescriptions (Nandraj, 2019). Thus, while the CEA, 2010, prescribes input level standards for infrastructure, human resources, supportive services and medical equipment, it does not give any process and outcome standards. Apart from complaining to the provider-specific professional councils, such as the State medical council/boards or the ethics and registration boards, and file a complaint under the Consumer Protection Act, 2019, which have their own limitations, there is no legal provision for grievance redressal for patients and consumers.

Opposition by the private sector, led by the IMA in different States is a major challenge in the drafting of a suitable CEA in some of the States, and its implementation in the others. As discussed above, in several States including Punjab, Goa and Tamil Nadu, the private sector has been pressurising the government to relax some of the clauses of the Act and keep certain kinds of facilities out of the purview of the Act, owing to misinformed and irrational concerns such as the CEA, 2010 leading to 'license and inspector raj', curtailment of the freedom of medical practice and levy of stringent

punishment on doctors. (Nandraj, 2018). Hence, in the States that have neither adopted the Central CEA, 2010, nor have their own updated Act, the health facilities are required to follow only the allied regulatory requirements, according to the State specific Shops and Establishment Act, Drugs and Cosmetics Act, 1940, Bio-Medical Waste Disposal Rules, 2016 etc., without any Regulation specific to the services provided by these clinical establishments. Thus, issues with the adoption and implementation of the CEA, 2010, leave the sector effectively unregulated.

The Consumer Protection Act, 2019, is for consumers of all types of goods and services, from home appliances to patients suffering due to medical negligence. The persons presiding upon the cases in consumer courts may not always have the expertise to go into the medical details of the medico-legal cases, which may sometimes affect the judgements pronounced, especially with no scope for cross-examination and the judges relying solely on affidavits and reports (Datta, 2014).

The MoHFW, GoI advised all the States/UTs to invoke section 2 of the Epidemic Diseases Act, 1897, to manage the COVID-19 pandemic and enforce the advisories issued by it from time to time, in this regard (Perappadan, 2020). Invoking the Epidemic Diseases Act, 1897 and the Disaster Management Act, 2005, by the State and Union governments to manage the COVID-19 pandemic, gave rise to several concerns regarding the delivery of health care services during the pandemic (Disaster Management Act, 2005; Epidemic Diseases Act, 1897). For instance, while there were complaints of private hospitals overcharging patients for COVID-19 treatment despite the regulation of costs by the government, the representatives of the IMA reported harassment of doctors by administrators who enforced government directives, but themselves lacked medical expertise. Converting private hospitals in small towns to COVID-19 hospitals compulsorily, though they lacked infrastructure or personnel to manage such patients were also opposed. The Association of Health care Providers of India (AHPI) challenged the Delhi government's order asking private hospitals to reserve 80 percent of intensive care beds for COVID-19 patients, on the grounds that it hampered care to other patients who needed those beds (BMJ, 2020).

OUTREACH SERVICES

Health care services provided outside of fixed health facilities are referred to as outreach health care services. These health care services are required to meet the needs of certain groups of population, who face barriers in accessing services due to geographic, economic, or social reasons. In the Indian context, restricted access may be due to geographical reasons (living in remote hard-to-reach rural areas, hilly terrain, desert areas, islands, riverine population, flood-prone areas), social status (persons belonging to scheduled castes (SC), scheduled tribes (ST), women, elders, children, disabled/physically or mentally challenged) or economic reasons (urban poor, migrant workers, homeless, slum dwellers). The nature of outreach health care services may vary depending on the site of providing services (where), population coverage (to whom), service providers (by whom), services coverage (what) and frequency (when). Outreach services may be provided by the public and/or the private sector.

The significant aspect of outreach services is that they take health care closer to where people are, thereby overcoming some of the access barriers. Hence, they can be very crucial in meeting the needs of the vulnerable population groups. Regulation of outreach health care services is important, to ensure that the services adhere to certain standards and do not compromise on quality and safety. Different models of outreach health care services are operational in India, such as fixed day-fixed site approach, home visits by community health workers/ANMs, mobile units, medical camps, tests being provided at home, home-based care and more recently virtually-telemedicine consultation. This chapter discusses the regulations related to four modes of outreach service delivery, that is, home-based care, medical camps, mobile medical units and telemedicine.

Home-Based Care

Home-based care is defined as care given to ill/infirm people in their homes, to promote, restore, rehabilitate and maintain maximum levels of comfort, function and health, including care towards a dignified death. It can be classified into preventive, promotive, therapeutic, rehabilitative, long-term maintenance and palliative care categories. It may be provided by formal and/or informal caregivers and may be both, clinical and non-clinical. Home-based care may have either of the three objectives, that is, to substitute for acute care hospitalisation or long-term care institutionalisation, or to prevent the need for institutionalisation and maintain individuals in their own home or community. For instance, people with commonly occurring diseases/conditions that can be effectively managed at home, such as hypertension, diabetes, people who need extended care though not necessarily hospital care, such as those recovering from illnesses/surgeries, people suffering from chronic

illnesses such as HIV/AIDS, mental illness, people with disabilities, elderly needing assistance with activities of daily living. The overall goal of home-based care is to provide high quality, appropriate and cost-effective care to individuals that will enable them to maintain their independence and the best possible quality of life (Havens, 1999; Western Cape Government, n.d.; World Health Organization, 2002). s

The spectrum of home-based care in India has evolved over the years. From living in a joint family household, where care was essentially provided by the immediate family members, often the women of the household, home visits by hakims/vaids, practitioners of modern medicine for the treatment of episodic illnesses, home deliveries conducted by dai's to home visits by community health workers, such as ASHAs/ANMs, to the commercially provided health care, like post-operative care, palliative care, care of persons with disabilities or chronic illnesses, physiotherapy, laboratory investigations, assistance with activities of daily living, social and emotional support etc. Home-based care in India is fragmented and unorganised, and largely outside the purview of health regulation. In its 11th meeting, the National Council for Clinical Establishments (NCCE) decided that "registration and regulation of home-based care will not be done under CEA" (DGHS, 2018). With very limited regulation, there are concerns about the quality of service providers and services, especially with the increasing demand for home-based care (IANS, 2017).

Regulation of home-based care can help improve the quality of services in home health care (Ganesh, 2020; IANS, 2017) as in some other countries, where it is more organised and regulated. In the USA, home health care professionals are licensed practical nurses, therapists or home health aides, with many working for home health agencies and home health care franchises. Home health care agencies are regulated by State and federal laws and are often Medicare and Medicaid certified. Due to the regulatory requirements, services provided by these agencies are supervised and controlled, including the qualifications of the service providers/caregivers (Feigenbaum, n.d.; Manchester Speciality Programs, 2021). In several countries in Europe, the governments are involved in home care provision. In cases where home care is outsourced to private providers, they are often required to be registered and to comply with certain minimum standards of care to receive public financing. In the Netherlands and Germany, home care is funded through health insurance. Germany, The Netherlands, and Scotland have national standards for home care services, such as minimum training criteria required for home care workers, which are guided by legislations. Annual audits are carried out by external bodies in Germany and The Netherlands, to assess adherence to quality under the ISO standards, and accreditation is awarded if the audits meet the standards. Scotland and Sweden operate a national compulsory registration scheme. Regular inspections, investigation of specific complaints, annual user surveys are some of the mechanisms employed to maintain quality checks. Germany, The Netherlands

and Scotland operate sanctions if quality standards are not adhered to, while Sweden uses a reward-based system to meet the required standards. However, privately funded home care that people purchase from private agencies independent of the government is largely outside the scope of governmental home care regulation (Genet et al., 2012; Kiersey & Coleman, 2017).

Home health care professionals may be considered a part of the service provider group, known as allied health care professionals or paramedical professionals. This category of providers is diverse in India. The recently enacted National Commission for Allied and Health care Professions (NCAHP) Act, 2021, seeks to provide for regulation and maintenance of standards of education and services by allied and health care professionals. One of the categories of professionals mentioned in the Act is "Community Care, Behavioural Health Sciences and other Professionals", who may be similar to home health care professionals. The Rules of the Act are yet to be formulated (for more information on the Act, please refer to the chapter on allied health care professionals). Currently, home-based care is provided by the government and private for-profit and not-for-profit companies and organisations, with little regulation. However, both the people engaged in providing home-based care and home-based care per se need to be organised, standardised and regulated in the country.

Medical Camps

Medical camps are make-shift health facilities that usually provide specific/limited health interventions. They may be organised by the government, charitable organisations, private for-profit hospitals, non-profit organisations, pharmaceutical companies or by business groups, as part of their corporate social responsibility (CSR). Services provided may include health information, consultations, screening, diagnostics, follow-ups, voluntary blood donations, surgeries, such as cataract, dental-related, tubectomy and vasectomy, referral, prescription of medicines, as well as dispensing medicines. These may be free, subsidised or at market cost.

Medical camps have been organised as part of GoI's population control strategy and the National Programme for Control of Blindness (NPCB), since the 1970s. The scope of service in the camps has expanded from laparoscopy to minilap and non-scalpel vasectomy, from targeted to non-targeted and from the random surgery camp system to one based on Standard Operating Procedures (SOPs). Until the late 1970s, emphasis was on male sterilisation carried out in sterilisation camps. However, during the 1980s, female sterilisation started becoming popular in the wake of opposition to coercive vasectomy camps conducted during the emergency period. Additionally, more advanced laparoscopic techniques, introduction of women-centred health programmes such as the Reproductive and Child Health (RCH) programme and cash incentives for family planning users were other factors that

contributed to the greater acceptance of sterilisation services by women (Pallikadavath et. al., 2016). The GoI's family planning programme began focussing mainly on female sterilisation. Consequently, the onus of sterilisation on men reduced and women, often poor women were forced for sterilisation by way of giving financial incentive, as well as social shaming for having "too many" children. Inadequate use of temporary methods of contraception and men's reluctance to undergo sterilisation made women the target of the country's population control programme. The myth that sterilisation would affect men's "masculinity" and the belief that contraception is women's responsibility, meant that despite the commitment to a target free approach, women's sterilisation in camps was common in most States to meet the annual "expected level of achievement".

GoI and various State governments have issued guidelines for different outreach camps/medical camps, such as the standards for female and male sterilisation services, 2006; quality assurance manual for sterilisation services, 2006; voluntary blood donation programme - an operational guideline, 2007; operational guidelines on FDS (Fixed Day Static) approach for sterilization services, 2008; guidelines for schemes for the participation of voluntary organisations in NPCB, 2009; guidelines for State health society and district health society under the NPCB, 2009; guidelines for organising intensive health camps and communication activities in out migration districts; operational guidelines for conducting outreach sessions in urban areas, 2015 etc. These guidelines cover aspects, such as services that may be provided, possible sites for the camp, human resource requirement, post-camp follow-up etc. The voluntary blood donation programme - an operational guideline, 2007, issued by the National AIDS Control Organisation (NACO), specifies the process of organising blood donation camps. Blood banks desirous of organising such camps need to obtain permission from the State Blood Transfusion Council (SBTC), to hold the camp and follow the outlined procedure for the pre-camp, camp and post-camp phases (NACO, 2007c).

There have been concerns about violation of autonomy, coercion to participate, incentives acting as "inducements", surgical complications, infection, lack of follow-up and medical support in medical camps, particularly in surgical camps (Dutta et al., 2020). Due to several incidents of post-surgery complications faced by patients who sought care at eye camps and sterilisation camps, surgeries in such camps are now prohibited and non-government organisations are required to seek prior permission from the district health authorities, before organising any medical camps (PTI, 2015; Sairam, 2013; Tribune News Service, 2014). In 2015, MoHFW, GoI directed that eye camps be used only for screening and surgeries are to be performed in fixed operation theatres (Rajiv, 2015). Similarly, the Supreme Court has directed the Union Government to stop mass sterilisations camps because of several deaths that have taken place in such camps across the country, over the years. Hence, the fixed-day static approach is adopted to provide sterilisation services in a health facility, by

trained providers posted in the same facility, on fixed days, throughout the year in a regular and routine manner. The Government of India's Family Planning Indemnity Scheme provides monetary compensation to victims in case of death due to sterilisation, failure of sterilisation or complication due to sterilisation. The implementation of the scheme is to be reported in the public domain (on the MoHFW's website), as per the SC orders (Family Planning Division, 2013; Supreme Court of India, 2016). However, in 2014, 11 women died in a 'sterilisation camp' organised by the State health department in Chhattisgarh, in which 83 women were sterilised by a single doctor in about six hours (Bhuyan, 2018).

There are also instances of medical camps being used as a business platform in an unethical manner by medical representatives of pharmaceutical companies, and the doctors with whom they organise such camps (Joelving, 2015). Though delivery of health care services through medical camps has been part of India's health care system for almost five decades, yet there are no legislations to regulate them. Registered health care practitioners, such as nurses, doctors of modern medicines or ISM & H, dentists and pharmacists, who may provide services in medical camps are regulated by their respective legislations. Nonetheless, it is imperative, that comprehensive regulations for providing health care services through medical camps are formulated.

Mobile Medical Health Services

Mobile medical health services, also known as mobile clinics or mobile health vans, or more commonly known in India as Mobile Medical Units (MMU), is an innovative health care model to deliver health care services that link community and clinical settings. MMUs are intermittent ambulatory services and outreach services that typically include a combination of preventive care, such as screening or health promotion, and curative services. MMUs can be trucks, buses, vans, jeeps, cars, boats and trains, for the transport of health care personnel, equipped with basic equipment and drugs. An MMU is a customised vehicle, with equipment, medical supplies, skilled human resources and diagnostic kits (National Health Mission, 2021b; World Health Organization, 2021b). MMUs have been developed as a response to reach populations living in remote, difficult areas, address humanitarian emergencies and populations cut off from mainstream services, because of geography and climatic conditions. They have helped to take health care to the doorstep of populations, particularly rural, vulnerable and under-served areas (Chanda et al., 2019). In urban areas, MMUs serve habitations of marginalised communities like ragpickers, homeless persons and migrants that live on the peripheries of cities and towns, or along railway tracks or under flyovers and bridges. In rural areas, MMUs provide services in areas with limited or a lack of access to health care services like tribal, hilly, desert, islands, riverine or

flood affected, snowbound, or conflict-affected areas. People living in these areas may have difficulty accessing basic services. Additionally, because of lack of infrastructure it may be difficult to establish fixed services in such areas and the staff like the doctors, nurses and ANMs, may find it difficult to live there (MoHFW, 2015b).

MMUs provide several services, like preventive and health promotion activities, such as (1)vaccinations, (2) screening for cancer, (3) diabetes, (4) hypertension, (5) dental conditions, (6) mental health services like counselling, and (7) treatment and referral for acute illnesses, such as acute respiratory infections, minor injuries, diarrhoea, malaria, maternal emergencies (Khanna & Narula, 2016). National Health Mission, MoHFW, GoI has issued 'Operational Guidelines for Mobile Medical Units, 2015' that outline the services to be provided under 12 thematic areas, duties of the medical and paramedical staff, and have proposed a list of medical equipment, drugs and consumables. An MMU is envisaged to provide (i) outreach services by ANMs in areas where no outreach services exist, (ii) a broader set of clinical services by a doctor and her/his team, with the ANM/ASHA playing a mobilisation role, and (iii) facilitate referral back-up to a functional primary health care system and specialist services as required. The guidelines enable the States to restructure implementation mechanisms for MMUs, to enable optimal utilisation of vehicles and staff through convergence, while ensuring that the outcome of the MMU contributes to the objectives of reaching the last mile and the unreached, with more than just basic OPD services and a limited range of RCH services (MoHFW, 2015b). Literature supports that this innovative model for health care delivery could help alleviate health disparities and strengthen the otherwise weak health systems. With the provision of basic primary health care services till the last mile, MMUs supplement and complement the existing public and private health sector in advancing the universal health coverage agenda. In India, MMUs are commonly operational under National Health Mission, the universal name "National Mobile Medical Unit" (National Health Mission, 2021b).

Legislations Governing MMUs

The CEA, 2010, defines mobile clinics as a facility specially fabricated on a vehicle providing examination, consultation, prescription to outpatients, including dispensing of medicines, basic laboratory services, vaccination facilities and procedures by a general practitioner/specialist/super-specialist doctor to those in remote/specified areas, who have access to little or no medical facilities. It identifies three main types of mobile clinics.

1. Mobile Clinic with Consultation and Dispensary: The operation of mobile clinics is to render primary health care services to those in remote/specified areas, who have access to little or

no medical facilities. The services offered may include one or more than one speciality of allopathy medicine, AYUSH, dental, physiotherapy, wellness, etc.

2. Mobile Clinic with procedures in local/regional anaesthesia: This is a facility providing general/basic examinations, consultations, prescriptions to outpatients by a general practitioner(s)/specialists/super-specialist doctor(s) in a mobile vehicle. They may provide preventive, diagnostic and curative services, in addition to those mentioned above. Preventive services include immunisation, antenatal and postnatal care; diagnostic services, such as minimum investigation facilities, for example, haemoglobin tests, urine examination for albumin, sugar and microscopic examination, diseases like leprosy, tuberculosis, and locally endemic diseases to be detected and referred, ECG & ultrasonography facilities; and curative services Ie treatment for minor ailments and geriatric cases etc., appropriate referral of cases for medical specialists etc. The services offered may include one or more than one speciality of allopathy medicine, AYUSH, dental, physiotherapy, wellness, etc. This may also deliver health care services of rehabilitative nature.
3. Mobile Dental Van: The van may be towed or self-propelled, ranging from smaller, one-chair to two-chair units that can be used for examination, preventive, and treatment services. Mobile units with more than one chair would be recommended for full treatment services.

The CEA, 2010 prescribes minimum standards for mobile clinics with regard to (1) infrastructure, (2) human resources, (3) equipment, (4) instruments, (5) drugs, (6) record maintenance, (7) reporting, (8) legal/statutory requirements, and (9) basic process. A general practitioner/specialist doctor/super-specialist doctor may be posted as per the scope of services, provided by the MMU. The services provided by the medical professionals at the MMU should align with their qualification, training and registration. A doctor is an allopathic doctor with minimum MBBS qualification registered with a State/Union medical council; a pharmacist should at least have a diploma in pharmacy; a staff nurse should be a qualified staff nurse with general nursing; a counsellor for HIV/AIDS counselling should be a nurse who has received training for counselling and laboratory techniques; a support staff; and the driver should have requisite licenses and registration.

The Drugs and Cosmetics Rules, 1945, mandate a license to distribute drugs from a motor vehicle. The licence is issued by the State licensing authority in Form 19-AA, and the application should be accompanied by a fee of Rs. 500. MMUs can collect, process and transfuse blood only in emergency situations, for which they are exempted from the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940, and Rules made thereunder to operate a blood bank. They instead need to fulfil certain

conditions laid down in Schedule K, pertaining to the screening of blood, adequate infrastructure and supervision of a qualified medical officer.

Telemedicine

Telemedicine refers to health care that is provided remotely, by means of telecommunications technology. Telemedicine uses various types of Information Communication Technology (ICT), to overcome geographical barriers and increase access to health care services. The WHO gives the following broad definition, *"…The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities…".*

The three distinct purposes of telemedicine are to:

- Provide clinical support;
- Overcome geographical barriers, connecting users who are not in the same physical location;
- Improve health outcomes.

The origins of telemedicine can be traced back to the second half of the 19th century, though the first published account of it is in the early 20th century when electrocardiograph (ECG) data were transmitted over telephone wires. The use of telemedicine in its modern form started in the 1960s and in the initial days, television was used for medical consultation (World Health Organization, 2010).

The scope and use of telemedicine have increased manifold over the last two decades, with the advent of more advanced technologies and greater access to mobile/smartphones and the internet (World Health Organization, 2010; Chellaiyan et al., 2019). While particularly useful to reach out to people living in remote areas with limited access to physical services, it is fast becoming popular among providers and patients because of its convenience. As the use of telemedicine grows, so do the concerns around confidentiality, consent, data privacy, professional conduct, the standard of treatment etc (Ateriya et al., 2018). Until recently, it was not clear whether practising telemedicine is legal in India. In 2019, the Karnataka Medical Council (KMC) advised doctors in the State not to provide online services otherwise they could face penal action, including cancellation of their registration (Yasmeen, 2019). Prior to that, in 2018, the Bombay High Court in the case of *Deepa Sanjeev Pawaskar and Anr.* v. *State of Maharashtra,* denied two gynaecologists anticipatory bail in the case of a patient

who they had advised treatment over the phone when she was admitted to their nursing home in their absence, and the patient died. The court considered it a case of criminal negligence, essentially because the treatment was prescribed without appropriate diagnosis and not because it was prescribed over the telephone (Bombay High Court, 2018). However, it was interpreted that telephone consultation would make the doctor liable for prosecution under Section 304 of the Indian Penal Code (IPC), for culpable homicide not amounting to murder (Pinto, 2019).

Since telemedicine is a combination of ICT and medical services, laws related to both ICT and the medical profession are applicable to it, in India. The laws related to ICT include the Information Technology (IT) Act, 2000, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, and the Information Technology (Intermediaries Guidelines) Rules, 2011.

The laws discussed in earlier chapters, such as the Indian Medical Council Act, 1956, National Medical Commission Act, 2019, Consumer Protection Act, 2019 and the Drugs and Cosmetics Act, 1940, are applicable in case of telemedicine consultation. Additionally, an amendment to the "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002", introduced specific guidelines for telemedicine called the "Telemedicine Practice Guidelines" that became effective from 25 March 2020. The guidelines have been incorporated under a new section, '3.8 Consultation by Telemedicine' that has been added to chapter 3 of the Regulations. Clause 3.8.1 reads *"Consultation through Telemedicine by the Registered Medical Practitioner under the Indian Medical Council Act, 1956 shall be permissible in accordance with the Telemedicine Practice Guidelines contained in Appendix 5 (of Code of Conduct)".* The notification of these guidelines provides a legal basis for the practice of telemedicine in the country (Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2020). The guidelines use the same definition of telemedicine as given above by the WHO.

Who Can Provide Telemedicine Services?

The newly notified Telemedicine Practice Guidelines, 2020, permit doctors enrolled in the Indian Medical Register under the IMC Act, 1956 (now NMC, 2019), or in the State Medical Register under the equivalent State Act to practice telemedicine, without the requirement of any separate registration. However, they would be required to complete a mandatory online course to be developed by the Board of Governors (BoG) in supersession of the Medical Council of India/NMC,

within 3 years of its notification. The doctors can charge fees for telemedicine consultation in the same way as for in-person consultation and need to provide receipt/s for the same to the patient. The guidelines are not applicable to the practitioners of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy. The guidelines specify that only a registered medical practitioner is entitled to counsel or prescribe and directly communicate with the patient. The technology platforms based on artificial intelligence/machine learning are not allowed to counsel the patients or prescribe any medicines. Such platforms could assist and support a doctor on patient evaluation, diagnosis or management, but the final consultation must be directly delivered by the doctor.

How Can Telemedicine Services Be Provided?

According to the guidelines, any communication channel that leverages IT platforms, via three primary modes - video, audio or text, may be used for telemedicine. Any medium such as telephone, mobile or landline phones, chat platforms like WhatsApp, Facebook Messenger etc., other mobile applications (apps) or internet-based digital platforms for telemedicine, or data transmission systems like skype/email/fax etc. may be used. The guidelines specify that the first consultation between the doctor and the patient need not be an in-person consultation, and the doctors in India can provide services to patients located in any State, through teleconsultation. However, they do not provide consultations outside the jurisdiction of India. Telemedicine consultation may be between a doctor and patient or caregiver or another doctor, or a health worker like a nurse, allied health professional, mid-level health provider, ANM or any other designated health worker, as the case may be. The setting for consultation between a doctor and a health worker on behalf of a patient may include health camps, home visits, mobile medical units or any community-based interaction. If the patient is a minor, teleconsultation can be held only if an adult is present with the patient and the doctor needs to ascertain the adult's identity.

When Can Telemedicine Services Be Provided?

The Telemedicine Practice Guidelines, 2020, allow the doctor to decide on a case-to-case basis whether a telemedicine consultation is appropriate in a given situation or an in-person consultation is needed, in the interest of the patient. If the doctor feels that the information provided by the patient is inadequate, then s/he can request for additional information, including laboratory or radiological tests. Depending on the case and professional judgment, the doctor can provide health education, and/or counselling related to the specific clinical condition and/or prescribe medicines as appropriate. If at any stage the doctor is of the opinion that the situation is not appropriate for further telemedicine consultation, then s/he should provide health advice/education as appropriate, and/or refer the

patient for an in-person consultation. In case of emergency, telemedicine services are to be avoided if alternative in-person care is available, and telemedicine consultation should be limited to first aid, life-saving measures, counselling and advice on referral. In all cases of emergency, the patient must be advised for in-person interaction with a doctor at the earliest. The guidelines do not permit the use of digital technology to conduct surgical or invasive procedure remotely. The guidelines also forbid the use of telemedicine for research and evaluation, and continuing education of health care workers.

The guidelines support and encourage the use of telemedicine for interaction between doctors or a specialist for a patient. Such consultations can be initiated by a doctor based on professional judgement, and the treating doctor is responsible for the treatment/consultation given to the patient. Interaction between doctors may include sharing of radiographic images (X-rays, CT, MRI, PET/CT, SPECT/CT, MG, Ultrasound), from one location to another, that is, teleradiology; transfer of image-rich pathology data between distant locations for the purposes of diagnosis, education and research, that is, telepathology; and access to eye specialists for patients in remote areas, ophthalmic disease screening, diagnosis and monitoring, that is, teleophthalmology.

Prescribing Medicines during Teleconsultation

The guidelines specifically state that prescribing medicines without an appropriate diagnosis/provisional diagnosis would amount to professional misconduct. They place certain limitations on prescribing medicines during teleconsultation, depending upon the nature of the disease/condition, type of consultation and mode of consultation such as for minor ailments or chronic diseases, video or telephonic consultations, first consultation or follow-up consultation. Medicines are divided into different lists accordingly. Medicines that have a high potential of abuse and could be harmful if not used according to medical advice, cannot be prescribed during a teleconsultation. These include medicines listed in Schedule X of Drugs and Cosmetics Act, 1940, and any narcotic and psychotropic substances listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985. Medicines for certain diseases which can be diagnosed only by video consultation, such as skin/eye infections can be prescribed only if the teleconsultation is via video. If the follow-up consultation is for the continuation of care for the same medical condition, the doctor can re-prescribe the original set of medications for a refill and ‘add-on’ medications, to optimise the underlying medical condition. Medicines for chronic diseases (such as asthma, diabetes or hypertension) can be re-prescribed during teleconsultation, on the basis of an earlier prescription obtained during an in-person consultation less than six months ago.

A prescription can be sent through any electronic medium such as email, WhatsApp etc., as a photo/scan/digital copy of a signed prescription or an e-prescription. The doctor is required to issue a prescription as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, and according to the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945. A sample format for prescription is suggested in the guidelines but is not mandatory to follow. The doctor has to provide a photo/scan/digital copy of a signed prescription or e-Prescription to the patient, via email or any messaging platform. The doctor requires the explicit consent of the patient to transfer the prescription directly to a pharmacy.

Protection of Patients and Consumers

According to the Telemedicine Practice Guidelines, 2020, the doctors using telemedicine are required to uphold the same professional and ethical norms and standards, as applicable to traditional in-person care, within the intrinsic limitations of telemedicine. Principles of medical ethics, including professional norms for protecting patient privacy and confidentiality as per the IMC Act, 1956, shall be binding, must be upheld, and practised. The fact that the teleconsultation took place over a mobile app or email or telephone, cannot be taken as a defence by a doctor against an allegation of medical negligence. Every doctor is expected to know the limitation of teleconsultation and advise or prescribe accordingly.

The guidelines require that the telemedicine consultation should not be anonymous, and both the patient and the doctor need to know each other's identity, with there being a mechanism for the patient to verify the credentials and contact details of the doctor. If the teleconsultation is the first consultation of the patient with the doctor, then the doctor has to confirm the patient's identity by asking the patient's name, age, address, email id, phone number or any other identification that may be reasonable. The same is not necessary in case of a follow-up consultation unless specifically required.

A patient's consent is necessary for any telemedicine consultation. The consent can be implied if the patient initiates the telemedicine consultation, as happens in the case of a physical consultation when a patient approaches a doctor. Explicit consent is needed if instead of the patient, a health worker, doctor or caregiver initiates the telemedicine consultation. Explicit consent must be part of the patient records and the patient can send it as an email, text or audio/video message, for example, "Yes, I consent to avail consultation via telemedicine" or any such communication in simple words. The guidelines permit the caregiver alone to consult on behalf of the patient if the age of the patient is 16 years or less, or if the patient is incapacitated (due to medical conditions like dementia or physical disability etc.). The caregiver will need to have a formal authorisation or a verified document

establishing his/her relationship with the patient, and/or should have been verified by the patient in a previous in-person consult (explicit consult).

The guidelines explicitly state that a doctor cannot violate a patient's privacy and confidentiality by adding them to an online group (such as a support group to disseminate health education for a particular condition), without their consent. They cannot disclose or transfer any information that may identify the patient without the prior written consent of the patient. The guidelines specify the requirement for doctors to abide by the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, and with the relevant provisions of the Information Technology Act, 2000, data protection and privacy laws, or any applicable rules notified from time to time for protecting patient privacy and confidentiality, and regarding the handling and transfer of such personal information regarding the patient. To that extent, the doctor may be liable to pay compensation for failure to protect 'sensitive personal data or information', under section 43A of the IT Act, 2000. Sections 65 to 74 of the IT Act, 2000 detail the cyber offences and the minimum punishment the offender is liable against, for example, data tampering in the computer source document, violation of privacy, etc. Section 72 of the IT Act, 2000, recognises the breach of confidentiality and privacy as an offence, although the scope and impact of the offence are limited (Information Technology Act, 2000).

The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, define 'sensitive personal data or information' as including inter alia physical, physiological and mental health condition, sexual orientation and medical records and history. The Rules of 2011 have mandated the consent of the information provider before disclosing sensitive personal data to a third party. The organisation providing telemedicine services as a body is liable for compensation for any negligence, in implementing and maintaining reasonable security practices and procedures while dealing with sensitive personal data or information.

One of the major limitations of the IT Act, 2000, and Rules for Data Protection is that most of the provisions only apply to 'sensitive personal data and information', collected through 'computer resource'. In the landmark case of Justice K S Puttaswamy (Retd.) & Anr. vs. Union of India and Ors., in 2018, the constitution bench of the Supreme Court held the Right to Privacy as a fundamental right, subject to certain reasonable restrictions. Following this, the draft Personal Data Protection Bill, 2019, was introduced by the Minister for Electronics and Information Technology in the Lok Sabha in December of 2019 and is currently under review. The Bill is expected to provide for the protection of personal data of individuals and proposes the Data Protection Authority for the same.

At the same time, the guidelines clarify that the doctor will not be held responsible for breach of confidentiality if there is reasonable evidence to believe that the patient's privacy and confidentiality have been compromised, by a technology breach or by a person other than the doctor. Doctors are not permitted to solicit patients for telemedicine through any advertisements or inducements.

Information Provision

The doctor needs to display the registration number accorded to him/her by the respective State Medical Council/MCI, in all communications exchanged with the patient such as on prescriptions, in electronic communication (WhatsApp/email etc.), on fee receipts, website etc.

A doctor is required to maintain the patient records, such as case history, phone logs, email records, chat/text record, video interaction logs, investigation reports, documents, images, diagnostics, digital/non-digital data, prescription records, as prescribed from time to time. In case of any violation of the guidelines, penalties as per the IMC Act, 1956/NMC Act, 2019, and other relevant laws would be applicable. Any patient who may be aggrieved by the doctor's conduct during teleconsultation can complain to the respective State Medical Council with whom the doctor is registered. The State Medical Council would have to take necessary action, as per the provisions of the IMC Act, 1956/NMC Act, 2019.

Electronic Health Records Standards 2016 notified by the MoHFW, GoI via a Circular dated 30 December 2016, lay down conditions when a patient's health information may be disclosed to an appropriate authority as mandated by law without the patient's prior authorisation for certain specified national priority activities, including notifiable/communicable diseases. The standards also state the privileges of the patients to ask for information from the practitioner, such as copies of their medical records, withhold the disclosure of their medical records to a third party and details of information shared about them with a third party. Also, the practitioner can refuse to disclose information to anyone, if s/he feels that the release of the information would endanger the life or safety of patients and others.

Grievance Redressal

Patients can complain against the practitioners in the respective professional council under the State Medical Council Act/IMC Act, 1956/NMC Act, 2019, or appropriate consumer forums, if there is a deficiency in services for which they have been charged, under the Consumer Protection Act, 2019.

Aggregators

The Telemedicine Practice Guidelines, 2020, lay the guidelines for the operation of technology platforms (mobile apps, websites etc.), which provide telemedicine services through a network of practitioners enrolled on their database. Such platforms (commonly known as aggregators) are required to conduct their due diligence and ensure that the practitioners they enrol are duly registered with the national medical council or respective State medical council and comply with the relevant statutory provisions. The platforms need to provide the name, qualification, registration number and contact details of all the listed doctors. In case of any non-compliance, the technology platform is required to report the same to the Board of Governors, (in supersession to the MCI) who may take appropriate action. The aggregator platforms need to ensure that there is a proper mechanism in place to address any queries or grievances that the end customer may have. In case any specific technology platform is found in violation, the Board of Governors (in supersession to the MCI) may blacklist it and no doctor may then use that platform to provide telemedicine services.

As a due diligence measure to be taken by intermediarie[4], the Information Technology (Intermediaries Guidelines) Rules, 2011, promulgated under the Information Act, 2000, require the intermediary to publish the rules and regulations, privacy policy and user agreement, for access or usage of the intermediary's computer resource by any person. The intermediary shall inform its users that in case of non-compliance with rules and regulations, user agreement and privacy policy for access or usage of intermediary computer resource, the intermediary has the right to immediately terminate the access or usage rights of the users to the computer resource of intermediary and remove non-compliant information. The intermediary is also required to publish on its website the name and contact details of a grievance officer, as well as a mechanism for filing a complaint. The grievance officer is required to redress the complaints within one month from the date of receipt of the complaint.

In January 2021, the MoHFW, GoI directed all the States and UTs to take action against online health service aggregators, who may be operating in violation of the law. The directive followed a Delhi High Court Order in the case of Dr Rohit Jain vs Govt of NCT of Delhi and Ors in August 2020, wherein the Court directed the concerned respondent authorities to initiate action, in accordance with the law, including the CEA, 2010, if applicable, against any illegal online health service aggregators operating

[4] As per the definition under the IT Act, 2000, section 2, (w) "intermediary", with respect to any particular electronic records, means any person who on behalf of another person receives, stores or transmits that record or provides any service with respect to that record and includes telecoms service providers, network service providers, internet service providers, web-hosting service providers, search engines, online payment sites, online-auction sites, online-market places and cyber cafes. In this context the aggregators providing health care services would fall under the above definition.

in Delhi in violation of any Rules, Regulations or Government Policies, applicable to the facts of the case. The prayer in the said case was to seek a ban on the collection of diagnostic samples by online health service aggregators for testing of COVID-19 infection, as they are not registered under the CEA, 2010, or any other regulation and have no medico-legal liability. The petition sought direction to issue guidelines for registration and minimum standards to be followed for sample collection by online aggregators (High Court of Delhi, 2020; Garima, 2021).

In conclusion, the combination of technology and medicine that telemedicine brings together has several advantages, such as it saves the patient's cost, time and effort of travelling to meet a doctor, and is quick and convenient for both the patient and the doctor. The advantages of telemedicine were particularly evident during the COVID-19 pandemic. The travel restrictions and risk of in-person consultation led to several people consulting doctors remotely, for both COVID and non-COVID related health care needs. At the same time, telemedicine has its limitations due to restricted access to technology, the impersonal nature of interaction and the potential for misuse and abuse. Therefore, the Telemedicine Practice Guidelines, 2020, are very timely to regulate this mode of health care delivery. As telemedicine is an evolving discipline, there is a need to review guidelines periodically using the learnings, to ensure that they respond appropriately to situations as they emerge.

SUPPORTIVE SERVICES

LABORATORIES AND DIAGNOSTICS

Laboratory and diagnostic services play a key role in the provision of quality health care, as they contribute significantly to medical decision making (Jain & Rao, 2016). Diverse types of laboratories are present in India, both in the public and private sectors. They may be 'hospital-attached' laboratories or 'stand-alone' laboratories. Stand-alone laboratories account for 45-50 per cent of the market, organised laboratories that are part of larger diagnostic chains have a 25-30 per cent share, and hospital-based diagnostic centres account for the rest (Trivedi, 2017). The Clinical Establishments (Registration and Regulation) Act (CEA), 2010, defines laboratories and diagnostic centres as clinical establishments that may be independent or part of another establishment like a hospital, nursing home, clinic, etc. where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic services with the aid of laboratory or other medical equipment, are usually carried out. These may provide simple to critical diagnostic procedures, such as radiological investigation supervised by a radiologist and clinical laboratory services by laboratory specialist, usually performed through referrals from doctors and other health care facilities.

The diagnostic centres may be equipped to perform tests from one or more of the following departments such as (1) haematology, (2) serology, (3) biochemistry, (4) clinical pathology, (5) microbiology, (6) radiology, (7) cardiology, etc. Haematology diagnostic centres typically analyse whole blood specimens to perform complete blood picture, complete blood count and examine blood films, etc. Haematological tests can help diagnose anaemia, infection, haemophilia, blood-clotting disorders and leukaemia (Johns Hopkins Medicine, 2021). Serological Assays are used for screening of blood products for the risk of certain chronic infections, evaluation of the immune status, and need for prophylactic treatments in connection with organ transplantations. Immunoassays are the most commonly conducted serology tests for the diagnosis of infectious diseases like HIV, syphilis, TB and viral hepatitis (Steingart et al., 2012). Clinical microbiology focuses on aspects of patient infections, from testing samples to identifying bacterial, viral, fungal and parasitic agents, to determining the susceptibility of microorganisms, to various antimicrobial agents. Microbiology includes culturing of clinical specimens, including faeces, urine, blood, sputum, cerebrospinal fluid and synovial fluid, as well as possible infected tissue (ScienceDirect, 2021). Virology laboratories are concerned with the identification of viruses in specimens, such as blood, urine and cerebrospinal fluid. Clinical biochemistry involves performing different tests on serum or plasma, to provide quantitative testing for substances, such as lipids, blood sugar, enzymes and hormones. Urinalysis is also commonly

performed to detect a wide range of disorders, like urinary tract infections, kidney disease and diabetes (National Health Mission, 2021a).

Imaging centres or radiology laboratories detect abnormalities and anomalies, through imaging and scanning tests. X-rays are the most common form of radiological testing, which help doctors to examine the internal organs of patients. They are used widely by dentists, cardiologists, orthopaedic specialists, etc. Magnetic Resonance Imaging (MRI) scans are used for detecting tumours or cancers in the brain, injuries of brain or ligaments, multiple sclerosis, etc. Ultrasound, also known as sonography, is used for examination of the internal organs, by producing pictures of the concerned internal organs. Computed Tomography or CT scan is another common type of imaging technology for generating 3D pictures of blood vessels, vein bones, soft tissues, etc.

CEA, 2010, classifies diagnostic centres as (i) Clinical/Medical Diagnostic Laboratory - a laboratory where microbiological, serological, chemical, haematological, immune-haematological, immunological, toxicological, cytogenetic, exfoliative cytogenetic, histological, pathological or other examinations are performed on materials/fluids derived from the human body, for the purpose of providing information on diagnosis, prognosis, prevention or treatment of disease (ii) When medical diagnostic laboratories are attached to hospitals to provide services to the patients of the hospital, they are known as 'Hospital Laboratories' (iii) A medical laboratory called the 'Private (or community) Laboratory', is a stand-alone laboratory that may receive referrals from general practitioners, insurance companies, clinical research sites and other health clinics. These can also be called reference laboratories where more unusual and obscure tests are performed. (iv) 'Diagnostic Imaging Centres' could be general and/or advanced that provide radiology (general/interventional), electromagnetic imaging or Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) Scan and ultrasound services. Laboratories and imaging centres may have stand-alone collection centres that function under the respective registered clinical establishments.

Registration and Licensing

Only in 2010, the laboratories and diagnostic centres were regulated under the Clinical Establishment Act, 2010. The Act covers all types of laboratories and diagnostic centres, irrespective of location, ownership, and systems of medicine, type, size, and services offered. As of March 2021, CEA, 2010, is applicable in 11 States and 6 UTs in the country. Other than the CEA, 2010 (where applicable), laboratories have to comply with the Bio-Medical Waste Management Rules, 2016 and Atomic Energy

(Radiation Protection) Rules, 2004, that pertain to safe handling of radiation generating equipment including X-ray and other diagnostic radiological equipment.

All types of laboratories and diagnostic centres need to be registered with the district registering authority in States/UTs where CEA, 2010 is applicable. The registration is to be renewed every five years. The penalty for operating laboratories and diagnostic centres without registration can be up to Rs. 50,000 for the first offence, Rs. 200,000 for the second contravention and may extend to Rs. 500,000 for any subsequent contravention. Clinical Establishments (Central Government) Rules, 2012, specify conditions that the clinical establishments need to meet to continue their registration under the Act. These include display of rates/fees for the various services/tests available, which are to be fixed within the range determined by the Union/State Governments, maintain and provide electronic health/medical records of patients, and information and statistics as required by other laws applicable at the time.

In the 11th meeting of the National Council for Clinical Establishments held in 2018, it was decided that the collection centres shall be part of the main laboratories, and responsibility and accountability in respect of compliance of minimum standards by collection centres shall be of the parent laboratory. Hence, collection centres are not to be registered separately but as a part of the main laboratory.

Quality and Standards

Clinical Establishments (Central Government) Amendment Rules, 2018, list the minimum standards for medical diagnostic laboratories (or pathological laboratories) registered under the CEA, 2010. These Rules prescribe that every clinical establishment relating to diagnosis or treatment of diseases, where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services, are carried on with the aid of a laboratory or other medical equipment, is required to comply with the minimum standards of facilities and services as specified in the Schedule. The scope of services and minimum standards for medical diagnostic laboratories (or pathological laboratories) are prescribed separately for basic, medium and advanced category of laboratories. Minimum standards are prescribed for infrastructure, space requirement, furniture and basic signage within or outside the facility, to display information. The information to be displayed includes the name of the person-in-charge, qualification, registration number, services provided (like haematology, biochemistry, clinical pathology, histology, cytology, molecular genetics, etc.), timings and fee structure by type of investigation, including special and routine tests (Clinical Establishments (Central Government) Amendment Rules, 2018).

Clinical Establishments (Central Government) Amendment Rules, 2018, provide human resource requirement (both essential and desirable) for basic, medium and advanced type of medical diagnostic laboratories (or pathological laboratories), and their minimum qualifications. The Rules prescribe that the authorised signatory would be liable for the authenticity of the laboratory test reports. Clinical Establishments (Central Government) Amendment Rules, 2020, provide detailed human resource specifications for the basic composite, medium and advanced types of diagnostic laboratories. The Rules, 2020, provide guidance on the signing authority and clinical interpretation of laboratory reports. The Rules, 2020, state that persons with M.Sc./Ph.D. in (1) Pathology (2) Medical Microbiology (3) Medical Biochemistry (4) Medical Genetics (5) Biotechnology (6) Immunology (7) Molecular Biology (8) Applied Biology may sign the test reports generated by them, with a mandatory disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such. Any interpretation of laboratory results or opinion thereon must be co-signed by a medical doctor registered with the Medical Council, and the co-signee medical doctor shall be responsible only for the opinion or interpretation given.

The Clinical Establishments (Central Government) Amendment Rules, 2020, mention that medical tests should be undertaken on the advice of a registered medical practitioner. The Rules, 2020, prescribe that a qualified laboratory technician (Diploma or Bachelor of Science in Medical Laboratory Technology or Master of Science in Biochemistry or Microbiology from a recognised university), working in a medical diagnostic laboratory registered under a Union or State Clinical Establishments Registration Act, as applicable, and a health care worker in a Government National Health Programme trained for conducting identified specific tests, may conduct the tests and generate test results which shall be submitted to the authorised signatory, as applicable (Clinical Establishments (Central Government) Amendment Rules, 2020).

Clinical Establishments (Central Government) Amendment Rules, 2018, provide the list of minimum medical diagnostics laboratory equipment/instruments with quantity, reagents/consumables and sterilisation/autoclave, and policy of annual maintenance contract or comprehensive maintenance contract and records for equipment. The Rules, 2018, also specify standards for basic processes like infection control, quality control, patient education, SOPs, etc.

Under the Drugs and Cosmetics Act, 1940, the diagnostic kits and reagents used by laboratories are defined as 'drugs', and therefore they have to be approved by the Central Drugs Standard Control Organisation (CDSCO). Medical devices are also regulated as drugs under the DCA, 1940. Schedule M

III of the DCR, 1945, pertains to quality management system for notified medical devices and in-vitro diagnostics. The provisions of Schedule M are applicable to manufacturers of finished devices, in-vitro diagnostics, mechanical contraceptives (condoms, intrauterine devices and tubal rings), surgical dressings, surgical bandages, surgical staplers, surgical sutures and ligatures, blood and blood components collection bags, with or without anticoagulants intended for human or animal use. Until 2005, only four categories of medical devices were notified as drugs-disposable hypodermic syringes, disposable hypodermic needles, disposable perfusion sets and in-vitro diagnostic devices for HIV, Hepatitis B and Hepatitis C. In 2005, 10 categories of medical devices, such as (1) cardiac stents, (2) catheters, (3) intra ocular lenses, (4) orthopaedic implants, (5) heart valves, (6) internal prosthetic replacements etc. were defined as 'drugs' and brought under the purview of the DCA, 1940. For the regulation of import, manufacture, clinical investigation, sale and distribution of medical devices, the MoHFW, GoI notified the Medical Devices Rules, 2017, that came into effect from 1 January 2018. The Medical Devices Rules, 2017, classify the medical devices and in vitro diagnostic medical devices into four categories based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule. The regulatory procedure for medical devices varies according to their categorisation, with higher-risk devices having more regulations and a more stringent conformity assessment process (Medical Devices Rules, 2017). The Medical Devices (Amendment) Rules, 2020, increased the notified categories of devices to 37 and require all device makers to conform to International Organization for Standardization (ISO) 13485 standards, to ensure that quality standards are maintained, and no faulty devices are sold in the market. The MoHFW via another gazette notification issued in February 2020, brought under regulation virtually every kind of medical device, including an instrument, apparatus, appliance, implant, material or other article, whether notified or not, by classifying them as drugs under the DCA, 1940.

The violation of the Medical Devices Rules, 2017 can lead to the initiation of criminal prosecution under the DCA, 1940, which can lead to imprisonment or fine or both. For example, the manufacture or sale of substandard devices is punishable with imprisonment of 10 years, which may extend to life imprisonment.

In accordance with the Atomic Energy Act, 1962, the Union Government promulgated the Atomic Energy (Radiation Protection) Rules, 2004, the Atomic Energy (Working of the Mines Minerals and Handling of the Prescribed Substances) Rules, 1984, the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987, the Atomic Energy (Factories) Rules, 1996 and the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012, for control of and for ensuring safety in activities

relating to the use of atomic energy. The Atomic Energy Regulatory Board (AERB) has been established to perform the regulatory and safety functions envisaged in the Act.

National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the Quality Council of India (QCI), that offers a voluntary accreditation system for laboratories. The NABL accreditation is a formal recognition of the technical competence of a laboratory, based on third party assessment in accordance with international guidelines. Of the estimated 100,000 to 110,000 laboratories in India, around 4,000 have been accredited by NABL (Services: Quality Accreditations, NABL, 2021). However, since the accreditation by NABL is quite expensive, small and medium size companies cannot afford it. Basic quality standards as laid down in the CEA, 2010, may therefore be a more inclusive benchmark for the entry of diagnostic services (Trivedi, 2017).

Protection of Patients and Consumers

As per section 33 of the CEA, 2010, the district registering authority, or an officer authorised by the CEA, 2010, can carry out an inspection as and when required and may restrain a laboratory/diagnostic centre from carrying on its services, if the inspection of the establishment reveals imminent danger to the health and safety of patients. Any violation of the provisions of the CEA, 2010, may lead to a monetary penalty being levied upon the concerned party.

Clinical Establishments (Central Government) Amendment Rules, 2018, prescribe the display of safety signage and caution, and segregation of bio medical waste as per Biomedical Waste Management Rules, 2016 including radioactive materials, toxic chemicals, microbial agents and infected biological material. The medical diagnostic laboratories (or pathological laboratories) have to be registered under the provisions of Biomedical Waste Management Rules, 2016, with the respective State or Union Territories' Pollution Control Board. The Clinical Establishments (Central Government) Amendment Rules, 2018 prescribe that it is essential for all types of laboratories to have grievance registration and disposal mechanism.

The Consumer Protection Act, 2019, is meant to protect the interests of consumers, and to establish authorities for timely and effective administration and settlement of consumers' disputes. The Act is applicable to health services in case negligence or deliberate withholding of relevant information by the provider causes loss or injury to the consumer. Central Consumer Protection Council, State Consumer Protection Councils and District Consumer Protection Councils are to be established to offer

advice on promotion and protection of consumer rights under the Act. National, State and district consumer disputes redressal commissions are to be formed to entertain the consumers' complaints.

Information Provision

Medical Diagnostic Laboratories (or Pathological Laboratories) need to maintain date wise and speciality wise reports and medico-legal records and other information of all patients, as per the provisions of Clinical Establishments (Central Government) Amendment Rules, 2018. Every clinical establishment is required to furnish such returns, statistics and other information to the district authority/State council/national council, as may be prescribed by them from time to time.

To prevent the spread of the COVID-19 in India, GoI invoked the Epidemic Diseases Act, 1897, making it mandatory for all the diagnostic and laboratory facilities to share information with the administration on all the positive COVID-19 cases to prevent the spread of the disease. In case laboratories fail to comply with the timely provision of such information, an FIR can be filed under the Epidemic Diseases Act, 1897 and IPC sections 269/270 for alleged actions, leading to the spread of the disease (Bhatnagar, 2020; Perappadan, 2020). The Delhi Government issued Regulations directing all hospitals to set up special flu corners to screen and test patients with suspected coronavirus, send information of suspected/confirmed positive cases to the district health authorities, prohibit private laboratories from carrying out tests for coronavirus in the initial period of the pandemic, restrict information dissemination without prior permission of the Department of Health and Family Welfare, Government of National Capital Territory of Delhi, to prevent the spread of rumours and misinformation (Delhi Epidemic Diseases, COVID-19 Regulations, 2020; Wire Staff, 2020).

Gaps and Challenges

Until the CEA, 2010 was enacted, the laboratory services were not regulated. Many of the State legislations do not include laboratories within their ambit and hence have no mandatory minimum standards, in terms of quality, technology, infrastructure and qualification of personnel for setting up and operating them. This has led to the proliferation of several small laboratories with varying standards and practices. Issues of non-standardisation of service quality and supplier-induced demands are prevalent in the diagnostic industry (Competition Commission of India, 2018). The industry has been functioning under market-led and self-imposed norms. Practices such as hiring unqualified professionals, using sub-standard equipment and proxy digital signatures are common in the absence of effective regulation (Express News Service, 2018; EH News Bureau, 2019).

During the COVID-19 pandemic, the GoI deviated from the usual course of minimal intervention in regulating private laboratories to regulating every aspect of SARS-CoV-2 testing, through the Indian Council of Medical Research (ICMR). Though diagnostic kits for SARS-CoV-2 are considered "drugs" under the DCA, 1940 and should be approved by the CDSCO, they also required validation by the ICMR during the pandemic. The guidelines and regulations issued by the ICMR and the manner in which they were implemented under the Epidemics Diseases Act, 1897 and the Disaster Management Act, 2005, gave rise to concerns about restricting the country's testing capacity, cost of tests and data sharing (Kaur et al., 2020).

The authority for signing of laboratory reports has been a contentious issue with concerns, such as whether laboratory test reports should be treated as medical certificates, and therefore follow the provisions of the Indian Medical Council Act, 1956, wherein only medical practitioners registered with MCI or State Medical Council are authorised to sign the medical certificates. There have been judicial interventions too in the matter (Express News Service, 2018). The Clinical Establishments (Central Government) Amendment Rules, 2020, were amended so that persons with M.Sc./Ph.D. in Pathology/ Medical Microbiology/Medical Biochemistry/Medical Genetics/Biotechnology/Immunology/ Molecular Biology/Applied Biology can sign the test reports generated by them, with a mandatory disclaimer to the effect that the reports are for the use of medical practitioners and are not medical diagnosis as such. However, the matter is back in the courts as a pathologist filed a petition in the Delhi High Court seeking the abrogation of these Rules. The plea in the Court is that allowing nonmedical persons, that is, M.Sc./Ph.D. holders to sign medical diagnostic reports is illegal and ultra vires of the CEA, 2010. It is argued that the notification was issued without following the due process of law, as prescribed under the CEA, 2010. Under Section 7 of the Act, the National Council for Clinical Establishments needs to meet and take decisions regarding the determination of minimum standards for clinical establishments, whereas no such meeting of the National Council was held (Pharma Biz Bureau, 2020). The issue, therefore, remains unresolved.

PHARMACIES

A pharmacy is an establishment that acts as a delivery point for pharmacy services. It can be defined as a store or shop or place where drugs and medicines are dispensed, compounded or prepared. During the 700 AD century, the appearance of apothecaries marked the beginning of the earliest known pharmacies. In most European countries, apothecaries developed from the traders who traded in spices, which included crude drugs and prepared medicines. The apothecaries became a distinct occupational group in the thirteenth century. The modern history of British pharmacy began with the foundation of the Pharmaceutical Society of Great Britain in 1841. The developments in Britain influenced the growth of pharmacy in India. Scotch M Bathgate, who established a chemist shop, was the first person to start the practice of pharmacy as a profession in 1811 in Calcutta (now Kolkata). During the late 1950s, pharmaceutical industrialisation occurred leading to the split of clinical and industrial pharmacies. Pharmacies became retail outlets of pharmaceutical industries. Hospital pharmacies led to the onset of different forms of clinical pharmacy such as ambulatory care pharmacy, oncology pharmacy, community pharmacy and internet pharmacy. It also changed the role of the pharmacists (Debnath, 2017; Khakurel et. al., 2019; Pharmapproach, 2020).

Medicines can be dispensed through different types of establishments, based on the function and role of pharmacists and pharmacies. Hospital pharmacies dispense drugs and advise patients about the medicines which have been prescribed. The inpatient hospital pharmacies work with other medical professionals such as doctors, nurses, to ensure accurate dispensing of medications for the inpatients admitted in hospitals. The outpatient hospital pharmacies dispense and advise patients on the medications prescribed by the doctors. Clinical pharmacies are set up in a clinic or any health care setting. Community pharmacies are traditionally called pharmacists or chemist shops. They provide advice and information along with supplying prescription medicines to the patients. Industrial pharmacies include the pharmaceutical industry, which involves research, production, packaging, quality control, marketing, and sales of pharmaceutical goods. E-Pharmacies are defined as an online market for the sale of pharmaceutical drugs through the internet (Pharmacy Practice Regulations, 2015; Smith, 2019).

The Drugs and Cosmetics Rules (DCR), 1945 of India define pharmacy, as *"…to include every store or shop or other places where drugs are dispensed, measured or weighed or made up and supplied; or where prescriptions are compounded; or where drugs are prepared; or which has upon it or displayed*

within it, or affixed to or used in connection with it, a sign bearing the word or words —Pharmacy, Pharmacist, Dispensing Chemist or Pharmaceutical Chemist; or which, by sign, symbol or indication gives the impression that the above mentioned activities are carried out within the premises..." Retail pharmacies are the most common and visible pharmacies in India. The Drugs and Cosmetics Rules, 1945, define retail sale as *"…a sale whether to a hospital, or dispensary, or a medical, educational or research institute or to any other person other than a sale by way of wholesale dealing."* The retail pharmacy market has been growing at an average of 18 percent per annum over the last few years. Approximately 90 million unorganised retail pharmacies are present in India today (Ravichandran, 2019).

The DCR, 1945 provides a distinction between pharmacy and retail store like chemist and druggist, where the former maintains a pharmacy for dispensing drugs along with compounding against prescriptions, and the latter only dispenses drugs on prescription. Both require a registered pharmacist for operation. However, in practice, it is difficult to distinguish between the two because the compounding of drugs is no longer practised in India. Rule 65 section 15 of DCR, 1945, mentions various kinds of retail stores which dispense medicines in India: (1) 'Drugstore' displayed by such licencee's who do not require the services of a registered pharmacist. (2) 'Chemists and Druggists' displayed by such licencees who employ the services of a registered pharmacist, but do not maintain a pharmacy for compounding against prescriptions. (3) 'Pharmacy', 'Pharmacist', 'Dispensing Chemist' or 'Pharmaceutical Chemist' displayed by such licencees who employ the services of a registered pharmacist and maintain a pharmacy for compounding against prescriptions. In 2019, the Government of India decided to call medical shops selling medicines as 'pharmacy', in line with international pharmacy practice and discontinue the terminology of 'Chemists and Druggists'. However, the proposed amendment to the Drugs and Cosmetics Rule, 1945, is yet to be introduced by the GoI (Perappadan, 2019).

Legislations Governing Pharmacies

The Drugs and Cosmetics Act, 1940, enacted by the Union Government regulates the import, manufacture, distribution, and sale of drugs and cosmetics through licencing. The Act mandates the sale of drugs through a qualified person. It monitors the quality, safety and efficacy of drugs or cosmetics sold in the market. The Central Drug Standards Control Organisation (CDSCO) is India's main regulatory body for pharmaceuticals, entrusted with responsibilities by the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. The Drug Controller General of India (DCGI), who is also

the Central Licence Approving Authority is the key official within the CDSCO. Matters of quality of drugs, the introduction of new drugs and import licence for new drugs are managed by the DCGI (MoHFW, 2020). Under the DCA, 1940, the Union Government constituted the Drugs Technical Advisory Board (DTAB), to advise the Union and State Governments on technical matters related to the administration of the DCA, 1940 and to conduct other functions assigned to it by the Act.

In the States, the Food and Drug Administration or State Drugs Controller of each State is the key responsible agency. The State Licencing Authority appointed by the State government is the competent authority for enforcement of DCA 1940 and Rules made thereunder. The State Licencing Authority is responsible for issuing licences for the sale of drugs (retail or wholesale or restricted sale of drugs), regular inspection of pharmacies as per the DCA, 1940 and Rules framed thereunder, grievance redressal in case of a complaint against pharmacies. They are also responsible to take legal actions in the event of suspicion of supply of substandard or adulterated or spurious drugs through pharmacies.

The Pharmacy Act, 1948, is another legislation that governs the role of pharmacists functioning in the pharmacy. The Pharmacy Council of India (PCI) is a statutory body governed by the provisions of the Pharmacy Act, 1948. PCI is responsible to regulate the professional conduct of pharmacists and sets minimum requirements to register as a pharmacist in India (Pharmacy Council of India, 2018a). Other Union government level legislations, such as the Narcotic Drugs and Psychotropic Substances Act, 1985; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; Consumer Protection Act, 2019; and the Information Technology Act, 2000 and the Rules thereunder, govern the activities related to the sale of drugs.

Registration and Licensing

Part VI of DCR, 1945, provides guidelines for who, how, and where can one obtain a new licence from the State government to sell, stock, exhibit or offer for sale or distribute drugs, other than homoeopathic medicines. The State government appoints the licencing authority, which issues two types of drug sale licence, that is, wholesale and retail sale of drugs within the State jurisdiction. Different licences are issued for different schedules of drugs, like in form 20, 20A, 21, 21 A, etc. for the sale of allopathic drugs by retail or for a restricted licence. A restricted licence is issued to dealers who sell, stock or exhibit or offer for sale, or distribute drugs by retail without using the services of a qualified person.

At present, there is no separate provision in the Drugs & Cosmetics Act, 1940 and Drug and Cosmetic Rules, 1945 that describe or regulate the functioning of E-pharmacy in India. Rule 65 mandates the signing and stamping of the prescription, along with dispensing of medicines by the pharmacist. Currently, the regulatory mechanism governing the offline retail pharmacy business is also applied to E-pharmacies, but in a limited manner. The lack of clarity to regulate, control and monitor the sale of drugs through the online platform has led to conflicts between conventional retailers and online pharmacy associations (Shankar, 2020). Ministry of Health and Family Welfare proposed an amendment to the DCR, 1945 in August 2018, to regulate E-pharmacy, Drugs and Cosmetics (Amendment) Rules, 2018. The draft rules of 2018 define "E-pharmacy" as a business of distribution or sale, stock, exhibit or offer for sale of drugs, through the web portal or any other electronic mode. Part VIB, that is, the sale of drugs by E-pharmacy prescribes provisions to regulate E-pharmacies. However, the draft rules, are yet to be notified (Draft Drugs and Cosmetics (Amendment) Rules, 2018).

Renewal of Registration/Licences

The State licencing authority is responsible to renew the licence for sale, stock, or distribution of drugs. The Drugs and Cosmetics (Tenth Amendment) Rules, 2017, introduced that the drugs sale licences once issued shall be renewed, if the licencee deposits licence retention fee every five years, before the expiry, unless the licences are suspended or cancelled by the licencing authority. In case of non-payment for more than 6 months after the expiry of the licence, the drugs sale licences would be cancelled. Drugs and Cosmetics (Eleventh Amendment) Rules, 2019, are introduced to promote permanency of drugs licences and ease of continuation of business (Drugs and Cosmetics (Tenth Amendment) Rules, 2017; Drugs and Cosmetics (Eleventh Amendment) Rules, 2019).

Quantity

The Drugs and Cosmetics Rules, 1945 prescribe under Rule 64 that the licencing authority empowered to issue drugs sale licence should consider the average number of licences granted or renewed, during the three years immediately preceding; and to the occupation, trade or business ordinarily carried on by such applicants during the period aforesaid.

In case of issuing a retail drug licence to sell, stock or exhibit for sale or distribute drugs specified in Schedule X under Form 20F, the licence should be granted or renewed only to a pharmacy and in areas where a pharmacy is not operating, such licence may be granted or renewed to a chemist and druggist. As such, DCA 1940 and DCR 1945 does not control or restrict the number of pharmacies, or their distribution on a geography or population basis.

Quality

Schedule N under the Drugs and Cosmetics Rules, 1945, describes the list of minimum equipment for the efficient running of a pharmacy business. The entrance of a pharmacy should bear the inscription "Pharmacy". The area of the pharmacy to be used for dispensing should not be less than six square meters for one pharmacist working with additional two square meters for each additional pharmacist. The dispensing department should be separated by a barrier to prevent the admission of the public. A pharmacy should have a dispensing bench covered with washable material like stainless steel, laminated or plastic, etc. Its premises should be well built, ventilated and lit, with sufficient dimensions for the storage of drug stocks. The floor should be smooth and washable; walls should be well plastered or painted without holes, cracks and crevices. Drugs, chemicals and medicaments should be kept in a room appropriate to their properties and stored meticulously, to prevent any deterioration of the contents. Every container should have an appropriate label, easily readable with names of medicaments as given in the Pharmacopoeias. Substances stated in Schedule X should be stored under lock and key in a cupboard and separated from the dispensing section with limited access.

Standard Dispensing Guidelines

Substances specified in Schedule H or H1 or X shall not be sold by retail, except on and in accordance with the prescription of a registered medical practitioner. The pharmacies should maintain a separate register for the sale of substance under Schedule H or H1 or X, with details of the drug, patient and prescribing RMP. In the case of substances specified in Schedule X, the prescriptions should be in duplicate, one copy of which should be retained by the licencee for two years. The supply of drugs specified in Schedule H or H1 or Schedule X to RMPs, Hospitals, Dispensaries and Nursing Homes should be made only against the signed order in writing, and it should be preserved by the licencee for two years. DCR, 1945 prohibits the advertisement of the drugs specified in Schedule H or H1 or X; and if required, the advertisement should be made only with the previous sanction of the Union Government (Schedule H: Drugs and Cosmetics Rules, 1945; Schedule H1: Drugs and Cosmetics Rules, 1945).

Schedule H includes a class of prescription drugs (551 drugs) listed under broad line items like antibiotics, analgesics, antipsychotics, narcotic drugs, etc. Schedule H1 includes potent antibiotics, anti-TB and habit-forming drugs that induce sleep, while Schedule X comprises habit-forming and narcotics drugs which have the potential of being abused. If a product contains a substance specified in Schedule H and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act,

1985, it should be labelled with the symbol "NRx" with a red colour base: *'Schedule H drug- Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only'* and conspicuously displayed on the left top corner of the label. If a product contains a Schedule H drug, it should be labelled with the symbol "Rx", displayed on the left top corner of the label and be also labelled with a warning in red colour base. Similarly, for products containing Schedule H1 substances labelling pattern will remain the same and the warning must contain: *'Schedule H1 Drug – Warning: It is dangerous to take this preparation except in accordance with the Medical Advice. Not to be Sold by retail without the prescription of a Registered Medical Practitioner'* (Tandon et al., 2017).

Section 5 of Schedule K exempts the drugs supplied by an RMP to the patients, or any drug specified in Schedule C supplied by an RMP at the request of another such practitioner, if it is specially prepared with reference to the condition and for the use of an individual patient, provided that he is not (a) keeping an open shop or (b) selling across the counter or (c) engaged in the importation, manufacture, distribution or sale of drugs.

Chapter 3, 'Prohibition, Control and Regulation' of the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985, details the power of the Union and the State Governments to permit, control and regulate the misuse of narcotic drugs listed under the Act. The NDPS Act, 1985, lists 200 psychotropic substances which cannot be sold without a prescription (Narcotic Drugs and Psychotropic Substances Act, 1985; Sharma et al., 2017). Section 52F of the Narcotic Drugs and Psychotropic Substances Rules, 1985 conferred under the NDPS Act 1985, permits the sale of essential narcotic drugs by a licenced chemist only with prescription subject to the provisions of the Drug and Cosmetics Rules, 1945 (Narcotic Drugs and Psychotropic Substances Rules, 1985). Certain restrictions under draft DCR, 2018, prohibit the E-pharmacy registration holder from dealing with respect to the drugs covered under the categories of the narcotic and psychotropic as referred to in the NDPS Act, 1985, tranquillizers and the drugs as specified in the Schedule X of Drugs and Cosmetics Rules 1945.

Schedule N of DCR, 1945 prescribes that a pharmacy should be conducted under the continuous supervision of a registered pharmacist, whose name should be displayed conspicuously on the premises. S/he should always put on clean white overalls. Pharmacy Practice Regulations, 2015 under the Pharmacy Act, 1948, mandate that registered pharmacists should dispense only those medicines as prescribed by the RMP and should not substitute the prescription. The provisions in the Regulations mandate that the pharmacist should check the legality of every prescription, which would have the details of the prescribing RMP and details of the drug, frequency of dose, etc. while dispensing

medicine. The draft Drugs and Cosmetics (Amendment) Rules, 2018, prescribe that E-pharmacies would require a valid prescription either written or electronic and the presence of a registered pharmacist, for dispensing drugs and answering the questions of the consumers.

Pricing and Cost Containment

Subject to the provisions of Drugs Prices Control Order (DPCO), 2013 and Drugs and Cosmetics Act, 1940, no pharmacy should withhold from the sale or refuse to sell any drug that is available to a customer intending to purchase such drug (Drugs (Prices Control) Order, 2013). Section 26 of the DPCO controls the sale prices of drugs to any consumer and it should not exceed the prices specified in the current price list. The National Pharmaceutical Pricing Authority (NPPA) is an independent body formed under the Ministry of Chemicals and Fertilizers in the year 1997, to implement and enforce the provisions of the DPCO at the national level. NPPA is responsible to (i) fix and revise the prices of scheduled drugs (Schedule I medicines of the DPCO subject to price control) and formulations, (ii) monitor prices of decontrolled drugs and formulations, (iii) monitor drugs availability and identify shortage, and (iv) implement and enforce the provisions of DPCO. The State Drugs Standard Control Organization/FDA Department is the implementing agency, to enforce the provisions of DPCO at the State level (Department of Pharmaceuticals, 2013). The latest version of the National List of Essential Medicines (NLEM) was published in 2015, which has been incorporated into the DPCO 2013 and contains 348 essential drugs.

Protecting Patients and Consumers

The State and the Union governments have powers to restrict the manufacture and sale of drugs, to prohibit substandard or adulterated drugs or drugs that may involve any risk to human beings, under Sections 18 and 26 A of the DCA, 1940, respectively. Drugs and Cosmetics Act, 1940, has provisions under Section 27 and 27A to issue a penalty for those who are associated with the sale or dispensing of any adulterated or spurious drugs without a valid licence. The Drugs and Cosmetics (Amendment) Act, 2008, introduced substantial enhancement in the punishment with minimum punishment being seven years, which may extend to life imprisonment for offenders involved in manufacture, sale and distribution of spurious and adulterated drugs or cosmetics, and provision for compensation to affected persons.

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 and Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955, mention a list of approximately 54 diseases, disorders or conditions for which no advertising of drug is permitted (section 3). The Act prohibits false or misleading advertisements that make wrong claims (section 4) and has provisions (section 7) to issue

a penalty to whoever contravenes any provisions of this Act or the Rules made thereunder (Drugs And Magic Remedies (Objectionable Advertisements) Act, 1954; Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955).

If an unregistered person engages in drug dispensing, they are punishable as per Section 42 of the Pharmacy Act, 1948. This section does not apply to the drug dispensing by RMPs for their patients.

Information Provision

Pharmacy Practice Regulations, 2015, recommend displaying the name of the pharmacy owner, name of the registered pharmacist along with their registration number, qualification and photograph in the pharmacy. Pharmacy Practice Regulations, 2015, recommend computerising prescription records for quick retrieval. If any request is made for medical records either by the patients/authorised attendant or legal authorities involved, a registered pharmacist should duly acknowledge and provide documents within 72 hours.

Schedule N of DCR, 1945, prescribes that in a pharmacy all records and registers should be maintained following the laws in force. Pharmacies should record drug details in a prescription register, as per the Drugs and Cosmetics Rules, 1945. The sale of Schedule H, H1 or X drugs should be recorded in a separate register giving the details of the RMP, patient and drug supplied. The pharmacies should allow an inspector to inspect all registers and records maintained under Drugs and Cosmetics Rules, 1945, and should supply such information to the inspector as s/he may require for ascertaining whether the provisions of the DCA, 1940 and Rules have been observed.

Under the Drug Price Control Order (DPCO), 2013, pharmacies need to display the price list and the supplementary price list, if any, as furnished by the manufacturer for easy access of consumers.

The draft Drugs and Cosmetics (Amendment) Rules, 2018, prescribe that the E-pharmacies are required to provide the details of their business, ownership, official logo. In addition, they have to provide details of the logistic service provider, return policy of dispensed drugs, name and details of the registered pharmacist; contact details of e-pharmacy including telephone number, mobile number and e-mail, address. E-pharmacies are also required to outline a procedure for lodging grievances and complaint redressal mechanism on the e-pharmacy portal. E-pharmacies should maintain and update, from time to time, the information regarding the drug's availability, types of drugs offered for sale, supply channels or vendor lists, details of registered pharmacists, registered medical practitioner on

the e-pharmacy portal. It should also keep a record of patient details on the e-portal. In the case of e-prescription, the same should be uploaded on the e-pharmacy portal.

Grievance Redressal

A complaint against a pharmacy can be lodged with the State Drug Control Department or the Food and Drug Administration of the concerned State. Inspectors appointed by the State licencing authorities can investigate any complaint against pharmacies made to them in writing within their area of jurisdiction, under section 51 of Drugs and Cosmetics Rules, 1945. They can also institute prosecutions in respect of breaches of the Act and Rules thereunder.

The draft DCR, 2018, prescribes that in the event of suspicion of supply of a substandard or adulterated or misbranded or spurious drug through e-pharmacy to any customer, the customer may file a complaint in writing to the concerned State Drugs Controller. The concerned authority should take action, as per the procedure specified in the Drugs and Cosmetics Act, 1940.

Pharmacies committing offences such as providing misleading information, selling spurious or expired medicine, overpriced rate than the maximum retail price can be challenged under Consumer Protection Act, 2019 and its Rules. Customers have a right to seek relief under the Act and they can claim compensation at the appropriate District Consumer Forum.

Gaps and Challenges

There is a conflict between the role of drug inspector and pharmacy inspector: The Pharmacy Act, 1948, has the provision to appoint an inspector to inspect at any premises where drugs are compounded or dispensed and submit a written report to the Registrar, or can enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist. Under the Drugs and Cosmetics Act, 1940, there is also a provision to appoint an inspector to conduct the inspection at any premises, wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed. While it may have positive consequences in terms of additional regulation systems, the presence of two inspecting authorities creates a regulatory conflict. This over-regulation also creates confusion among pharmacists as well as the regulating bodies, in terms of their roles and responsibilities and duplication of efforts.

Irrationality in the prescription of medicines is of two broad types - using irrational drugs available in the market and irrational use of rational, essential drugs available, for instance, prescribing antibiotics

for viral infection. It involves the government, the drug companies, the medical professionals and their professional associations for not exercising restraint (LOCOST, 2006). Pharmaceutical companies engage in aggressive promotion of branded generics and many useless, irrational, harmful fixed-dose combination drugs, by offering expensive gifts and other incentives to the medical practitioners. As of May 2018, it is illegal for doctors to take gifts beyond specified limits, from pharmaceutical companies; but it is not illegal for pharmaceutical companies to gift the same to the doctors (Srinivasan, 2018). The Medical Council of India has not been efficient in regulating the practices of medical practitioners, including rational prescription of medicines. It is common practice for people to directly approach the chemist for relief of symptoms like pain, fever, cough or diarrhoea. The chemists too are more than willing to advise and sell prescription drugs. This practice is so prevalent, that some companies now promote drugs to chemists directly (LOCOST, 2006; Jain et al., 2014).

The pharmacy retail market in India is characterised by organised and unorganised pharmacy retailers and is dominated by unorganised pharmacies. It is important to have a uniform nomenclature for calling a medical shop a 'pharmacy' selling drugs and medicines. Licenced retail outlets of drugs as per DCR, 1945 may be called Drugstore, Chemists and Druggists, or Pharmacy. However, Schedule N specifies essential standards for the efficient running of a pharmacy. Further, DCR 1945 uses 'Pharmacy', 'Pharmacist', 'Dispensing Chemist', or 'Pharmaceutical Chemist' in defining a "Pharmacy". The use of so many terms create confusion and gives scope to escape the legal framework. There is a need to harmonise the naming of retail sale units which are responsible for dispensing drugs. Similarly, the retail sale of drugs at hospital pharmacies needs distinction from retail sale in the open market.

Many non-essential drugs and drug combinations, which do not find mention in any standard pharmacology textbook, are licenced for manufacture in India and thus find their way in the Indian market. There is no Union or State law specific to the use or registration of brand names of medicines. A myth that is abundantly exploited by the drug companies is that branded drugs are of better quality than the drugs sold by their generic names (LOCOST, 2006).

The problems plaguing the Indian drugs industry are (1) prevalence of irrational, unscientific and harmful drugs; (2) the proliferation of brand names and very little prescription by generic names; (3) easy availability of medicines across the counter; (4) poor infrastructure for quality control; weak and poorly staffed regulatory administration; (5) poor regulation of the medical profession, retail pharmacists, pharmacy profession, and poor drug control; (6) lack of serious prosecution of those selling substandard, subtherapeutic and spurious drugs; (7) prescriptions influenced by aggressive

promotion of drug companies leading to over prescribing; (8) inaccurate diagnosis; (9) lack of up-to-date knowledge; (10) unethical practices like receiving commissions for prescribing certain drugs and sponsorship by drug companies of individual doctor's expenses, as well as of medical conferences, etc (LOCOST, 2006).

It is observed that one just needs to call a retail pharmacy and medicines would be delivered at home, without the requirement of a prescription. Considering such widespread practice, the Delhi High Court in 2019 directed the centre and State governments to act against pharmacies selling prescription medicines without a prescription. To control, monitor and track the sale of drugs via E-pharmacies is an additional and difficult challenge for the regulatory authorities. E-pharmacies or online selling of medicines helps the patients in medicine delivery at their doorsteps, without having to leave their home. Since there are no specific guidelines concerning the online sale of drugs and the draft rules to regulate the online market are yet to be enacted, the existing trend of the online sale of drugs is worrisome (Priyanka & Ashok, 2016; Gulati, 2020). The role of the E-pharmacy business in supporting health care delivery grew across the country in times of the COVID-19 pandemic. E-pharmacies offer more convenience and ease of access with limited mobility, but the delay in the notification of draft Rules is a concern for all the stakeholders.

BLOOD BANKS

Blood banks are one of the key supportive units of health care systems where blood is collected, tested, separated into components, stored, and prepared for transfusion and distribution to recipients.

Bloodletting was based on an ancient system of medicine in which blood and other bodily fluid were considered to be "humors," the proper balance of which maintained health. In 2500 BCE, the evidence of bloodletting from the foot and neck was found in a tomb illustration in Memphis, Egypt. In 1667, the first documented human blood transfusion was administered in France, where King Louis XIV's doctor transfused the blood of a sheep into a 15-year-old boy, who survived. Later in 1818, the first human-to-human transfusion was recorded by British obstetrician and physiologist, James Blundell. The benefits of bloodletting were beginning to be questioned in the second half of the 1800s, although some still considered it beneficial to "clear out" infected or weakened blood or to stop haemorrhaging (History of Blood Banking, 2021).

Evidence of blood depots was first noted in 1917, when an army doctor collected and stored type O blood with citrate-glucose solution, in advance of the Battle of Cambrai in World War I. The impact of war resulted in developing a network of facilities, to collect and store blood for use in transfusions at hospitals. In 1937, the term "Blood Bank" was coined by Dr Bernard Fantus at Chicago's Cook Co. In 1940, the US government established a nationwide programme for the collection of blood, called the “Plasma for Britain” programme for shipment to Great Britain. By the 1980s, hospital and community blood banks entered the era of transfusion medicine in which doctors trained specifically in blood transfusion participated in patient care (History of Blood Banking, 2021; Highlights of Transfusion Medicine History, 2021).

In India, the first blood bank was established in Calcutta (now Kolkata), West Bengal around 1942, to fulfil the blood needs of those injured in World War II. Government employees and those of British owned industrial houses volunteered to donate blood for this humanitarian cause. A decade later from 1954 onwards, Mrs Leela Moolgaokar, inspired by the blood need of her injured son, initiated voluntary blood donation drives in Bombay. In 1960, the concept expanded to medical colleges and universities in Kolkata, Ahmedabad and Chandigarh, along with a group of voluntary social workers and Red Cross Societies in Delhi. The HIV pandemic and the Public Interest Litigation (PIL) - Common

Cause versus Union of India in 1992, shaped the blood transfusion services and placed thrust on voluntary blood donation in India. In response to the HIV pandemic, blood safety became a vital component of the National AIDS Control Programme (NACP). The key objectives for blood transfusion services were the modernisation of blood banks, promotion of voluntary blood donation, human resource development and quality systems. The GoI adopted the National Blood Policy in 2002 and an Action Plan for Blood Safety in 2003 (Marwaha, 2015). The National Blood Policy, 2002, recommended the formation of Regional Blood Transfusion Centres in every State to collect, test, store and transfer blood and its components to peripheral blood banks, blood storage centres and hospitals, in order to ensure access to safe and adequate blood transfusion services in the peripheral and rural parts of the country (in a hub and spoke model) (NACO, 2007b).

Currently, blood banks in India are categorised into four types based on their administration, namely, public (government) sector, Indian Red Cross Society, non-government organisations (NGOs) or non-profit organisations, and corporate or commercial sector blood banks. As of 2016, there were 2760 blood banks in India according to the Central Drugs Standard Control Organisation (CDSCO), as stated in the report "Assessment of Blood Banks in India". The report identified 2626 functional blood banks across the country excluding military blood banks. Of these, 1131 (43%) were supported by the National AIDS Control Organisation (NACO), MoHFW, GoI. Maharashtra has the highest number of blood banks (308), followed by Tamil Nadu (265) and Uttar Pradesh (248). In the assessment, 2493 blood banks were analysed, which highlighted that the public and not-for-profit sector each owned 38 percent of the blood banks and the private sector owned 24 per cent. The majority of the blood banks (65.7%) had valid and current licences, while the remaining 34.3 percent had applied for renewal. Around 55 percent of NACO supported and 74 percent of non-NACO supported blood banks had a valid and active licence. The annual collection of these blood banks was 11.6 million units which are approximately 95 percent of blood requirement based on WHO's estimation, that is, blood donation by 1 percent of the population can meet a nation's most basic requirements for blood. However, it was also observed that 61 percent of all the blood banks were limited to only eight Indian States (NACO, 2016a).

Legislation Related to Blood Banks in India

In 1990, MoHFW, GoI contracted M/s A.F. Ferguson & Co., a management consultancy firm, to study the blood banking system in the country. The study highlighted the dismal state of blood banks in India. This led to a writ petition "Common Cause Vs Union of India" being filed in the Supreme Court of India in 1992. The Supreme Court of India in its landmark judgement passed the ruling that all blood

banks be licenced within two years, the concept of regular professional donors be eliminated from January 1998, and the Union Government take steps to establish the National and State Blood Transfusion Councils. Following which, the Drugs and Cosmetics Act (DCA), 1940, included 'blood' as a 'drug' under the Act, to ensure better regulation of the collection, storage, testing and distribution of blood and its components. The Drugs and Cosmetics (1st Amendment) Rules, 1992, detailed the process of collection, storage, processing and distribution of whole blood and blood components by blood banks, and made licensing mandatory for all the blood banks (Supreme Court of India, 1992; (Dhot, 2005).

Drugs and Cosmetics Rules, 1945 under 122EA 9 (d) define "*blood centres as authorized premises in an organization or institution as the case may be, for carrying out all or any of the operations including collection, apheresis, processing, storage and distribution of blood drawn from donors or received from another licenced blood centre and for preparation, storage and distribution of blood components*." The MoHFW, GoI vide notification GSR 166 (E) dated 11 March 2020 substituted the word "blood banks" with "blood centres".

The CDSCO, MoHFW, GoI is the National Regulatory Authority and licences are granted by it under Part VII of the Drugs and Cosmetics Rules, 1945, with the approval of the Central Licence Approving Authority i.e., the Drugs Controller of India. The Central licence approving authority with the approval of the Union Government has the provision to delegate the powers of signing licence for blood banks, under Rule 50A for a specified period. CDSCO along with State regulators is jointly responsible to grant licences to certain specialised categories of critical drugs, such as blood and blood products. State governments through State drug controllers are the licensing authority to issue licences to operate blood banks in their State jurisdiction.

In 1996, National Blood Transfusion Council (NBTC) was constituted with the objectives to promote voluntary blood donation, ensure safe blood transfusions, provide infrastructure to blood centres, and develop human resources, in accordance with the directive of the Supreme Court's 1992 judgment for blood banks. NBTC is a society registered under the Societies Registration Act, 1860, as a policy formulating apex body, in relation to all matters pertaining to the operation of blood banks in India. The NBTC is the central body that coordinates the State Blood Transfusion Councils (SBTCs), and also ensures the involvement of other Ministries and other health programmes for various activities related to blood transfusion services. It is responsible for information exchange and developing relationships with international organisations, developing a comprehensive quality management

system, and promoting and coordinating research and development in the country for blood transfusion services (MoHFW, 2021a).

National AIDS Control Organisation acts as a facilitator to blood transfusion services on behalf of the MoHFW, GoI. At the State level, the respective State AIDS Control Societies (SACS) are responsible for the smooth functioning of blood transfusion services, and to ensure access to safe and quality blood/ blood products, to all those in need of transfusions. To strengthen the blood banks across the country, NACO has been instrumental in providing support, in terms of equipment, consumables, human resource and capacity building since 1992. NACO's efforts at modernising blood banks, establishing model blood banks and setting up blood storage centres in rural areas have improved the quality of blood transfusion services in the country. The key strategies under National AIDS Control Programme Phase - IV (2012-2017) were strengthening management structures of blood transfusion services, streamlining the coordination and management of blood banks and blood transfusion services, and developing new initiatives such as the establishment of Metro Blood Banks and Plasma Fractionation Centre (NACO, 2014).

Registration of Blood Banks

Any individual or institution can apply for the opening of a blood bank following an application to the drugs controller, and subject to compliance with the minimum requirements as laid in the legislation, including the payment of a license fee. Blood and blood products are classified as drugs under the Drugs and Cosmetics Act, 1940, and hence a licence is required for opening a blood bank under Section 18 (c) of the Act. The State licensing authority is required to conduct an inspection of the premises through the inspector appointed by the Union Government under section 21 of the Act, and/or along with the expert in the field concerned, to verify whether the applicant has fulfilled the requirements. Inspector may then reject, grant or renew the licence, as the case may be under Rule 122F of Drugs and Cosmetics Rules, 1945. The license once issued is valid for five years and needs to be renewed thereafter as per rule 122F of the DCR 1945.

The Drugs and Cosmetics (Second Amendment) Rules, 2020, inserted that applications for grant or renewal of licences for the operation of blood banks should be made by the blood banks run by the Government, Indian Red Cross Society, a hospital, charitable trust or voluntary organisation. Blood banks run by charitable trusts or voluntary organisations need to be approved by a State or Union Territory Blood Transfusion Council, as per the procedure laid down in this regard by the NBTC.

In 2001, the Drug and Cosmetics Act, 1940, was amended to introduce the concept of “blood storage facilities”. The term “blood storage facilities” was substituted with “blood storage centres” in 2020.

The blood storage centres are opened within the existing government health care setup mostly with first referral units, as well as in private hospitals. Department of Health, MoHFW, GoI exempted blood storage centres run by first referral units, CHC, PHC or any hospital, from the purview of obtaining a licence as per Schedule K of DCR, 1945 (serial no. 5B). The aim is to ensure ample availability of whole human blood or its components in the said hospitals, without engaging any additional infrastructure or staff but satisfying some conditions of the State licencing authority. However, this exemption applies to those government facilities which transfuse less than 2000 units per annum of blood and/or its components. The approval is valid for a period of two years from the date of issue, unless sooner suspended or cancelled and needs to be renewed thereafter (MoHFW, 2014). Drugs and Cosmetics (1st Amendment) Rules, 2001 provided exemption of licensing for whole human blood collected and transfused by centres run by Armed Forces Medical Services in border areas, small mid-zonal hospitals including peripheral hospitals, field ambulances, mobile medical units and other field medical units including blood supply units in the border, sensitive and field areas under Schedule K of Drugs & Cosmetics rules, 1945 (serial no. 30).

Quality

Before the licence is granted or renewed, the licensing authority should inspect the establishment, in accordance with the provisions of the Rules and forward the inspection report to the Central Licence Approving Authority as per Drugs and Cosmetics Rules, 1945. Schedule F, Part XII-B and/or XII-C prescribe the requirements for the functioning of a blood bank and/or for preparation of blood components, in terms of space, personnel and equipment. It also prescribes that the blood banks should maintain adequate technical staff, have adequate storage arrangements for blood and blood products, maintain the record, and print information regarding the stability of whole human blood on the labels, etc.

Schedule F recommends general location and surroundings requirements for a blood bank. It recommends that the blood bank should be located at a place away from an open sewage, drain, public lavatory or similar unhygienic surroundings. The building construction should be well lit, ventilated and screened; permit hygienic and smooth operation of blood bank services; and avoid the entry of insects, rodents and flies. The employees should be provided with clean overalls, headgear, footwear and gloves, and be free from any contagious or infectious diseases. A blood bank should

have an area of 100 sq. mts. for its operations and an additional area of 50 sq. mts. for the preparation of blood components. Separate rooms for registration and medical examinations, blood collection, blood component preparation, sterilization-cum-washing store-cum-records, etc. are also recommended (Schedule F: Drugs and Cosmetics Rules, 1945). The recent amendment to the Drugs and Cosmetics Rules, 1945, added two additional areas: a counselling area with adequate privacy to conduct a thorough examination of individuals/donors, and an identified quality control area with a component preparation area.

The blood bank premises should be maintained properly to ensure adequate cleaning and maintenance of proper operations. It should conduct blood collection with minimal risk of contamination or exposure to activities and equipment unrelated to blood collection. The blood banks should have adequate storage and designated location for storing blood and blood components, and for storage of finished products before distribution or issue. They should also have provisions for quarantine, storage, handling, and facilities for safe and sanitary disposal of products and reagents not suitable for use and proper conduct of all packaging, labelling and other finishing operations.

Equipment, supplies and reagents used in the collection, processing, testing, storage and sale/distribution of blood and its components should be maintained in a clean and proper manner. The equipment should be observed, standardised and calibrated regularly on a scheduled basis, as described in the standard operating procedures manual under schedule F. Waste materials awaiting disposal must be stored safely and should conform to the requirements of the Pollution Control Board (PCB). All bio-medical waste must be dealt with in accordance with the provisions of the Biomedical Waste Management and Handling Rules, 1996.

Schedule F recommends that every blood bank should have four categories of full time competent technical staff. Under Rule 122G of the Drugs and Cosmetics Rules, 1945, the operation of blood banks should be conducted under the active direction and personal supervision of competent technical staff, consisting of at least one person who is a full-time employee, possesses a degree in Medicine (MBBS) with a diploma in clinical pathology/pathology and bacteriology/transfusion medicine/ immunohematology or blood transfusion, and some experience of working in a blood bank. Additionally, blood bank technician(s) must possess a diploma or degree in medical laboratory technology (M.L.T), with some months/years of experience in the testing of blood and/or its components. The facility must also have a registered nurse(s) and a technical supervisor (where blood

components are manufactured) possessing a diploma or degree in medical laboratory technology, with some months/years of experience in the testing of blood and/or its components.

Schedule F, Part XII-B prescribes that the good manufacturing practices (GMPs)/SOPs should be maintained and provided in writing, including all steps for collection, processing, compatibility testing, storage and sale or distribution of blood and/or preparation of blood components. Such GMPs or SOPs, as approved by the State licensing authority and Central licence approving authority, should be made available to all the staff posted for their use in the concerned areas. The blood and/or its components should be distributed on the prescription of a registered medical practitioner, as prescribed in schedule F of the Rules.

Pricing and Cost Containment

Patients pay blood processing charges to the blood banks, both in the government and non-government sector. The latest 'Guidelines on Processing Charges for Blood and Blood Components' were issued by the NBTC in 2014, with the basic principle of non-profitability in the blood banking system. The new nomenclature is “processing charges”, which is defined as the charges for the processing of the blood and blood components for safe blood transfusion to patients. It does not include the establishment cost, that is, cost of building, equipment etc. The processing charges are provided for both government and non-government blood banks. The State Government or State Blood Transfusion Council may provide its guidelines for processing charges, and additionally decide to provide the blood or blood components free of cost to any category of patient. It is mandatory to display the processing charges prominently in the blood banks for the patients' benefit. The guidelines of 2014 were reinstated in 2018, without any change in the processing charges (MoHFW, 2014).

Protect Patients and Consumers

Drugs and Cosmetics Rules, 1945, prescribe that inspection of the premises should be conducted by the inspector (s) before the licensing authority issues a licence or renewal of a licence, to operate a blood bank. Under Rule 122O, a licensing authority or Central licence approving authority can cancel or suspend the licence for a period as it thinks fit, either wholly or in respect of some of the operations of the blood banks, if the licencee fails to comply with any of the conditions of the licence, or with any provision of the Act or Rules.

Any person who collects blood meant for transfusion without a valid licence from the licensing authority is liable for penalty under Section 27 (b) (ii) of the Drugs and Cosmetics Act, 1940. If a person

is found guilty of manufacture or sale of blood contaminated with HIV/hepatitis B virus/non-sterile or blood which is not labelled or is operating a blood bank which is not in accordance with the conditions of the licence, s/he is liable to a monetary fine up to Rs. 10,000 and/or imprisonment up to five years, which may extend to a life term as per Section 27(d) of the DCA, 1940.

Information Provision

Schedule F of DCR, 1945 recommends that the licencee should maintain the following record books in detail, for a period of five years - a record of the blood donors, their clinical information, master records for blood and its components, issue register for blood transfusion, transfusion adverse reaction records, etc. A blood bank must issue the cross-matching report of the blood to the patient, together with the blood unit. Every bag containing blood and/or blood components should be labelled properly displaying the proper name of the product in bold letters, along with the name and address of the blood bank, licence number, serial number of the product, date of blood drawn and expiry date, coloured label as per the blood group, Rh group, results of Hepatitis/HIV/Syphilis test, and indicate donor classification, such as voluntary or replacement donor.

Grievance Redressal

In case a person is aggrieved by the order, in terms of an inspection report regarding grant or renewal of the licence passed by the licensing authority or Central licence approving authority, s/he can appeal to the State or Union Government within thirty days from the date of receipt of such order. In case of rejection of the licence application, the applicant has the provision to resubmit the form after satisfying the gaps within a period of six months along with an inspection fee to the licensing authority, as prescribed in Rule 122K of the Drugs and Cosmetics Rules, 1945. In case the licensing authority cancels or suspends the licence to operate a blood bank either wholly or some of its functions, the licencee can appeal against such an order to the State or Union government within three months.

Gaps and Challenges

The dual licensing system of obtaining a licence from both the State licencing authority and Central licence approving authority for operating a blood bank has made the process very tedious and confusing. Such excessive regulation and delays in setting up a mechanism to audit the blood banks are hindering blood safety considerations in India (Chandrashekar & Kantharaj, 2014). As mentioned above, licence of almost a third of the 2493 blood banks analysed by NACO in 2016 were pending renewal. This calls for simplifying the licencing system, for including use of technological modalities to provide a standardised, timely and transparent licensing process could be considered (NACO, 2016a).

The focus of the Drugs and Cosmetics Act, 1940, is more on the physical infrastructure and general operations of the blood bank. NACO and NBTC provide SOPs, good practices and issue guidelines to regulate and monitor blood banks, but their function is restricted only to an advisory role (Chandrashekar & Kantharaj, 2014). Additionally, there is overlap in the roles of NACO and SACs and the National blood transfusion council and State blood transfusion councils, as they both are involved in policy formulation in relation to the operation of blood banks. The resources could be better utilised by avoiding such duplication of agencies.

AMBULANCES

An Emergency Medical Service (EMS) system has been defined by Moore (1999) as "…*A comprehensive system which provides personnel, facilities, and equipment for the effective and timely delivery of health and safety services to victims of sudden illness or injury*…" (Moore, 1999). Over the years, the EMS system has evolved from a simple transportation service (ambulances) to a system in which medical care is provided, in addition to transportation (NHSRC, 2010).

During the 11th century, when religious wars were being fought between Christians and Muslims to secure control of the holy lands, the Knights Hospitaller set up hospitals to treat those wounded in battle. The first ambulance was used in the 15th century by Spanish forces, who used carts to transport patients from the battlefields during the Reconquest of Spain (Evolution of the Ambulance, 2010; History of the Knights of Malta, 2018). One of the earliest recognised ambulances was developed in France during the late 1700s when simple two or four-wheeled carts (horse-drawn carriages) were used to transport wounded soldiers who were unable to walk to the field medical facilities. Wars provided a fertile environment for the growth of patient transport services (Ortiz, 1998). In the early 19th century (1832), major advances were made in London with the introduction of a transport carriage system for Cholera patients. Between 1861-65 at the time of the American Civil War, US military physicians worked to provide a prehospital care system for soldiers using new techniques and methods of transport. Each ambulance cart was designed to accommodate two to three patients. The first known hospital-based ambulance service began in Ohio, United States in 1865, and was equipped with medical equipment and contemporary medicine (Graham, 2020). By the early 20th century, ambulances were running on gasoline, steam and electricity to transport the sick and injured. During World War I, the Red Cross Association brought in the first widespread battlefield motor ambulances to replace horse-drawn vehicles, and shortly before World War II (1939) modern ambulances geared with advanced medical equipment, physicians and radio were running (Bell, 2012; British Red Cross, 2018; Graham, 2020) .

Ambulances form an essential part of the health system acting as the primary providers of 24*7 response to medical emergencies. Their importance is realised in every critical life-saving situation. The primary objective of the ambulance is to transfer patients to the nearest hospital within the golden hour of their accident. Typically, ambulances are called for in two types of situations, (1) in scenarios of emergencies like road traffic accidents, cardiac arrests and trauma patients requiring prompt lifesaving response for transportation, from the site of the accident or home to the nearest

medical facility; (2) in transporting persons from their homes to hospitals and back home, such as cases of labour. They are also used as a referral transport system, that is, for the transportation of a patient from a health care facility to a higher medical facility and also as mortuary ambulances for the transportation of dead bodies. (Sundararaman et al., 2012; ZIQITZA Blogs, 2017). Ambulances have played a crucial role in the COVID-19 pandemic across the world, acting as one of the main supportive units of the health care system.

Existing Systems

India has various ambulance services based on the type of vehicle used for transportation, dependent on geographical location or situation of emergency or disaster. The most common mode of patient transportation uses road networks. Road ambulances can be cars, vans, all-terrain vehicles, etc. The *National Ambulance Code* in its guidelines for 'Constructional and Functional Requirements for Road Ambulances', defines an "*ambulance as a vehicle equipped and ergonomically designed for transportation or emergent treatment of sick or injured people, and capable of providing out-of-hospital medical care during transit or when stationary* (National Ambulance Code, 2013). Transportation of patients also happens through railway lines (rail ambulance), air (air ambulance) and waterways (boat ambulance). Boat ambulances were first started in the Majuli district of Assam in 2009, and today they are an integral part of 108 services to transport patients from riverine areas to health care facilities. Bike ambulances have also been introduced in India specifically to transport patients from remote tribal locations inaccessible to larger ambulances (ZIQITZA Blogs, 2017).

From the 1990s to 2005, efforts to provide ambulance services in India were restricted to highway accidents or urban cities. There have been significant progress post-2005 after the introduction of the 108 – a toll-free telephone number, which started as a public private partnership in Andhra Pradesh to boost EMS in India (Sharma & Brandler, 2014). NHM today operates patient transport services under Dial-in 108 and 102 ambulance services, collectively called National Ambulance Services (NAS). Presently, the facility of Dial-in 108 or 102 is available in 35 States/and UTs. The '108 Model' is the most widespread response model in India, where one ambulance is positioned for every 100,000 population. Approximately, 10,599 ambulances are being supported under the 108 emergency transport systems throughout India. Dial-in 108 is an emergency response system, primarily designed to address patients of critical care, trauma and accident victims, etc. and provide free emergency transportation. The model aims at reaching the patients/emergency sites within 20 minutes in urban areas and 40 minutes in rural areas, and to shift the patient to the nearest hospital within 20 minutes after reaching him/her (NHSRC, 2010; National Health Mission, 2020).

In India, a multitude of providers (individuals, private/corporate hospitals, public-funded hospitals/programmes, charities, non-profits, political and religious institutions/organisations), run ambulance services for patient transport and referral. The Supreme Court of India in 1989 mandated the delivery of care by hospitals in an emergency, regardless of a patient's paying and medico-legal status (under Article 21 Right to Life of the Constitution of India).

Legislation Related to Road Ambulances in India

The Parliament of India enacted the Motor Vehicles Act (Act No. 59 of 1988) in 1988 applicable to the whole of India, repealing the Motor Vehicles Act, 1939. The Central Motor Vehicles Rules (CMVR), 1989 under the Motor Vehicle Act (MVA) of 1988, prescribe minimum standards for granting licenses to drivers, registration of motor vehicles, standards for construction, equipment and maintenance of motor vehicles, control of transport vehicles and control of traffic, and offences and penalties and procedures for those who violate the provisions of the Act and Rules (Motor Vehicles Act, 1988; Central Motor Vehicles Rules, 1989). The working group on emergency care set up by the Ministry of Road Transport and Highways in 2011, observed that the real concept of an ambulance is missing in India, with an absence of standardisation of ambulance design across various parameters. Most of the ambulance specifications were written by medical specialists who were unable to translate the user requirements into automobile terminology. There were certain inherent limitations in the laws which allowed goods vehicles to be converted as ambulances for passenger application without incorporating essential safety features in a patient compartment, like a side door, forward-backwards seating, occupant restraints, certified electrical systems, etc. The working group recommended that there was a need to formulate the “National Ambulance Code” with necessary amendments in Central Motor Vehicle Rules, 1989. The National Ambulance Code (NAC) drafted under the aegis of the Ministry of Road, Transport and Highways, GoI, laid down the constructional and functional requirements of the road ambulance. The Ministry approved the NAC as Automotive Industry Standard – 125 (AIS-125) and the necessary amendments were notified in CMVR, 1989 in September 2016. All the road ambulances that ply on the road after 1 April 2018, should have mandatory compliance with the standards specified under NAC, superseding the earlier provisions contained in the CMVR, 1989.

The State government by notification under Section 68 of the Motor Vehicle Act, 1988, constitutes State transport authority and regional transport authority (RTO) (not in case of Union territories), to exercise and discharge the powers and functions specified under the Act and Rules framed therein. State Transport Authority is responsible to coordinate and regulate the activities and policies of RTOs

and discharge functions of RTOs, where there is no such authority. RTO is a government organisation that maintains a driver and vehicle database, responsible to register a transport vehicle as a road ambulance, issue a driver's licence to operate an ambulance, conduct vehicle inspections to check if the ambulances on the road comply with the Motor Vehicles Act, 1988. RTO is also responsible to suspend or cancel the renewal certificate for ambulance registration if it does not comply with the MVA, 1988 and its Rules.

Exercising the powers conferred by Section 41 of the Motor Vehicles Act, 1988, the Union Government categorised motor vehicles into transport and non-transport vehicles vide statutory order (S.O.) 451(E) in 1992. Ambulances were added under the category of transport vehicle. The order defined an *"ambulance as a vehicle specially designed, constructed or modified and equipped and intended to be used for emergency transportation of persons who are sick, injured, wounded, or otherwise incapacitated"*. The Union Government introduced the revised definition of road ambulance in clause "z", (zb) under Central Motor Vehicles (Ninth Amendment) Rules, 2016. *"Road Ambulance means a specially equipped and ergonomically designed vehicle for transportation and/or emergent treatment of sick or injured people and capable of providing out of hospital medical care during transit or when stationary, commensurate with its designated level of care when appropriately staffed*" (Central Motor Vehicles (Ninth Amendment) Rules, 2016).

Licensing

Chapter IV of the Motor Vehicles Act, 1988, mentions in detail the necessity, why, how, and where the registration of the vehicle as ambulances should be done. Ambulance vehicles are registered under section 41 of the MVA, 1988, at the State or Regional Transport Authority of the concerned State or Union Territory. State governments and Union Territories are empowered to list their conditions for the registration, within the scope of the Central Act (mentioned under section 138 (2) (d) of the Act). The State government appoints the licencing authorities, which issue licences for ambulances that are operational within the respective State jurisdiction.

A certificate of registration issued under the MVA, 1988 is valid for a period of 15 years from the date of issue. The certificate is renewed under section 45 of the Motor Vehicles Act, 1988. Section 66 (3) (c) of the Motor Vehicles Act, 1988, exempts the ambulances from a mandatory permit[5] issued by the State or Regional Transport Authority mentioned in chapter V, that is, control of transport vehicles.

[5] Permit means a permit issued by a State or Regional Transport Authority or an authority prescribed in this behalf under the Motor Vehicle Act, 1988 authorising the use of a motor vehicle as a transport vehicle. The owner of a transport vehicle

Standards

The road ambulance is required to comply with homologation[6] requirements given in standards notified under Central Motor Vehicle Rules, 1989 and National Ambulance Code. Wherever there is a difference in the homologation requirements given in other standards notified under CMVR 1989 and National Ambulance Code, the requirements of the NAC are applicable.

The Central Motor Vehicles (Ninth Amendment) Rules, 2016, have specified that the road ambulances of categories M and L manufactured on and after the 1st of April 2018, should be in accordance with Automotive Industry Standard (AIS): 125 (Part1)–2014 as amended from time to time, as prescribed in the National Ambulance Code, for all types of ambulances. 'Category M' indicates four-wheeler vehicles, and 'Category L' indicates two and three-wheeler vehicles used for transport and/or emergency care of patients.

The NAC has defined different types of road ambulances for vehicle registration under the provisions of the MVA, 1988. The NAC has classified four main types based on the level of care they can provide, for transport and/or emergent care of patients.

1. Type A Road Ambulance/Medical First Responder: Road Ambulance designed to provide emergent out-of-hospital medical care to patients when stationary. This vehicle is suitable for the terrain it is to be used in but will not have the capability to transport patients in a supine state or provide them medical care inside the vehicle.[7]
2. Type B Road Ambulance/Patient Transport Vehicle: Road ambulance designed and equipped for the transport of patients who are not expected to become emergency patients.
3. Type C Road Ambulance: Basic Life Support (BLS) Ambulance: A vehicle ergonomically designed, suitably equipped, and appropriately staffed for the transport and treatment of patients requiring non-invasive airway management/basic monitoring.
4. Type D Road Ambulance: Advanced Life Support (ALS) Ambulance: A vehicle ergonomically designed, suitably equipped, and appropriately staffed for the transport and treatment of emergency patients requiring invasive airway management/intensive monitoring.

---

cannot use his vehicle on any public place unless it is covered with a valid permit, in accordance with the conditions specified under the act.

[6] Homologation is the process of certifying vehicles or a particular component in a vehicle that it has satisfied the requirements set by various statutory regulatory bodies.

[7] Ambulance which can provide emergency services at parked position only. It cannot transfer patient in supine position, nor can it provide services while moving/transporting.

For clear visibility and recognition of ambulances, NAC standardises the structural and functional requirements to be met by road ambulances, with respect to their colour, conspicuity improving items, emblems, warning lights, sirens and recognition of personnel.

- ***Colour****:* The exterior colour of the road ambulance should be brilliant white withstanding regular cleaning and weather resistant (RAL code[8] – 9010).
- ***Conspicuity Improvement Units*** (RAL code 3024): Markings made under this should be in brilliant red. No less than 50 percent of the front side of the vehicle should be sulphur yellow, RAL-Code 1016 in contrast to no less than 10 percent brilliant red, RAL Code 9010.
- ***Emblems***: The word "AMBULANCE" on the yellow background, a minimum of 65 percent of the hood width, shall be in mirror image (reverse reading) for mirror identification by drivers ahead. All "AMBULANCE" markings must follow a 7:1 ratio, length to height. The emblems (every other sign, symbol or marking not referred to under 'Conspicuity improvement units') are only allowed in a non-reflecting manner, and the size cannot be bigger than 60 percent of the "AMBULANCE" markings. Ambulance Calling Number (YYY) if available, must be displayed on the side and back of the road ambulance.
- ***Warning Lights***: Type A and B road ambulances have flashers fitted at the appropriate locations, as per the vehicle type. Type C and D road ambulances should have warning lights as follows: the blue and red lights will have a minimum intensity of 100cd at daylight and 200cd at night. They should be mounted rectangular to the horizontal ground minimum angle at 45 degrees. All lights must flash between 2Hz to 4Hz. Red lights during the day and blue lights during the night should be flashed. Central Motor Vehicles (Ninth Amendment) Rules, 2016, allow ambulances to use red, white or blue light**.** The blinker type of red light with purple glass fitted to an ambulance van used for carrying patients or the warning lamps fitted on road ambulance should be in accordance with NAS (Annexure-1 of AIS:125 (Part1)-2014). It also prescribes that for all types of road ambulances, the top lights (warning lamps) fitted in them as specified under NAS should be in accordance with AIS:125 (Part1)-2014, till the corresponding Bureau of Indian Standards (BIS) specifications are notified under the Bureau of Indian Standards Act, 1986.
- **Sirens** with loudspeakers should be mounted in all types of ambulances. The frequency range permitted for these sirens is 500 Hz to 2,000 Hz. Wail and yelp signals cycle between 10 – 18 per minute and 150 – 250 per minute respectively is permitted. A public address system

[8] RAL code is a color matching system which defines colors for paint, coatings, and plastics.

working at all times from the driver's seat. The siren switch can only be used when the warning lights are on. The CMVR, 1989, allows road ambulances to use horns and sound signals as approved by the registering authority in whose jurisdiction such vehicles are kept on, under Rule 119. The Central Motor Vehicles (Ninth Amendment) Rules, 2016, specifies that the road ambulances should follow the requirements for sirens as per AIS:125 (Part 1)-2014, till the corresponding BIS specifications are notified under the Bureau of Indian Standards Act, 1986.

The Motor Vehicles (Driving) Regulations, 2017, prescribe that the vehicles designated by the State Government for emergency services, including a vehicle used as an ambulance should operate the multi-toned horn (siren) and the multi-colored light with flasher, only when the vehicle is responding to an emergency call or an alarm. When the multi-toned horn and the flasher are on, the ambulance has the right of way over all the other vehicles (Motor Vehicles (Driving) Regulations, 2017).

Under section 138 (2) (d), Chapter VIII, MVA, 1988, State governments are empowered to make rules to control traffic in the State. The State government has a provision to provide an exemption to ambulances from all or any other provisions of Chapter VIII subject to certain conditions. The provision exempts ambulances from general traffic rules, such as speed limits, driving regulations, traffic signals, parking, etc., if the State government notifies rules exempting ambulances from them. Road ambulances are also exempted from the mandatory speed governors (speed limiting device or speed limiting function) for commercial vehicles mentioned in Rule 118 under Central Motor Vehicles (Amendment) Rules, 2015.

Driver in a Road Ambulance

There is no minimum educational qualification required for a driver's licence to drive an ambulance, as per the Central Motor Vehicles (Eighth Amendment) Rules, 2019. As per the Central Motor Vehicles (Amendment) Rules, 1993, the ambulance driver must successfully pass a course consisting of the syllabus (A to K) mentioned in the CMVR, 1989, from any institute recognised by the State government. In case the driver has a first-aid certificate issued by St. John Ambulance Association, he need not undergo Part K of the syllabus which deals with first aid. Apart from this, there is no requirement of any other training or any specific qualification for the driver to acquire the driver's license for an ambulance.

Paramedical Staff in a Road Ambulance

Till recently there was an absence of legislation that prescribed the minimum requirement, in terms of human resources to operate an ambulance. In March 2021, the Parliament passed the National

Commission for Allied and Healthcare Professions Act, 2021, which recognises 'Emergency Medical Technologist' (Paramedic, ISCO3258) and 'Advance Care Paramedic' (ISCO2240), as allied and health care professionals under the professional category of Trauma and Burn Care Professionals. Both these categories of allied health care professionals would now be regulated, in terms of their education, registration and scope of services through the trauma, burn care and surgical/anaesthesia related technology council (National Commission for Allied and Healthcare Professions Act, 2021). As per the Indian Public Health Standards in a district Hospital - one driver and two technicians are required to operate one ambulance, in terms of human resources requirements (DGHS, 2012).

The NAC recommends safety requirements for the protection and easy identification of personnel working in a road ambulance. Safety garments are protective clothing that gives protection against heat and flame for ambulance personnel and should conform to at least ISO[9] 14116:2008.

In the COVID-19 pandemic, MoHFW has released SOPs to guide ambulance drivers and technicians while transporting suspected COVID-19 patients or those who have developed complications, to the health facilities. The SOPs prescribe strict adherence to cleaning and decontamination protocols, standard precautions while managing such patients, and training of all the ambulance staff (technicians as well as drivers) on common signs and symptoms of COVID-19. The SOPs also prescribe that local authorities should link all the ambulances in the area with the centralised call centre to ensure an adequate number of ambulances, based on population and a response time of 20 minutes in case of transporting COVID-19 patients (MoHFW, 2020b).

Charges and Fixing Rates

The transport department of the concerned State has the power to fix the cost of ambulance services, under the powers conferred to the State government by the Motor Vehicle Act, 1988. However, it is not mentioned clearly as to how the rates of private ambulance services can be fixed. Different State-level publicly financed emergency response and patient transport systems are available. These services are provided free of cost to the patients and the cost is borne by the Union or State government (National Health Mission, 2020). Ministry of Health and Family Welfare, GoI issued guidelines for all those ambulances, for which operational and capital expenditures are supported under NHM.

[9] International Organization for Standardization (ISO) 14116:2008 specify protective clothing requirement for protection against heat and flame. Clothing material should reduce the possibility of its burning and prevent the personnel from any hazard.

During the COVID-19 pandemic, instances from various States were reported where the cost of private ambulances increased drastically. For example, in Maharashtra, ambulance charges peaked at Rs 30,000 for transporting COVID-19 patients for 10 to 15 km. In Kolkata, ambulance services increased charges up to Rs 6,000 – 8,000 to transport COVID-19 patients for 5 km. Ambulance services in Bihar were noted to increase at least 5 to 10 times the normal price for transportation (Newsroom, 2020). Under the MVA, 1988 the transport dept can fix the cost of ambulance services use per km, however they failed to implement the regulation.

Protecting Patients

The Motor Vehicles Act, 1988, has provisions to refuse the renewal of the certification or suspend or cancel the registration of the vehicle, in case the registering authority or other prescribed authority has reason to believe that the vehicle fails to comply with the requirements of the Act or the Rules made thereunder, and constitute a danger to the public.

The Central Motor Vehicles (Twentieth Amendment) Rules, 2016, introduced the provision of vehicle location tracking devices and emergency buttons for all public service vehicles. The provision is not mandatory for road ambulances. However, State governments have the authority to make it mandatory for road ambulances, if they so decide. For example, in February 2020, State of Kerala made it mandatory for all road ambulances to have a GPS facility installed (Express News Service, 2020).

The Motor Vehicles (Amendment) Act, 2019, introduced a provision to punish those who obstruct ambulances. It added Section 194 E, according to which failure to allow free passage to emergency vehicles, that is, fire service vehicle or an ambulance or other emergency vehicle as may be specified by the State Government will call for imprisonment up to six months, or a fine of Rs. 10,000 (Motor Vehicles (Amendment) Act, 2019).

Gaps and Challenges

In the last two decades, the GoI has implemented many schemes to improve the transport and ambulance services, like State-run call-centre based ambulance systems, decentralised public-private partnerships and local innovations by civil societies, to provide basic transport services. A study by Raju & Maurya (2018), underlined the current realities surrounding the 108 services and cited critical issues responsible for its compromised services. Factors such as insufficient supervision by the State

governments, like lack of due diligence in the tendering process, rising costs and idling of ambulances due to procedural delays in tender procurement, delay in payment of operating expenditure to the private provider and inadequate performance monitoring, are highlighted in the article based on various State audit reports like those from Kerala, Odisha, Madhya Pradesh and Karnataka. Another important issue in the functioning of ambulances was the non-fulfilment of conditions, as per the memorandum of agreement, like maintenance of equipment and vehicles, geographic information system tracking, skill upgradation, networking with government hospitals and generating awareness among the public about 108 services (Verma, 2020). A review of Centralised Accident and Trauma Services (CATS) in New Delhi in 2012 concluded that of the 152 State-run ambulances, only 21 had advanced life-support facilities (such as defibrillators, ventilators, etc. for use in critical cases), 10 had basic life support systems (without drugs or ventilators), and the remaining 80 percent were just white vans with stretchers (Singh & Gupta, 2014). Though the ambulance service today has developed into a highly trained professional emergency medical service in India, it is still viewed as a patient transport service running with merely a driver and a ward boy.

Existing legislations have comprehensively covered the structural elements (in terms of manufacturing, physical assembling of the vehicle), functional elements (where to register, how to operate), and availability of essential drugs and equipment as minimum standards in a road ambulance. Apart from the implementation challenges, factors like access to ambulances according to the population and geography, charges of ambulance service levied by the private operators, safety of the patients, paramedical staff and attendants while transportation remain unregulated.

PROFESSIONAL ACTIONS

ABORTION

The term 'abortion' refers to the termination of pregnancy before the foetus is capable of survival outside the uterus (Abortion, 2003). Abortion, also called miscarriage may be spontaneous, or induced. Safe or unsafe induced abortion depends on who performs it, how, and under what conditions. The WHO defines unsafe abortion as the termination of pregnancy carried out by a person who does not possess the necessary skills or training, or one that takes place in an environment that does not meet minimal medical standards, or both (World Health Organization, 2012a).

At the time of Independence from the British in 1947, induced abortion (referred to as 'abortion' henceforth) was a criminal act in India under sections 312 to 316 of the Indian Penal Code (IPC), 1860 unless performed to save the life of the pregnant woman. However, "an appreciable number of abortions" took place in India every year, most of them performed by people with no medical competence and in "wholly undesirable" conditions, as observed by the Mudaliar Committee (1959-61)[10] (Ministry of Health, 1961). In 1964, the Ministry of Health, Government of India established a committee under the chairpersonship of Mr. Shanti Lal Shah, the then Minister for Public Health, Law and Judiciary, Government of Maharashtra to examine the issue of abortion in the country (Chattopadhyay, 1974). The Committee, popularly known as the Shah Committee, estimated that in India's then population of 500 million, there were nearly 6.5 million abortions per year, of which 2.6 million were perhaps spontaneous/ natural and 3.9 million were induced. The major concern of the Committee was the dangers of unsafe induced abortion, i.e., morbidity and mortality among women. From the experience of different countries that it analysed the Committee concluded that legalisation of abortion helped countries in reducing mortality among women due to unsafe abortion. It therefore recommended that women's access to abortion be expanded by liberalising the existing provisions under the IPC, on medical and humanitarian grounds (Ministry of Health and Family Planning, 1966).

The Shah Committee report became the basis for Government of India to liberalise abortion laws in the country. First introduced in the Rajya Sabha in 1969, the Medical Termination of Pregnancy (MTP) Act, 1971 (Act No. 34 of 1971) was passed by the Parliament in August 1971. The Bill was introduced in the Parliament as a measure of emancipating women, and defended on eugenic, humanitarian and

[10] Ministry of Health, Government of India constituted the Health Survey and Planning Committee under the Chairpersonship of Dr A.L. Mudaliar, Vice Chancellor, University of Madras, in 1959 to review the developments in the health sector in the country since the publication of the report of the Health Survey and Development Committee (Bhore Committee) in 1946 to guide future health programmes in the country.

health grounds. The Medical Termination of Pregnancy Act, 1971 came into effect in April 1972, legalising abortion in certain conditions so that women's health and lives could be protected from the dangers of unsafe abortion (Medical Termination of Pregnancy Act, 1971). The MTP Rules, 1975 and MTP Regulations, 1975 were subsequently framed to specify how the provisions of the Act may be implemented (Medical Termination of Pregnancy Rules, 1975; Medical Termination of Pregnancy Regulations, 1975). The Parliament was able to legislate on a subject (public health) that is otherwise listed under the State list in the Constitution of India, through entry I of the concurrent list which includes criminal law including matters pertaining to the IPC within its purview. Since abortion was criminal under the IPC and the Parliament sought to modify the provisions of the IPC by making exception to criminalisation of abortion in certain specified circumstances, entry I of the concurrent list authorised it to legislate on the matter (Jacob, 1974).

The MTP Act, 1971 was amended in 2002, the Medical Termination of Pregnancy (Amendment) Act, 2002 (Act No. 64 of 2002) (Medical Termination of Pregnancy (Amendment) Act, 2002). The MTP Rules, 1975 and the MTP Regulations, 1975 were amended in the year 2003 (Medical Termination of Pregnancy Rules, 2003; Medical Termination of Pregnancy Regulations, 2003). A further amendment to the MTP Act, 1971, the MTP (Amendment) Act, 2021 (Act No. 8 of 2021) was notified on 25 March 2021 (Medical Termination of Pregnancy (Amendment) Act, 2021).

Under What Conditions Is Abortion Allowed?

Section 3(2) of the MTP Act, 1971 specifies the conditions under which a pregnancy may be terminated, that is, if the life of the pregnant woman is in danger or if there is risk of grave injury to her physical or mental health. The Act considers the anguish arising due to pregnancy caused by rape, or failure of contraception as grave injury to the pregnant woman's mental health. If there is substantial risk of the child being born with physical or mental abnormalities leading to serious handicap, abortion under the MTP Act is permitted. The MTP (Amendment) Act, 2021 defines "termination of pregnancy" as a procedure to terminate a pregnancy by using medical or surgical methods.

The MTP (Amendment) Act, 2021 increases the gestation period up to which a pregnancy may be terminated legally to 20 weeks from the earlier 12 weeks on the opinion of one registered medical practitioner and if it is between 20 and 24 weeks, then on the opinion of two medical practitioners. It further permits the termination of pregnancy necessitated due to a substantial foetal abnormality, as diagnosed by a medical board, at any time during the pregnancy, with no upper limit for the gestation

period. Apart from increasing the gestation period up to which a pregnancy may be terminated legally, an enabling amendment in the MTP (Amendment) Act, 2021 is that it allows single women to access abortion. In section 3(2), explanation 1 is amended to read 'any woman or her partner' instead of 'any married woman or her husband' and the phrase 'or preventing pregnancy' is added after 'limiting the number of children'.

Who Can Perform Abortion Legally?

Section 2(d) of the Act defines a Registered Medical Practitioner who can provide abortion services. A medical practitioner who possesses a recognised medical qualification as mentioned in clause (h) of section 2 of the Indian Medical Council Act, 1956, is registered with a State Medical Council, and possesses the necessary experience or training in gynaecology and obstetrics as prescribed in the Rules made under the MTP Act, 1971, can perform abortion. According to clause 3 of the MTP Rules, 1975, the necessary experience/training comprises six months house job in or one year of practice in obstetrics and gynaecology at any hospital. It also includes assisting a registered medical practitioner in performing twenty-five abortions or possessing a post-graduate degree or diploma in gynaecology and obstetrics.

Whose Consent Is Required To Perform Abortion?

Section 3(4) of the principal Act calls for taking only the woman's consent, unless she is below 18 years of age or "lunatic" as defined in the Indian Lunacy Act, 1912, in which case the consent may be given by her adult guardian. In the MTP (Amendment) Act, 2002 the term "lunatic" is replaced with the term "mentally ill" as defined in the Mental Health Act, 1987 that replaced the Indian Lunacy Act, 1912.

Despite the legal provision, a common practice followed by several medical practitioners from the early years of the MTP Act, 1971 is refusing to provide abortion services to women who visit alone or if the husband or a close relative does not give written consent (Duggal & Ramachandran, 2004; Kelkar, 1974). Adopting such a practice is going beyond the provisions of the law and could restrict women's access to legal abortion services. At the same time, the Supreme Court, in the case of Suman Kapur vs Sudhir Kapur, ruled that a wife undergoing abortion without informing her husband amounts to mental cruelty and that the husband is entitled to seek divorce on such ground (Supreme Court of India, 2008).

Where Can Abortion Be Performed Legally?

Section 4 of the MTP Act, 1971 specifies the health facilities where an abortion may be performed. These include government and private health facilities approved by the government for the purpose. MTP Rules, 1975 lay down the requirements to be fulfilled by a private health facility to gain

government's approval to provide abortion services, the procedure for applying and acquiring the certificate of approval as well as the process of regular inspection of the health facilities and the cancellation of their approval if the need arises. The MTP (Amendment) Act, 2002 decentralises the authority to approve private facilities from the State level to a district level committee headed by the chief medical officer of the district, to reduce delays in the approval of facilities. The amended MTP Rules, 2003 prescribe a time limit of maximum two months from the date of receiving the application for the committee to inspect the facility and another two months to issue the certificate of approval if the facility fulfils all the required conditions. If shortcomings are found during the inspection, the facility can correct them and the committee is expected to issue the certificate of approval or within two months. However, there is no mention of further course of action in the event the approval process is not completed within the stipulated time period. In order to make it easier for women to access legal and safe abortion during early gestation, the MTP Rules, 2003 relax certain requirements for the provision of medical abortion. They permit trained/experienced RMPs to terminate pregnancies up to seven weeks' gestation using medical methods of abortion at facilities which may not be approved under the Act, provided they have referral linkage with approved facilities and display certificate to that effect from the referral facility.

Cognizant of the fact that there may be emergency situations in which all the above requirements may not necessarily be fulfilled, section 5 of the Act allows the RMP to terminate a woman's pregnancy to save her life irrespective of the gestation period, opinion of a second practitioner, place where termination is performed as well as whether s/he has training/experience in gynaecology and obstetrics. The amendment to section 5 in the MTP (Amendment) Act, 2002 introduces imprisonment of two to seven years for non-registered medical practitioners who perform abortions, for owners of unapproved facilities providing abortion services and for the practitioners providing services at such facilities.

Issues of Concern

The MTP Act, 1971 provides conditional access to abortion with the final decision resting with the provider/medical board. Though the Act allows providers to interpret the conditions permitted in the Act liberally, yet women have to give an explanation that fits within one of those conditions. Hence, women have to concede failure of contraception in order to be eligible for legal abortion. Such a conditionality completely ignores the reality of a large number of women who may have no control over their own bodies and sexuality, including the use of contraception. The increase in gestation period up to which abortion may be sought came about in the MTP (Amendment) Act, 2021 after a long struggle by women's groups. Though the MTP (Amendment) Act, 2021 broadens the criteria for

women to seek legal abortion yet it does not alter the fundamental nature of abortion laws in India. Abortion continues to be permitted only in certain conditions and one or two doctors or a medical board have the decision-making authority, rather than the women themselves. To that extent, the amendment goes back on what was proposed in the draft MTP (Amendment) Bill of 2014, which was abandoned. It permitted pregnancy up to 12 weeks to be terminated on the request of a woman without enquiring the reason for it.

Another viewpoint that opposes increasing the gestation limit for abortion is that it could open the door for sex-selective abortions. Counterview to this is that implementation of one law should not hamper the services to be provided under another law. Implementation of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) (PCPNDT) Act, 1994, that prohibits sex selection and sex determination of the foetus, should be dealt with separately without conflating it with the MTP Act, 1971 (Krishnan, 2015). Another objection to raising the gestational limit for abortion is on the grounds of potential disabilities in the foetus. The disability rights groups argue that foetal abnormality should not be specified as a separate reason for permitting abortion as it reinforces the eugenic notion that persons with disabilities are not wanted in society. Such a clause may be discriminatory, and the decision should be left to the pregnant woman, depending on the medical advice and her life circumstances (Jain, 2020). It is argued that if abortions can be safely performed at any gestational age in case of 'foetal abnormalities', the same can then be done for other reasons as well.

The requirement of setting up medical boards to diagnose 'substantial foetal abnormalities' in case of pregnancies more than 24 weeks as specified in the MTP (Amendment) Act, 2021, takes the decision-making further away from women.

The MTP (Amendment) Act, 2021 is weak on protecting the privacy and confidentiality of the woman seeking abortion as it introduces a new section 5A which makes it incumbent on the provider to reveal her identity to a person authorised by any law in force at that time. This provision can be used to harass the woman as well as the provider, for instance eliciting information while monitoring the enforcement of the PCPNDT Act, 1994. The draft MTP (Amendment) Bill, 2014 which was abandoned, on the other hand provided absolute protection of the woman's privacy by directing that the provider shall not reveal her identity.

Section 3(3) of the MTP Act, 1971 permits a broad interpretation of risk of injury to the pregnant woman's health by allowing the medical practitioner to take into consideration her "actual or reasonably foreseeable environment" while forming an opinion in good faith. However, the fact that any action of theirs that falls outside the purview of the Act may be considered criminal under the IPC,

thereby inviting stringent punishment, makes the medical practitioners extremely cautious and conservative in their approach towards providing abortion legally (Jain, 2019).

Access of adolescent girls to legal abortion services under the MTP Act, 1971 has come into conflict with the Protection of Children from Sexual Offences (POCSO) Act, 2012. The POCSO Act, 2012 is a legislation to protect children, defined as people below 18 years of age, from sexual offences. The POCSO Act, 2012 directs any person, including a medical practitioner, who has knowledge that a sexual offence has been committed against a 'child', to report it to the special juvenile police unit or the local police. Failure to report may lead to imprisonment for six months or fine or both (Protection Of Children from Sexual Offences Act, 2012). Such mandatory reporting is in conflict with the provisions of confidentiality under the MTP Act, 1971 and may deter doctors from providing abortion services to adolescent girls. Girls would also be concerned about their own identities being revealed and may therefore be compelled to resort to illegal abortion (Jain & Tronic, 2019; Ravindran et al., 2019).

The MTP Rules 2003 permit medical abortion (using mifepristone and misoprostol combination) up to seven weeks of pregnancy while the Drug Controller General of India approved the use of the combi-pack to terminate pregnancy up to nine weeks in 2008. The WHO recommends that the medical methods of abortion may be used up to 12 weeks' gestation (Coalition of Civil Society Organisations, 2020; Rastogi & Chandrashekar, 2019). The MTP (Amendment) Act, 2021 does not address this inconsistency. Secondly, there is evidence that abortions performed by trained mid-level health-care providers are as safe and acceptable as those conducted by physicians (Jejeebhoy et al., 2012; World Health Organization, 2012b). In fact, the abandoned MTP (Amendment) Bill, 2014 had proposed to include registered health care providers of Ayurveda, Unani, Siddha and Homeopathy (AYUSH) as well as nurses and auxiliary nurse midwives within its fold. However, the Indian Medical Association (IMA) vehemently opposed the proposal on the grounds that it would encourage quackery and put women's health at risk. IMA also claimed that allowing non-MBBS personnel and mid-level providers to perform abortions would be a violation of the Clinical Establishments Act, 2010 which does not permit the paramedical personnel to conduct medical procedures (Economic Times, 2014; Gupta, 2019). The MTP (Amendment) Act, 2021 does not mention anything about expanding the provider base.

Amendments to the Act and its Rules and Regulations over the years responded to some of the issues that arose in the effective implementation of the Act. However, as discussed above several concerns are yet to be addressed. Access to abortion remains conditional with the decision-making power vested in the hands of the provider(s) or a medical board. For the providers too, the possibility of being

prosecuted under the IPC, limits the use of their discretionary power to provide greater access to legal abortion services. Additionally, the conflict with other laws such as the PCPNDT Act, 1994 and the POCSO Act, 2012 makes the providers even more cautious. Discrepancy between what is legally permissible and medically recommended, that is, use of MMA up to seven weeks though WHO recommends its use up to 12 weeks' gestation and expansion of the provider base also limits access to legal abortion services.

There is a need to locate abortion within the paradigm of women's rights over their bodies, and their sexuality and reproductive choices. The fundamental nature of abortion laws in India needs to change so that abortion can be availed like any other medical procedure without any discrimination, rather than as an exception to its criminal status under the IPC.

TRANSPLANTATION OF HUMAN ORGANS

Transplantation is an act of surgical removal of human cells, tissues, or organs from one person and placing them into another person. WHO defines transplantation as the transfer (engraftment) of human cells, tissues or organs from a donor to a recipient to restore functions in the body (World Health Organization, 2009). Organ transplantation is an established form of treatment that is often the only life-saving therapy for end-stage organ failure. It is needed when the recipient's organ has failed or has been damaged due to illness or injury. Transplantation of human cells, tissues or organs also restores essential functions where no alternatives of comparable effectiveness exist. The most transplanted organs across the world are the kidney, liver, heart, lungs, pancreas, and intestines (World Health Organization, 2021c).

Modern transplantation skills developed in the early 20th century due to the innovations in the clinical and surgical field. The first successful experiment that led to widespread interest in organ transplantation was demonstrated in 1902 in Vienna which involved dog to dog kidney transplants. Corneal transplantation was the first successful human tissue transplanted in 1905. The first human kidney transplant was performed by Soviet surgeon Yuri Y Vorony, transplanting a kidney from a patient dying of head injury in 1933. Simultaneous efforts were then started in the 20th century to achieve a functioning transplanted organ. In early 1950, centres across Europe and the USA attempted kidney transplant but with little success. Finally in 1954, the first kidney transplants between living patients were conducted in Boston and Paris. The world’s first liver transplantation was performed in 1963 but the first successful liver transplantation happened in 1967 (National Organ and Tissue Transplant Organization, 2013; Sulania et al., 2016). The first ever human kidney transplantation in India was done at Bombay in 1965 using a cadaver donor and the first successful live donor kidney transplant was done in 1971 (Acharya, 1994). The successful liver transplantation in India was performed much later in 1998 (Narasimhan et al., 2016). Since then India has become one of the leading countries in terms of the total number of transplantations done in a year in the world after the USA and China (Bakshi, 2021). Most organ donations (92%) in India are from live donors and the remaining (7%) from cadavers (National Organ and Tissue Transplant Organization, 2019).

According to the latest information (2019), approximately 153,863 solid organs were transplanted globally with a 4.8 percent increase compared to 2018. Kidneys (100,097) were the most transplanted solid organs followed by liver (35,784) and heart (8,722) in 2018. Some 40,608 transplantations were

from deceased donors (Global Observatory on Donation and Transplantation, 2019). No country in the world is able to meet the demand for organ transplantation. It is estimated that less than 10 percent of the global organ transplantation need is covered. Nearly 60 people around the world receive an organ transplant each day while 13 people die because of non-availability of organs. In 1991, the WHO through the World Health Assembly endorsed the set of guiding principles (revised in 2010) addressing ethical aspects of organ transplantation such as the voluntary and unpaid donation, issues of universal access to transplant services, the availability, safety and quality of the procedures (World Health Organization, 2021c).

India fares poorly in organ donation with thousands of people dying, waiting for organs to be donated. Every year an estimated 0.5 million people die due to the non-availability of organs in India. The country's organ donation rate is 0.34 persons per million population, one of the lowest compared to the statistics around the world (Tamuli et. al., 2019). India needs nearly 0.25 million organs each year, 0.18 lakh kidneys, 30,000 livers and 50,000 hearts (Sulania et al., 2016). However, as of 2018, only 7,936 kidneys, 1,945 livers and just 241 hearts were transplanted in India (National Organ and Tissue Transplant Organization, 2018). The corneal donation and transplant programme is relatively well managed in India, with approximately 68,000 corneas being collected in 2018-19 against the annual target of 50,000 (National Programme for Control of Blindness & Visual Impairment, 2018).

Lack of awareness and misconception of brain death among medical professionals and public, lack of a robust system for identification and maintenance of brain-dead donors, cost of organ retrieval, maintenance and transplant, lack of transparency in the system, misuse or commercial selling of organs, socio-cultural beliefs including the desire to be buried/burnt completely, dynamics of decision making for actual donation and lack of organisational support including sufficient transplant centres, well-trained transplant coordinators are major challenges to India's organ donation programme (Sulania et al., 2016; Nagar, 2019). Since demand is more than the supply the commercial selling of organs for monetary benefits is common especially among people facing financial difficulties (Shroff, 2009). Further the cost of organ retrieval, maintenance and transplant is also another factor.

The revolution of corneal (or eye) transplantation reached India in 1945 and various eye banks developed in 1950s. Simultaneously, the kidney transplantation attracted foreign patients to India from rich countries. Private centres conducted more renal transplantation than government institutions in the early years of transplantation. Following the growing demand of transplantation in India, the first statutory step was taken in 1957 to control the eye transplantation and regulate the

eye donation system. The Bombay Corneal Grafting Act, 1957 was the first organ transplantation related law passed in India (Singh et al., 2019). Till late 1980s, States of Maharashtra (e.g., Maharashtra Kidney Transplantation Act, 1982), Tamil Nadu, and Karnataka had legislation that regulated the transplantation of kidney from deceased donors (Agarwal et al., 2012). Union Territory of Delhi passed Ear Drums and Ear Bones (Authority for Use for Therapeutic Purposes) Act, 1982 and the Eyes (Authority for Use for Therapeutic Purposes) Act, 1982. However, realising the need to provide for a comprehensive law at the Union government level, growing transplants among unrelated people and unregulated practice of organ trafficking, the Government of India passed a legislation at the Union government level in 1994, Transplantation of Human Organs Act, 1994 (Act No. 42 of 1994). It repealed the Ear Drums and Ear Bones Act, 1982 and the Eyes Act, 1982.

Legislation on Organ Transplant in India

Transplantation of Human Organs Act, 1994 was aimed at regulating the removal, storage, and transplantation of human organs for therapeutic purposes and prevention of commercial dealings in human organs. The Act was amended in 2011 adding "tissues" with human organs and renamed as Transplantation of Human Organs and Tissues Act, 1994 (Transplantation of Human Organs and Tissues Act, 1994; Transplantation of Human Organs (Amendment) Act, 2011). Subsequently, the Transplantation of Human Organs Rules, 1995 were amended in 2008, 2011 and 2014 (Transplantation of Human Organs Rules, 1995). Currently, the Transplantation of Human Organs and Tissues Act (THOTA), 1994 has been adopted by 16 States and all Union Territories including Delhi namely, Goa, Himachal Pradesh, West Bengal, Rajasthan, Sikkim, Jharkhand, Kerala, Uttar Pradesh, Maharashtra, Orissa, Punjab, Manipur, Assam, Chhattisgarh, Bihar, and Gujarat (MoHFW, 2019).

Institutional Mechanism and Regulatory Bodies

National Organ and Tissue Transplant Organization (NOTTO) is a national level organisation set up under the MoHFW, GoI. Under NOTTO, five Regional Organ & Tissue Transplant Organization (ROTTO) at Chandigarh, Mumbai, Chennai, Kolkata, and Guwahati have been set up. The NOTTO and ROTTO have been set up to implement the National Organ and Tissue Transplant Programme of the country to promote organ donation by bridging the gap between demand and supply of organs for transplantation. NOTTO is responsible for laying down policy guidelines and protocols for various functions, network and monitor transplantation activities of regional and State organisations, compile and publish all registry data from States and regions, assist in data management surveillance and create awareness, promotion of organ donation and transplantation activities (MoHFW, 2015a).

Transplantation of Human Organs (Amendment) Act, 2011 mandated the establishment of human organs and tissues removal and storage networks at the national, regional, and State level. The National Human Organ and Tissue Removal and Storage Network and the National Biomaterial Centre (or National Tissue Bank) have been established in Delhi under the apex national body NOTTO. The networks will gradually expand to include States and Regions of the country as per the provisions of the Act.

The National Human Organ and Tissue Removal and Storage Network is responsible for networking with transplant centres, retrieval centres and tissue banks; coordinate all activities required for procurement of organs and tissues including medico-legal aspects; allocation, transportation, storage and distribution of organs and tissues within Delhi and create awareness, advocacy and training workshops and other activities for the promotion of organ donation. National Biomaterial Centre or National Tissue Bank (NTB) is responsible to take care of the tissue allografts of bone and bone products, skin, cornea, heart valves and vessels. NTB is responsible to coordinate donor tissue screening, removal of tissues and storage, tissue tracking, records maintenance, data protection and confidentiality, quality management in tissues, patient information on tissues, development of guidelines, protocols and standard operating procedures, training and assisting as per requirement in registration of other tissue banks.

The organ sharing and networking policy of States or locations of hospitals are not binding on the Armed Forces Medical Services (AFMS) and the armed forces is free to have their policy of organ or tissue allocation and sharing as per the Transplantation of Human Organs and Tissues (THOTA) Rules, 2014. The Directorate-General AFMS may have its own networking between the AFMS hospitals and are permitted to accept organs when available from hospitals other than AFMS within their State jurisdiction.

THOTA, 1994 and its Rules recommend constituting regulatory authorities at the hospital, district, or State level to regulate the procedure of removal of human organs or tissues or both. The Appropriate Authority is constituted under THOTA, 1994 to regulate the removal, storage, and transplantation of human organs. A hospital is permitted to perform such activities only after being licensed by the Appropriate Authority. It is responsible to grant registration or renew the registration of hospitals as permitted under section 15 and suspend or cancel the registration under Section 16 of the THOTA, 1994. The powers of the Appropriate Authority include inspecting and granting registration to the hospitals; enforcing the required standards; conducting regular inspections of the hospitals to

examine the quality of transplantation and conducting investigations into complaints about a breach of any provisions of the Act. The members of the Appropriate Authority will be appointed by the Union Government for Union territories and State governments will appoint their respective Authority by notification.

The Authorisation Committee is constituted under the Transplantation of Human Organs (Amendment) Rules, 2008. The purpose of the Authorisation Committee is to regulate the process of approval or rejection of transplants between the recipient and donors other than a near relative. The primary responsibility is to ensure that the donor is not being exploited through monetary consideration to donate their organ. The Authorisation Committee has to check the genuine motive of donation, ensure the donor is not being exploited for monetary consideration, understands the potential risks of the surgery and there is no middleman/tout involved. They must evaluate all available evidence submitted as per the requirement of the Act and Rules made thereunder before deciding approval or rejection of the transplantation. The approval of the Authorisation Committee is mandatory for the institution where the transplant is to be undertaken (Transplantation of Human Organs (Amendment) Rules, 2008). The composition of the Authorisation Committee is prescribed by the Union Government from time to time. The State Government and the Union territories may constitute one or more Authorisation Committees as per the requirement. The Authorisation Committee should be hospital-based if the number of transplants exceeds 25 in a year at the respective transplantation centres. In smaller towns, there are State or District level Authorisation Committees if transplants are less than 25 in a year in the respective district. No transplantation team member of the institution would be a member of the respective Authorisation Committee (Yadla, 2019).

Transplantation of Human Organs (Amendment) Act, 2011 recommends constituting an Advisory Committee under Section 13 of the Act. The Union and the State Governments as per the requirement can constitute an advisory committee for two years to aid and advise the appropriate authority to discharge its functions. The Union Government is responsible to prescribe the terms and conditions for appointment to the Advisory Committee. THOTA, 1994 also prescribes for the Competent Authority to be responsible to permit near-related transplants. Its member can be the head of the institution or hospital conducting transplantation or committee constituted by the head of the institution or hospital for the purpose, who are not a part of the transplant team.

Who Can Donate to Whom?

The THOTA, 1994 clearly lays out various procedures under Chapter 2 of the Act. The Act has provided different forms for applying for organ transplantation. Any donor may authorise the removal, before his death, of any human organ of his body for therapeutic purposes as specified in Forms 1(A), 1(B), and 1(C) along with submission of proof of identity, address, marriage, family photographs, etc.

Near Relative Living Donors: This includes spouse, son, daughter, father, mother, brother, sister, grandparents, or grandchildren as per the THOTA Rules, 2014. The transplantation can happen between persons related genetically or between a married couple upon submitting mandatory documentary evidence as per the requirements of the Act and the Rules. If transplantation is between near relatives, then permission is to be sought from the competent authority. The role of the competent authority in case of near relatives is to verify the evidence of relationship between donor and recipient with relevant certificates.

Swap Organ Donors: The Transplantation of Human Organs (Amendment) Act, 2011 introduced the concept of swap donation upon approval from the Authorisation Committee. When the members of two different near relative families fail to donate their organ to their own family member due to the reason of unmatched blood groups then families can exchange their organs with each other, called swap transplant.

Foreign Donors*:* In case of foreign donors donating to their near relatives living in India, the transplantation is permitted. In case of foreigners, both donor and recipient, coming for transplantation in India, the transplant is permitted in India with permission from a senior embassy official of the country of origin. The Authorisation Committee is required to examine the cases of all Indian donors consenting to donate organs to a foreign national (who is a near relative), including a foreign national of Indian origin, with greater caution and should be considered on case-to-case basis. Indian living donors wanting to donate to a foreigner other than near relative are not considered. In case of foreign donors, the Authorisation Committee finds some gross disparity between the status of the recipient and the donor, or the information provided by them, it can reject the application to prevent commercial dealing.

Deceased Donors*:* Deceased donation can be either after brain death (brain stem death) or after cardiac death. Even if the donor has pledged his organs before the death in form 7, the consent of a near relative or person in lawful possession of the body is required (Sahay, 2018).

Regulation and Registration of Hospitals

As per THOTA, 1994, "…hospital includes a nursing *home, clinic, medical centre, medical or teaching institution for therapeutic purposes and other like an institution...*" According to the THOTA, 1994 registration of a "hospital engaged in the removal, storage or transplantation of any human organ" and "tissue banks engaged in recovery, screening, testing, processing, storage, and distribution of tissues" for therapeutic purpose must be done with the Appropriate Authority in a prescribed form and manner along with the due payment of fees. Transplantation of Human Organs and Tissues Rules, 2014 have prescribed in detail the minimum conditions and standards in terms of general manpower requirement for specialised services and facilities, equipment specific to organ or tissue being transplanted, experts and their qualifications, standard guidelines for facility and its premises (Transplantation of Human Organs and Tissues Rules, 2014). The licence to a hospital is issued for a period of 5 years and hospital can renew the license after that period. Each organ requires a separate license from the Appropriate Authority. In case, the hospital is registered under the Clinical Establishment (Registration and Regulation) Act, 2010, they must follow the minimum standards prescribed in respect of manpower, equipment, etc., as prescribed under the Act (Yadla, 2019).

Some hospitals do not have facilities for organ transplantation but can treat seriously ill patients who can be potential donors of organs in the event of death. Such hospitals are known as human organ retrieval centres registered under sub-section 1 of Section 14 of the THOTA, 1994. Any hospital having ICU facilities along with workforce, infrastructure, and equipment as required to diagnose and maintain the brain stem dead person and to retrieve, transport organs and tissues including the facility for their temporary storage can register as a retrieval centre. Registration of retrieval centre also requires ICU facilities along with prescribed expertise and should be attached to the nearest government hospital designated for post-mortem, for retrieval in medico-legal cases.

Role of Medical Practitioners

The THOTA, 1994 recognises a registered medical practitioner as someone who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 and who is enrolled on a State Medical Register. The Transplantation of Human Organs and Tissues Rules, 2014 have defined the minimum standards for experts and their qualification. These standards are must for the registration of a hospital either for organ or tissue transplantation.

(i) Kidney Transplantation: M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. training in a recognised transplant centre and having attended to adequate number of renal transplantations as an active member of team.

(ii) Transplantation of liver and other abdominal organs: M.S. (Gen.) Surgery or equivalent qualification with three years post M.S. experience in the speciality and having one year training in the respective organ transplantation as an active member of team in an established transplant centre.

(iii) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation: M.Ch. Cardio-thoracic and vascular surgery or equivalent qualification with at least three years' experience as an active member of the team performing an adequate number of open-heart operations per year and well-versed with coronary by-pass surgery and heart-valve surgery.

(iv) Cornea Transplantation: M.D. or M.S. or Diploma (DO) in ophthalmology or equivalent qualification with three months post M.D. or M.S or DO training in corneal transplant operations in a recognised hospital or institution.

(v) Other tissues such as heart valves, skin, bone, etc.: Postgraduate degree (M.D. or M.S.) or equivalent qualification in the respective specialty with three months post M.D. or M.S training in a recognised hospital carrying out respective tissue transplant operations and for heart valve transplantation, and the qualification and experience of expert shall be M.Ch. degree in Cardiothoracic and Vascular Surgery (CTVS) or equivalent qualification with three months post MCh training in a recognised hospital carrying out heart valve transplantation.

To declare a patient brain stem dead, certification will be done by a panel of four doctors: hospital administrator, resident doctor of the hospital, neurologist/neurosurgeon/physician, intensivist, and anaesthetists, and treating doctor. Transplantation of Human Organs and Tissues Rules of 2014 have included anaesthetists, critical care specialists, intensivists, physicians, or surgeons to facilitate brain stem death declaration in case a neurologist or a neurosurgeon is not available. After the certification of brain stem death of the person, the medical practitioner must ask the near relative or person in lawful possession of the deceased's body that whether the donor had authorised the removal of their organs or tissues after their death, for therapeutic purposes. After the near relative or person in lawful possession of the body authorises removal and gives consent for donation of human organs or tissues of the deceased person, the RMP through the transplant coordinator should inform the authorised registered Human Organ Retrieval Centre through authorised coordinating organisation by available documentable mode of communication, for removal, storage or transportation of organs or tissues. In case of live organ donation, RMPs must ensure that the donor has been informed of all possible side effects, hazards and complications, the donor's physical and mental evaluation has been done and has submitted the mandatory forms.

National Organ and Tissue Transplant Organization developed standard operative procedures (SOPs) in 2014 for organ retrieval from deceased donors, retrieval of cornea/ heart/kidney/liver, management of the brain-dead organ donor in the operation theatre and intensive care unit.

Transplantation of Human Organs (Amendment) Act, 2011 introduced the concept of “transplant co-ordinator" who is a person appointed by the hospital for coordinating all matters relating to removal or transplantation of human organs or tissues or both and for assisting the authority for removal of human organs in accordance with the provisions of the Act. A transplant co-ordinator can be an employee of the registered hospital having qualification of degree in recognised field of medicine/nurse/bachelor’s/master’s degree in social work, psychiatry, sociology, social science, and public health.

Information and Registry

Section 13 D of the Transplantation of Human Organs (Amendment) Act, 2011 recommends developing a national registry for human organ and tissue donation & transplant. Transplantation of Human Organs and Tissues Rules, 2014 defines the scope and role of the national registry based on the type of information. As per Section 32 of the THOTA Rules, 2014 the following national registries are proposed:

1. **Organ Transplant Registry** includes demographic data about the patients, donors, hospitals, recipients, donor follow up details, transplant waiting list, etc, collected from all the retrieval and transplant centres. The hospitals or institutions are required to update their websites regularly in respect of the total number of transplantations done, reasonable details of each transplant and the same data should be accessible for compilation, analysis, and further use by authorised persons of respective State and Union Governments. The data is to be collected preferably through a web-based interface or paper submission.
2. **Organ Donation Registry** includes demographic information of hospitals, donors (both living and deceased), the primary cause of death in case of the deceased donor, associated medical illnesses, driving license or any other document of the person pledging donation, transplant coordinator, organs or tissue retrieved, outcome of donated organ or tissue, details of recipient, etc.
3. **Tissue Registry** includes demographic information on the tissue donors, site of tissue retrieval or donation, primary cause of death in case of deceased donors, relevant laboratory tests, driving license or any other document pledging donation, donation requested by whom, identity of counsellors, tissue(s) or organ(s) retrieved, demographic data about the tissue recipient, hospital conducting transplantation, transplant waiting list, outcome of transplanted tissue, etc.

4. **National Organ or Tissue Donor Pledge Registry** is a computerized database which records the wishes of people who have pledged for organ and tissue donation. Person during their life can pledge to donate their organ(s) or tissue(s) after their death through the Form 7 and submit it in paper or online to the respective networking organisation. The pledger has the option to withdraw the pledge through intimation. The national registry is to be compiled based on similar registries at State level.

Grievance Redressal

Any person aggrieved with regard to the restrictions on removal and transplantation of human organs by the Authorisation Committee and suspension of registration of hospital/ tissue bank by the Appropriate Authority, can file a complaint within 30 days in writing with a copy of order to Union or State Government against the respective order as per Section 17 of the THOTA, 1994.

As per THOTA, 1994, commercial buying or selling of organs in any way is punishable and has significant financial as well judicial punishment. As per the Transplantation of Human Organs (Amendment) Act, 2011, in case of removal of organs without authority, violator can be imprisoned for 10 years or fined Rs. 2 million or both. The doctor can be deregistered for three years at the first time and permanently deregistered for the subsequent offence. Anyone held for commercial dealing in organs or falsification of documents will be imprisoned for 5 to 10 years or fine of Rs. 2 million to 10 million or both, and any other violation of the provisions of the THOTA, 1994 will result in imprisonment for 5 years or fine of Rs. 2 million or both.

Conclusion

Transplantation of Human Organs and Tissues Act, 1994 made the commercial dealings in human organs and tissues illegal and donation from deceased donor, after brain death or cardiac death, a legal option. Despite that commercial organ trafficking has neither stopped nor has the number of deceased donors increased to take care of organ shortage. Even after three decades of the legislation, deceased donation contributes only 7 percent of the total. There remains a large scope for improvement in increasing deceased donation, especially from the cases suffering fatal road traffic accidents (Nagar, 2019).

One of the concerns in organ transplantation is the lack of national and State-level data on the number of donors, patients on the waiting list to estimate the actual supply gap. THOTA, 1994 has recently added the constitution of the national and regional networking as one of its objectives. If implemented successfully, it would be a step forward and help in matching organ donors and recipients via data

analysis. Considerable progress has been made in the establishment of an organised system in the country for organ procurement from deceased donors and their distribution and transplantation to the needy citizens. But a Parliamentary Standing Committee on Health and Family Welfare report has stressed the need to strengthen the infrastructure, administration, human resources, and budget for improving the organ donation in the country and bridge the demand-supply gap (Bakshi, 2021).

ILLNESSES AND DISEASES

MENTAL HEALTH

The WHO defines, "…*Mental health is a state of well-being in which an individual can realize his or her abilities, interact positively with others, cope with the stressors of life and study, work productively and fruitfully, and contribute to his or her family and community*…" Good mental health plays a vital role in personal wellbeing, family relationships, professional development, and positive contributions in societies and countries. Social determinants like poverty, childhood adversity, and violence are key risk factors in developing a mental health condition (World Health Organization, 2008) (Patel et al., 2018).

Historically, people with mental health conditions have experienced the violation of their basic human rights, rights to liberty and treatment and continue to experience such violations to date. Such abuse or violation may occur from their family members, friends, caregivers, professionals, health institutions, community, and law enforcing agencies. Hence protective mechanisms like legislation help in protecting vulnerable groups and ensure appropriate, adequate, and humane health care services. The Madhouses Act, 1774 of Great Britain was one of the earliest laws in mental health which aimed to better restrict the private trade in lunacy, regulate the licences of madhouses and prevent patient mistreatment and malpractices (Crane, 2013). Modern treatments of mental health conditions saw the establishment of hospitals and asylums beginning in the 16th century (Farreras, 2021). In 1908, the mental hygiene movement was started in the USA by the consumers of psychiatric services and professionals interested in improving the quality of treatment of people with mental disorders. The 18th and 19th centuries saw a rise in the growth of the humanitarian view of treating mental illness.

The Global Burden of Diseases (GBD) study in 2017 provided comprehensive estimates of the prevalence and disease burden due to mental health conditions which include (1) depressive disorders, (2) anxiety disorders, (3) schizophrenia, (4) bipolar disorder, (5) idiopathic developmental intellectual disability (IDID), (6) conduct disorder, (7) autism spectrum disorders, (8) eating disorders, (9) attention-deficit hyperactivity disorder (ADHD), and other mental disorders (Sagar et al., 2020). This study estimated that that 792 million people, that is, 10.7 percent globally (males 9.3% and females 11.9%) were living with a mental health condition (Ritchie & Roser, 2018). In 2017, one in seven Indians were affected by mental health conditions with varying severity which is more than the one in ten people globally. In India, 45.7 million had depressive disorders and 44.9 million had anxiety disorders. Depressive disorder was the leading contributor to the total mental health conditions DALYs

(33.8%), followed by (1) anxiety disorder (19.0%), (2) idiopathic developmental intellectual disability (10.8%), (3) schizophrenia (9.8%), (4) bipolar disorder (6.9%), (5) conduct disorder (5.9%),(6) autism spectrum disorders (3.2%), (7) eating disorders (2.2%), (8) attention-deficit hyperactivity disorder (0.3%), and (9) other mental disorders (8.0%) (Sagar et al., 2020). The mortality due to suicide in India is 16.3 per 100,000 population (2018) (World Health Organization, 2018).

In India, the concept of modern mental health care can be traced to the British period. The 18th century witnessed the era of institutionalisation where people with mental health conditions were kept in lunatic asylums for psychiatric treatment, away from family and society. The first asylum was established in Bombay in 1745 and later in Calcutta and Madras, treating primarily the European soldiers posted in India, more for custodial purposes and less for curative care (Nizamie & Goyal, 2010). The British introduced many laws for controlling the care and treatment of people with mental illness in British India. The first law in British India was the Lunatic Removal Act 1851 to regulate the transfer of British patients back to England but was stopped in 1891. In between that period, many other laws like the Lunacy (Supreme Courts) Act 1858, the Lunacy (District Courts) Act 1858, the Indian Lunatic Asylum Act 1858 (with amendments passed in 1886 and 1889) and the Military Lunatic Act 1877 were passed. These Acts were passed to detain patients indefinitely with no chance of recovery or discharge, and resulted in neglected management of the mentally ill and only restrained patients in asylums with poor living conditions (Narayan & Shikha, 2013). In 1912, the Indian Lunacy Act was enacted by the British government to develop better conditions for the mentally ill and replaced the word lunatic asylum with a mental hospital. However, the Act neglected human rights and primarily gave custodial services to patients with mental health conditions. In 1946, the “Bhore Committee,” surveyed mental hospitals and reported professional inadequacies in terms of training of health personnel and students in psychiatry, absence of occupational and diversionary therapies, and separate child psychiatry units. The committee suggested modernisation of hospitals, attachment to medical colleges, and establishment of mental health care institutions with adequate treatment facilities, trained staff for caring the persons with mental health conditions (Nizamie & Goyal, 2010; Firdosi & Ahmad, 2016). There is a shortage of psychiatrists and psychologists in India as compared to the prevalence of mental health conditions. Currently, there are only 0.7 psychiatrists against the desirable figure of more than 3 psychiatrists per 100, 000 population (Garg et al., 2019).

The UN Convention on the Rights of Persons with Disability (CRPD) was adopted by the UN General Assembly in 2006 and came into force in 2008. WHO's Mental health Gap Action Program (mhGAP) in 2008 identified eight priority mental health conditions and was adopted with the highest level of

political commitment by all 194 ministers of health in the World Health Assembly in 2013 (World Health Organization, 2008; Patel et al., 2018).

Legislation on Mental Health in India

India being a signatory to the UDHR, 1948, the Indian Psychiatric Society suggested that the Indian Lunacy Act, 1912 was inappropriate and submitted a draft of a Mental Health Bill in 1950. The Mental Health Act was enacted in 1987 repealing the Indian Lunacy Act, 1912. This Act, (Act No. 14 of 1987) was a progressive step emphasising care and treatment of persons with mental health conditions rather than custody and mandated the setting up of central and State mental health authorities for mental health services; licensing procedures for psychiatric hospitals and psychiatric nursing homes; admission and discharge procedures of voluntary and involuntary patients; and inspection procedures for psychiatric hospital or psychiatric nursing home. It also had a section for the protection of mentally ill persons during treatment without the violation of human rights and penalties in case of contravention of the provisions of the Act (Mental Health Act, 1987) (Gopikumar, 2010). The Mental Health Act, 1987 focused primarily on the legal procedures of licensing psychiatric hospitals/ nursing homes, regulating admissions and guardianship of persons with mental health conditions. However, negligence of community-based mental health care, lack of attention to WHO guidelines on human rights and mental health care delivery, failure to cover rehabilitation and treatment after patient's discharge from hospital and insufficient financial support in the treatment for the carers and family were left out of the Mental Health Act 1987 (Gopikumar, 2010; Firdosi & Ahmad, 2016). These criticisms eventually culminated in the passing of the Mental Healthcare Act (MHA), 2017 (Act No. 10 of 2017) repealing the Mental Health Act of 1987.

The Mental Healthcare Act was passed by the Union Government in 2017, which aims to provide mental health care and services for persons with mental health conditions and to protect, promote and fulfil the rights of persons during the delivery of mental health care and services. It emphasised on the rights of a person with mental health conditions addressing the key gaps of the Mental Health Act 1987.

The Central Mental Health Authority (CMHA) (under the Central Government) and the State Mental Health Authority (SMHA) (under the State government) are statutory bodies established as per the provisions of the Mental Healthcare Act, 2017. The CMHA is responsible to register all mental health establishments (MHEs) under the control of the Union government, maintain a national register of all MHEs and mental health practitioners (clinical psychologists, mental health nurses and psychiatric

social workers) based on information provided by SMHAs, provide quality and service provision norms for different types of MHEs under the Union government and advise the Union government on matters relating to mental health care and services. The SMHA is responsible to register, supervise, and maintain a register of all MHEs, develop quality and service provision norms for establishments under the State authority, maintain a register of mental health practitioners, train law enforcement officials on the provisions of the Act, receive complaints about deficiencies in the provision of services and advise the State government on matters relating to mental health. The SMHA is responsible to constitute Mental Health Review Board (MHRB). MHRB is responsible to register and review advance directives, appoint nominated representatives, decide objections against mental health practitioners and MHEs, conduct inspections of MHEs, decide on nondisclosure of information of persons with mental health conditions and protect human rights (Mental Healthcare Act, 2017; Prashanth et al., 2019).

Mental Health Establishments

As per the Mental Healthcare Act, 2017, "*mental health establishment means any health establishment, including Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy establishment, meant for the care of persons with mental illness, established, owned, controlled, or maintained by the appropriate government, local authority, trust, whether private or public, corporation, cooperative society, organization, or any other entity or person, where persons with mental illness are admitted and reside at, or kept in, for care, treatment, convalescence, and rehabilitation, either temporarily or otherwise and include any general hospital or general nursing home established or maintained by the appropriate government, local authority, trust, whether private or public, corporation, cooperative society, organization or any other entity or person but does not include a family residential place where a person with mental illness resides with his relatives or friends*".

Sections 65 and 66 of MHA, 2017 provide the procedure for registration, inspection, and enquiry of mental health establishments. To register (either with the Central or State MHA), every MHE (in accordance with the Regulation of the concerned authority) must fulfil minimum standards of facilities and services, minimum qualifications for the personnel engaged in such establishments, provisions for maintenance of records and reporting, or any other conditions specified. Mental Healthcare (Central Mental Health Authority and Mental Health Review Boards) Rules, 2018 and Mental Healthcare (State Mental Health Authority) Rules, 2018 provide for provisional registration of MHEs, renewal and

permanent registration of MHEs under the concerned authority. Minimum standards and types of MHEs can vary across States (Mental Healthcare (Central Mental Health Authority and Mental Health Review Boards) Rules, 2018; The Mental Healthcare (State Mental Health Authority) Rules, 2018). The Union Government has not notified the minimum standards for the categories of MHEs but some States have notified the minimum standards or in the process of notifying unlike Delhi, Karnataka and Himachal Pradesh (Delhi State Mental Health Authority, 2018; Medical Dialogues Bureau, 2021).

Any person or organisation can apply for registration of a mental health establishment. The registration and renewal of the MHEs are granted both by the Central Mental Health Authority and State Mental Health Authority depending upon where the application is submitted along with the registration fee. In case of MHEs registered under the Clinical Establishments (Registration and Regulation) Act, 2010 or any other subsidiary law in the State, they can submit a copy of the said registration along with an application and an undertaking that the MHEs fulfil the minimum standards of the CEA, 2010 for that specific category. The concerned Authority (Central or State) will issue certificate of registration to the MHEs based on their registration under CEA, 2010. However, CEA, 2010 does not provide minimum standards specifically for different categories of mental health establishments. Under the CEA, 2010, minimum standards are given only for psychiatric services hospitals, psychiatric clinics and deaddiction centres.

The categories of MHEs as per the Mental Healthcare Act 2017 may vary from the three categories mentioned under the CEA 2010 or other State subsidiary law. The MHA, 2017 has a provision for regular inspection and audits of the MHEs, conducted either on the complaint concerning nonadherence to minimum standards or by itself without any request. Any MHE aggrieved by an order of the authority refusing to grant registration or renew or cancel registration may, within a period of 30 days from such order, appeal to the High Court in the State.

Mental Health Practitioners

The MHA, 2017 defines various health practitioners authorised to provide mental health care services as defined within the Act:

1. Medical Practitioner: A person possessing a recognised medical qualification as defined under the Indian Medical Council Act, 1956 or the Indian Medicine Central Council Act, 1970 or the Homoeopathy Central Council Act, 1973 and registered in the respective State register.

2. Psychiatrist: A medical practitioner possessing a postgraduate degree or diploma in psychiatry awarded by a university recognised by the UGC or by the National Board of Examinations and included in the first schedule to the Indian Medical Council Act, 1956 or any medical officer who, having regard to his knowledge and experience in psychiatry has been declared by the State government to be a psychiatrist.
3. Clinical Psychologist: A person possessing either a recognised qualification in clinical psychology from an institution registered under the Rehabilitation Council of India (RCI) under the RCI Act 1992 or with a postgraduate degree in psychology/ clinical psychology/ applied psychology and a master of philosophy in clinical psychology/ medical and social psychology obtained from any university recognised by the University Grants Commission established under the University Grants Commission Act (UGC), 1956 and approved and recognised by the RCI Act 1992.
4. Mental Health Nurse: A person possessing a diploma or degree in general nursing or diploma or degree in psychiatric nursing recognised by the Nursing Council of India established under the Nursing Council of India Act, 1947.
5. Psychiatric Social Worker: A person possessing a postgraduate degree in social work and a Master of Philosophy in psychiatric social work from any university recognised by the UGC established under the UGC Act, 1956.
6. Mental Health Professional: A psychiatrist as defined above or professional registered in the State register of the concerned State Mental Health Authority or a professional having a postgraduate degree (Ayurveda) in *Mano Vigyan Avum Manas Roga* or a postgraduate degree (Homoeopathy) in Psychiatry or a postgraduate degree (Unani) *in Moalijat (Nafasiyatt)* or a postgraduate degree (Siddha) in *Sirappu Maruthuvam*.

The MHA, 2017 for the first time uses the term 'mental health nurse', who it defines as a person possessing a diploma or degree in general nursing or diploma or degree in psychiatric nursing recognised by the Indian Nursing Council. However, a general nurse without qualification or training in handling mental health issues would not be equipped to provide mental health related services. Hence, this discrepancy in the Act needs to be addressed and the roles of nurses aligned with the provisions of the Indian Nursing Council Act, 1947 (Paul et al., 2019).

As per section 81, MHA 2017, medical practitioners and mental health professionals, as defined above, are required to comply with the guidance document while assessing a person to make mental health care or treatment decisions, as prepared by an Expert Committee appointed by the Central Authority. So far, a comprehensive guidance document for medical practitioners and mental health professionals containing procedures to make mental health care decisions as per the MHA 2017 is not available. The Central Government has provided guidelines for the management of common mental health

conditions such as psychosis, depression, alcohol use or substance use disorders, etc. under the National Mental Health Programme of India (MoHFW, n.d.).

Chapter 14 of the MHA, 2017 restricts a medical practitioner/mental health professional from discharging any function not authorised by the Act or specify or recommend any medicine or treatment not authorised by the field of his/her profession. Anyone knowingly serving as a mental health professional in a mental health establishment that is not registered under the Act is liable to a financial penalty extending up to Rs 25,000 as provided in the MHA 2017.

The MHA, 2017 has a provision to ensure the availability of mental health practitioners in all Central/ State government MHEs. Section 31 of the MHA, 2017 requires the Central/State governments to take steps to address the human resource availability in mental health services, to improve the skills of the available human resources, develop and implement educational and training programmes to deliver mental health interventions and better address the needs of persons with mental health conditions.

Prohibited Treatment Procedures

Certain procedures which have since been deemed as barbaric and violate patient's human rights as identified under the UN CRPD and its Optional Protocol have been prohibited under the MHA, 2017. These procedures are electro-convulsive therapy without the use of muscle relaxants and anaesthesia, electro-convulsive therapy for minors, sterilization of men or women when such sterilization is intended as a treatment for mental illness and chained in any manner or form whatsoever.

The MHA, 2017 restricts the psychosurgery for persons with mental illness unless the informed consent of the person on whom the surgery is being performed and approval from the concerned Board has been obtained. The Act also prohibits against seclusion or solitary confinement of persons with mental health conditions. It also limits the use of physical restraint unless it is the only means available to prevent immediate harm to the person concerned or others and is authorised by the psychiatrist in charge of the person's treatment at the MHE. The Act specifies that restraint should not be used as a form of punishment or deterrent in any circumstance and the use of restraint merely on the ground of shortage of staff in MHEs is prohibited.

Section 115 of the MHA, 2017 decriminalises a suicide attempt by a mentally ill person and imposes the responsibility on the government to rehabilitate such a person to ensure that there is no recurrence of a suicide attempt.

Cost of Mental Health Care and Services

Under Chapter V, Section 18 of MHA, 2017 provides the right to access mental health care and treatment from mental health services run or funded by the appropriate government. It recommends that every person should have access to mental health care services of affordable cost, of good quality, available in sufficient quantity, accessible geographically, without discrimination based on gender, sex, sexual orientation, religion, culture, caste, social or political beliefs, class, disability.

It recommends that no person with mental health condition (including children and older persons) is required to travel long distances to access mental health services and a range of appropriate mental health services as specified in sub-section (4) of Section 18 should be available in facilities run or funded by the government in each district, close to a place where a person with mental health condition resides. Till the time all the services are made available in a facility run or funded by the appropriate government, the appropriate government is required to make rules regarding reimbursement of costs of treatment at such MHEs. In case the child mental health services and old age mental health services are not available in the district where a person with mental health condition resides, then the person is entitled to access any other mental health service in the district and the costs of treatment at such establishments in that district will be borne by the appropriate government either Union or State or UT.

The State/UT Government will limit the cost of reimbursement as specified by the Union Government from time to time. The appropriate government is required to make rules for reimbursement of costs of treatment at such MHEs. Persons with mental health conditions living below the poverty line (BPL), including those without a BPL card or those who are homeless, are entitled to mental health treatment and services free of any charge at all MHEs run or funded by the appropriate government.

The Act also assures availability of free drugs (either from the Essential Drug List or essential medicines from Ayurveda, Yoga, Unani, Siddha, Homoeopathy, Or Naturopathy Systems) to all the persons with mental illness at MHEs run or funded by the government, from the CHCs to upwards in the public health system.

Rights of a Person with Mental Illness

The MHA, 2017 has included an important concept of an “advance directive” which gives patients the power to give their treatment preferences like how they would like to be cared for and treated for a mental health conditions or the treatment they would not like. Section 5 of the MHA, 2017 empowers

a person with mental health conditions to have the right to make an advance directive towards the way s/he wants to be treated for the illness and who her/his nominated representative shall be. In case of a minor, all the provisions relating to advance directive will be taken care of by the legal guardian, which is the nominated representative. This directive has to be vetted by a medical practitioner in accordance with the regulations made by the Central Authority. However, certain sections also provide scope to review, alter, modify, or cancel advance directive.

The Mental Healthcare Act, 2017 ensures that every person with mental health condition would be protected from cruel, inhuman, or degrading treatment in any mental health establishment. Every person with mental illness has the right to live in a safe and hygienic environment, the right to live with dignity, the right to relevant information concerning treatment, right to access their basic medical records, right to confidentiality, right to free legal services, right to equality and non-discrimination and right to complain in the event of deficiencies in care and treatment.

Grievance Redressal

Any person with mental health condition or their nominated representative or a representative of a registered non-governmental organisation, if aggrieved by the decision of any of the mental health establishments or whose rights under the Act have been violated, may make an application to the Mental Health Review Board constituted by the State Authority seeking redressal or appropriate relief. The complaint can be registered without any fee or charge as per section 77 of the MHA, 2017. In exceptional circumstances, the board may accept an application made orally or over the telephone from a person admitted to an MHE.

Any person or MHE aggrieved by the decision of the authority or a board may appeal to the High Court of the State in which the Board is situated within 30 days of such decision under section 83 of the MHA, 2017. The punishment for violating the provisions of the Act is imprisonment up to 6 months or Rs. 10,000 or both.

Other Union government Legislation Applicable to Mental Health

The Rights of Persons with Disabilities (RPwD) Act, 2016 (Act No. 49 of 2016) has implications for persons with mental health conditions who are vulnerable to the violation of their rights in line with the UN CRPD, 2008. It improved the definitions in mental health from its predecessor, the Persons with Disabilities Act, 1995. The RPwD Act, 2016 defines "*disability when a person with long-term physical, mental, intellectual or sensory impairment which, in interaction with barriers, hinders his full and effective participation in society equally with others*." It defines mental illness as "*a substantial disorder of thinking, mood, perception, orientation, or memory that grossly impairs judgment,*

behaviour, and capacity to recognize reality or ability to meet the ordinary demands of life but does not include retardation which is a condition of arrested or incomplete development of mind of a person, especially characterized by sub normality of intelligence." The major changes in the RPwD Act, 2016 include an increased focus on the rights of PwDs, measures to reduce discrimination, ensure equal opportunities in education and work and penalties for contravening the rules made under the Act (Rights of Persons with Disabilities Act, 2016; Narayan & John, 2017).

Chapter 5, Section 25 of the RPwD Act, 2016 focuses on the health care of persons with disabilities. As per section 25, appropriate Government (establishment financed by either Union or State Government) is required to take steps to ensure free health care especially in the rural area, barrier-free access in all government and private hospitals and priority in attendance and treatment. The appropriate Government is responsible to make schemes or programmes to promote health care, prevent disabilities occurrence, screen all the children at least once a year to identify at-risk cases and ensure availability of essential medical facilities and life-saving emergency treatment. The appropriate Government is also responsible to make insurance schemes available for their employees with disabilities as per Section 26. The RPwD Act, 2016 has a provision for grievance redressal in case a person with disabilities has been, is being, or may be abused or exploited by anyone including service providers and family members (Balakrishnan et al., 2019).

Gaps and Challenges

The Mental Healthcare Act, 2017 is progressive and patient-centric and grants the right to mental healthcare to 1.3 billion population of India. The Act is an optimistic step in mental health though it has some areas of concerns.

The National Mental Health Programme (NMHP) launched in 1982 was one of the earliest steps by the GoI to improve the mental health sector of the country. The Programme focused on ensuring the availability and accessibility of minimum mental health care for all and promote community participation in mental health service development (MoHFW, 2021b). The National Mental Health Programme of India advocates the integration of mental health into primary health care. The mandatory registration of all MHEs providing services to persons with mental illness under the MHA, 2017 may create implementation challenges in integrating mental health care into primary health care.

Many private hospitals, nursing homes may refuse to treat patients with mental health conditions as inpatients without the registration as per the Act. Many other providers like prisons, juvenile homes,

child protection centres, centres for the destitute, religious places such as temples, churches, and dargahs and centres run by faith healers provide mental health services in India. There is no clarity whether these will come under the purview of the Act (Mishra & Galhotra, 2018; Math et al., 2019).

Provision of “advance directive” is a first of its kind in health legislation in India. But the MHA, 2017 fails to acknowledge the meagre mental health resources especially in the semi-urban and rural areas, local factors like lack of awareness about mental health conditions which will create implementation challenges. Legal provision of the advance directive may also create difficulties to provide care by other stakeholders such as families and NGOs. From the doctor’s viewpoint, this may lengthen the process of patient admission and treatment (Math et al., 2019). One of the initial challenges in the current practice of MHA 2017 is the slow implementation response by the Governments towards the Act. Two years since the MHA, 2017 and Centre has not notified the minimum standards for distinct categories of mental health establishments and regulations with respect to the making of advance directive. Experts have also raised concerns about the poor infrastructure, inadequate mental health workforce in general health care settings, economics related to implementation, and political will for the successful implementation of the Act (Duffy & Kelly, 2019). The government will have to intensify the efforts to implement this aspirational law which aims to alter the fundamental approach of delivering mental health services including the concerned people's right to decide their own treatment.

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

The Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome, commonly referred to as HIV/AIDS continues to be a major public health issue globally. Acquired Immunodeficiency Syndrome (AIDS) was first discovered by the US Centers for Disease Control and Prevention in 1981 among men having sex with men in New York and California. The causative agent of AIDS, a retrovirus, now termed as human immunodeficiency virus (HIV) was identified two years later in 1983 (Cock et. al., 2011; Sharp & Hahn, 2011). HIV targets the immune system of the body and immunodeficiency results in increased susceptibility to a wide range of infections, cancers, and other diseases that otherwise healthy immune systems of people can fight off. HIV is transmitted from one infected person to another via the exchange of body fluids. The common routes are through sexual acts both heterosexual and homosexual, contaminated blood transfusion, sharing contaminated needles, syringes and other injecting equipment and drug solutions when injecting drugs and from mother to child (Kedia, 2016; World Health Organization, 2020c). HIV is amongst the most catastrophic epidemics of the world that has taken almost 33 million lives so far. By the end of 2019, an estimated 38 million people were living with HIV, and 68 percent adults and 53 percent children living with HIV globally were receiving antiretroviral therapy (ART). In 2019, approximately 81 percent of people living with HIV knew their status, 67 percent (25.4 million) were receiving ART and 59 percent had achieved suppression of the HIV with no risk of infecting others. Between 2000 and 2019, HIV-related deaths fell by 51 percent but because of gaps in health care services, 690,000 people died from HIV-related causes in 2019 and 1.7 million people were newly infected (World Health Organization, 2020c).

In India, the HIV infection was first detected in the mid-80s, among commercial sex workers in Chennai, Tamil Nadu. Subsequently, the first clinical case of AIDS was reported in 1986 from Mumbai. Studies from 1987 to 1991 revealed that commercial sex workers, people with sexually transmitted diseases (STDs) and professional blood donors were the initial groups infected with HIV. Later in 1991, the north-eastern State of India, Manipur reported an explosive outbreak of HIV among intravenous drug users. Recognising the HIV epidemic threat, the Indian Council of Medical Research initiated a sero-surveillance in 1985 which evolved into the HIV sentinel surveillance in 1994. The sentinel surveillance formalised into the annual surveillance system in 1998 under the National AIDS Control Programme (NACP) (Solomon et al., 2006). The National AIDS Control Organisation (NACO) was established in the year 1992, as the nodal organisation for policy/ guideline formulation at the national level and implementation of NACP through State AIDS Control Societies (SACS) in the States. Currently, some of the key strategies being adopted to accelerate the process of reversal of the HIV epidemic

are to prevent new HIV infections including parent to child transmission of HIV, information and communication strategies for behaviour change in high-risk groups, demand generation for HIV services and provide comprehensive care, support, and treatment to people living with HIV/AIDS (PLHA) (NACO, 2016b).

India has the third-largest HIV epidemic in the world, with 2.3 million people living with HIV in 2019 as per the India HIV Estimation report. Overall, the estimated adult (15–49 years) HIV prevalence was 0.22 percent in 2019 which has been declining since the epidemic's peak in 2000. In 2019, there were an estimated 69,200 new HIV infections, 58,900 AIDS-related deaths and an estimated 20,500 pregnant women required ART to prevent mother-to-child transmission of HIV. At a national level, AIDS mortality was estimated at 4.43 per 100,000 population in 2019 (NACO, 2019; Avert, 2020).

Worldwide, there is a relationship between HIV, and stigma and discrimination. Those who experience social stigma and discrimination are more vulnerable to HIV and those living with HIV are more vulnerable to experience stigma and discrimination. Population groups such as men who have sex with men, injection drug users and sex workers continue to face stigma and discrimination based on their sexual orientation or gender identity, health status, race, socioeconomic status, age, etc. Approximately one in eight people living with HIV is being denied health services because of stigma and discrimination, suggested data from 50 countries. Many people, often the most marginalised and stigmatised, continue to face human rights-related barriers to access essential health services for HIV/ AIDS (UNDP, 2016; Avert, 2017; Avert, 2019). Although ART is available for free at ART centres in India, its uptake remains low. This is so mainly because of difficulty in accessing ART clinics, HIV-related stigma, low levels of awareness and weak links between diagnosis and treatment. Literature has highlighted that HIV related discrimination is common in the form of refusing to treat and touch HIV positive patients, disclosing HIV status to other patients and medical staff, and charging additional fees in India. A study found that 55-80 percent of health providers in urban health facilities in India were inclined to prohibit women living with HIV from having children and endorsed mandatory HIV testing for female sex workers (94-97%), indicating discrimination on the basis of gender (Avert, 2017).

Legislation on HIV AIDS in India

The first HIV/AIDS Bill in India was drafted in 1989 but was withdrawn. In 2006, an NGO, Lawyers Collective, submitted draft legislation on HIV/AIDS to NACO as per the Government of India's (GoI) order of 2003. Since 2007, the Bill was modified several times owing to changing HIV scenario, reduced HIV prevalence in India, escalation of the NACP and inputs from the Legislative department and other

departments of GoI. Subsequently in 2015, the Department-related Parliamentary Standing Committee on Health and Family Welfare submitted the 85th report on the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Bill, 2014 (Department-related Parliamentary Standing Committee on Health and Family Welfare, 2015). Incorporating the recommendations from this committee, in 2017 a Union government legislation, Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act (referred to as HIV AIDS Act, 2017) (Act No. 16 of 2017) was passed and notified in September 2018.

The objective of the HIV AIDS Act, 2017 is to prevent and control the spread of HIV/AIDS; provide effective care, support, and treatment and protect the human rights of persons who are HIV-positive, affected by or vulnerable to the virus and syndrome. The Union Government is responsible to lay guidelines indicating policy or procedure or course of action relating to HIV and AIDS, to be followed by the Union Government, State Governments, governmental and non-governmental organisations and establishments and individuals dealing with the prevention, control, and treatment of HIV/ AIDS. Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Rules, 2018 specify National AIDS Control Organisation as the Central regulatory body in case of Union Government ((Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017; Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Rules, 2018).

For implementing HIV/AIDS related programmes in States, the respective SACS is the nodal agency as per the Act. HIV AIDS Act, 2017 states that both Union and State Governments are responsible to take measures to prevent the spread of HIV/AIDS, provide anti-retroviral therapy and infection management for persons with HIV/AIDS, facilitate access to welfare schemes especially for women and children and formulate HIV/AIDS education communication programmes.

Rights of People Living with HIV/AIDS

Chapter II of the HIV AIDS Act, 2017 prohibits discrimination against persons who are either HIV positive or living with HIV positive or ever lived with HIV positive persons (referred to as protected persons henceforth). Discrimination as per Section 3 includes denial or discontinuation, termination, or unfair treatment towards the protected person with regards to employment, health care services, educational establishments, use and access to public facilities, purchase or reside in property and provision of insurance. If a protected person is qualified, fit to perform a job and does not pose a risk to their co-workers, they cannot be deprived of their livelihood. The HIV AIDS Act, 2017 prohibits

mandatory HIV test to secure employment or access educational opportunities and prohibits publishing or communicating any visible representation of hatred against protected persons.

HIV screening/testing can only be undertaken voluntarily. Chapter 3 of the HIV AIDS Act, 2017 mandates informed consent from a person before conducting an HIV test, medical treatment, or research along with pre-test and post-test counselling of the person. However, informed consent is not required in case it is ordered by the court or where the test results will be anonymous such as for the purposes of screening by any licensed blood bank, medical research, or for epidemiological purposes. No person can be compelled to disclose his HIV status or confidential information of another person without written informed consent, unless in pursuance of a court order or between health care providers for the patient's treatment.

Under the provisions of this Act, an HIV positive woman who is pregnant cannot be subjected to abortion or sterilisation without her informed consent. Section 31 of the HIV AIDS Act, 2017 specifies that every person convicted of a crime and serving a sentence or detained under preventive detention laws like Juvenile Justice (Care and Protection of Children) Act 2000, the Immoral Traffic (Prevention) Act 1956 or any other law and is in the care or custody of the State-run homes and shelters, has the right to HIV prevention, counselling, testing and treatment services. A person between the age of 12 to 18 years who has sufficient maturity in understanding and managing the affairs of his family affected by HIV/AIDS (both parents and legal guardian) is competent to act as a guardian of another sibling below 18 years of age. The guardianship is also applicable in matters related to caring, protection and treatment amongst others as per section 32 of the HIV AIDS Act, 2017.

Obligations of the Health Care Provider

The HIV AIDS Act, 2017 defines "*Healthcare provider means any individual whose vocation or profession is directly or indirectly related to the maintenance of the health of another individual and includes any physician, nurse, paramedic, psychologist, counsellor or other individual providing medical, nursing, psychological or other healthcare services including HIV prevention and treatment services*".

The health care providers cannot deny their services to a protected person, have to provide services without discrimination, are not permitted to disclose a person's HIV status to their partner and must follow the treatment guidelines provided by the NACO in ART centres.

Indian Medical Council (professional conduct, etiquette and ethics) Regulations, 2002 recommend general duties and ethical responsibilities of doctors that have to be observed while providing services to HIV/ AIDS patients such as disclosure of information, treatment options and risks to the patient, protection of patient information, and not to abandon their duty for fear of contracting the disease themselves.

Obligations of the Establishment Providing HIV AIDS Care

The HIV AIDS Act, 2017 defines "*establishment as a body corporate or co-operative society or any organisation or institution or two or more persons jointly carrying out a systematic activity for a period of twelve months or more at one or more places for consideration or otherwise, for the production, supply or distribution of goods or services*."

Section 7 of the HIV AIDS Act, 2017 mandates that any testing or diagnostic centre or pathology laboratory or blood bank are required to conduct HIV tests as per the guidelines laid down by the Union Government. For a uniform and standardised approach, NACO has provided national guidelines for HIV testing to be followed by all workers working in the testing or diagnostic centres (NACO, 2015b).

As per the provisions of the Act, ART is a legal right of the person affected with HIV/AIDS. HIV AIDS Act, 2017 recommends that the Union Government should issue guidelines for ART and management of opportunistic infections as per Section 14. NACO has issued various national guidelines under the National AIDS Control Programme which are legally enforceable as per the HIV AIDS Act, 2017 such as Operational Guidelines for ART Services, Antiretroviral Therapy Guidelines for HIV-Infected Adults and Adolescents Including Post-Exposure Prophylaxis and National Guidelines on Second-line and Alternative First-line ART For Adults and Adolescents (NACO, 2007a; NACO, 2012; NACO, 2013). These guidelines are intended to assist doctors prescribing ART, health care teams working in the ART centres with practical issues regarding the treatment of HIV/AIDS, recommendations while dealing with special cases like HIV infection to new-born/ children and the role of the private sector in the provision of ART. ART is available free of cost since 2004 in India through the public run ART centres. Under the NACP, 528 public ART centres (as of 2016) are located in medical colleges, district hospitals and non-profit charitable institutions providing care, support and treatment services to PLHA in order to make treatment accessible (NACO, 2016b).

HIV AIDS Act, 2017 prescribes that every establishment engaged in health care services should provide a safe working environment where there is a significant risk of occupational exposure to HIV. The establishment should follow universal precautionary measures like education, training, personal protective equipment such as gloves, gowns and masks, hand washing, and employ safe work practices as per the Union Government guidelines. But this applies to health care establishments only when twenty or more staff are employed. Section 21 of the HIV AIDS Act, 2017 recommends that every establishment should designate a complaints officer who is responsible for grievance redressal in case of complaints of violations against the provisions of the Act in the establishment.

HIV AIDS Act, 2017 permits certain strategies/practices to be adopted by persons, establishments, or organisations for reducing the risk of HIV transmission/exposure/adverse impact, in a manner specified by the Union Government's guidelines that do not amount to criminal offence or attract civil liability. For example, (i) if someone supplies a clean needle to an injecting drug user for an exchange of a used needle as part of an intervention, or (ii) undertakes an intervention to administer Opioid Substitution Treatment (OST) to an injecting drug user, or (iii) provides safer sex information, counselling, material, and condoms to a sex worker or men who have sex with men as an intervention project. In all these examples, neither the provider nor the recipient of the intervention can be held criminally or civilly liable for such actions or be prohibited from implementing or using the intervention.

Section 11 mandates that every establishment keeping the records of HIV-related information should adopt data protection measures to prevent information disclosure as per the Union Government guidelines. Establishments should have a procedure to access information, provision for security systems to protect the information stored in any form and mechanisms to ensure accountability and liability of persons in the establishment. National Data Protection Guideline of NACP applies to all establishments keeping HIV related information from both the public and private sector. The guidelines specify how HIV-related information of people living with HIV will be stored, handled, accessed and protected in establishments (NACO, 2015a; NACO, 2018).

Insurance companies have largely excluded HIV from the purview of insurance products and only a limited number of private health insurers provide coverage for HIV /AIDS patients. The out-of-pocket expenses for HIV/ AIDS treatment are high. The HIV AIDS Act, 2017 prohibits denial of insurance based on the HIV status, though the use of actuarial calculations within the Act may limit access because of high insurance premium. In 2020, the Insurance Regulatory & Development Authority of India directed all the insurers providing health insurance to mention proper disclosure of underwriting policy covering persons with disabilities, people affected with HIV/AIDs, and mental illness in accordance

with the provisions of IRDAI (Health Insurance) Regulations, 2016. All the insurance companies are required to comply with various provisions of the HIV AIDS Act, 2017 and all Insurers (Life, General and Health Insurers) to comply with the circular by 1st October 2020 (Insurance Regulatory and Developmnt Authority of India, 2020).

Grievance Redressal

The HIV AIDS Act, 2017 recommends that court cases relating to HIV positive persons should be given priority. In any legal proceeding, if a protected person is a party, the court may pass orders that the proceedings be conducted by suppressing the identity of the person, in-camera, and restrict any person from publishing information that discloses the identity of the applicant.

As per the HIV AIDS Act, 2017, an ombudsman is appointed by each State Government to inquire into complaints within the jurisdiction related to the violation of the Act and the provision of health care services. The Ombudsman shall submit a report to the State government every six months stating the number and nature of complaints received, the actions taken, and orders passed. The Ombudsman is required to pass an order within 30 days of receiving the complaint and in cases of medical emergency of HIV positive persons, the order will be passed preferably within twenty-four hours of the complaint. Whoever fails to comply with an order given by an Ombudsman within the specified time, is liable to pay a fine extending up to Rs. 10,000 and an additional fine may extend to Rs. 5,000 for every day during which such failure continues. If anyone violates the provisions of Section 4 that restricts from publishing or communicating any visible representation of hatred against a protected person will attract imprisonment ranging from three months to two years or a maximum fine of Rs. 100,000 or both.

Conclusion

The social stigma and discrimination associated with the disease has prolonged the HIV epidemic in India. The HIV AIDS (Prevention and Control) Act, 2017 is expected to address the issues of social stigma and discrimination against PLHA both in community and health care settings. However, its implementation has been quite slow from the beginning. The Act received the Presidential assent in April 2017 but was notified more than a year later in September 2018. This too came after a PIL was filed in the Delhi High Court seeking reasons for the delay in notifying the Act (Human Rights Law Network, 2018). Since then, NACO has notified only the HIV AIDS (Prevention and Control) Rules 2018 and little has been done to put the Act into action. HIV AIDS Act, 2017 (Section 12) and Rules 2018 (Chapter 2) mention about notifying an ‘HIV and AIDS Policy for Establishments’ which will cover aspects of a safe working environment, informed consent for testing, treatment, etc. However, the Union Government has not notified such a policy yet. Similarly, State governments have not yet

appointed the Ombudsmen for grievance redressal as per the provisions of the HIV AIDS Act, 2017. Some States like Delhi, Goa, Jharkhand are in different stages of preparing rules for the appointment (Dutt, 2019; Bathini, 2020; Chari, 2020; NACO, 2020).

Anti-retroviral treatment is available free of cost since 2004 in India through the public run ART centres. HIV AIDS Act 2017, made “free ART treatment a legal right”. However, with 528 ART centres nationally for 2.3 million HIV positive persons, accessibility continues to be a challenge. The HIV AIDS Act, 2017 is expected to address the issues of HIV AIDS comprehensively at the national, regional and State level in line with the commitments made at the United Nations General Assembly Special Session on HIV/AIDS in 2001. But the slow progress on the implementation side is not encouraging and requires strong government commitment.

OUTBREAKS, EPIDEMICS AND PANDEMICS

The WHO considers a disease an outbreak when cases of a disease are more than what would normally be expected. The number of cases that would be considered as an outbreak varies according to what causes the disease and the size and type of previous and existing exposure to the cause (Meningitis Research Foundation, 2020). The WHO defines epidemic as the occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly more than normally expected. The number of cases indicating the presence of an epidemic varies according to the agent, size, and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence (World Health Organization, 2021a). A pandemic is defined as an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people, for example, the global COVID-19 pandemic. Seasonal epidemics that may cross international boundaries and affect a large number of people are, however not considered pandemics (Kelly, 2011).

Presently we are in the midst of the Corona virus pandemic (COVID-19), first identified in Wuhan, China in December 2019. COVID-19 is caused by the virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) leading to respiratory illness in human beings. As the disease spread widely, crossing national and international borders, the WHO declared the COVID-19 outbreak a public health emergency of international concern (PHEIC) in January 2020, WHO's highest level of alarm (Centers for Disease Control and Prevention, 2021). India recorded its first coronavirus case in January 2020. Since then, globally as of 6 May 2021, 155,665,214 confirmed cases of COVID-19, including 3,250,648 deaths have been reported to the WHO. India over the same period has reported 21,491,598 confirmed cases and 234,083 deaths (WHO, 2021d).

Regulations

The Epidemic Diseases Act, 1897 (Act No. 3 of 1897), was enacted 124 years ago “for the better prevention of the spread of Dangerous Epidemic Diseases” (Epidemic Diseases Act, 1897). The trigger for introducing the Act was the bubonic plague that broke out at that time in the then Bombay Presidency. Section 2 of the Act empowers the State governments to take such measures and prescribe temporary regulations as may be required to control an epidemic disease. Section 2A empowers the Union Government to inspect any ship leaving or arriving in port and for the detention of any person sailing or arriving therein. Section 3 provides for punishment under Section 188 of the Indian Penal Code (IPC) for disobeying any regulation or order made under the Act, with imprisonment

up to six months and/or fine up to Rs. 1,000. Section 4 provides legal protection to the implementing officers for "anything done or in good faith intended to be done" under the Act. Infamous for its brevity, the Act leaves several pertinent issues unaddressed and ambiguous. Since the Act does not define what constitutes 'dangerous epidemic diseases', there is no clarity on the criteria based on which a disease/event may be declared as 'dangerous' or 'epidemic'. The Act focuses on the government's powers but does not specify its duties in controlling/preventing an epidemic. It does not mention anything about the citizens' rights or any provision for them to seek legal recourse in case of abuse of power by the State in the implementation of the Act (Goyal, 2020). In the past, the Epidemic Diseases Act,1897 has been invoked to control the spread of communicable diseases, to segregate H1N1-affected persons and get them treated at recognised hospitals, to direct private hospitals to set up isolation treatment facilities and to notify cases of dengue and H1N1 (Rakesh P S, 2016). Most recently the GoI invoked the Act to control the COVID-19 pandemic. Most Indian States, such as Delhi, Uttar Pradesh, Maharashtra and Bihar, notified regulations under the Act authorising government officials to admit, isolate and quarantine people in certain situations (Goyal, 2020).

The 19th century Act is outdated and ill-equipped to respond to outbreaks and epidemics in the 21st century. For example, the Act focuses on isolation or quarantine measures and does not say anything about other scientific methods of outbreak prevention and control, such as vaccination, surveillance and organised public health response. It is purely regulatory in nature with no public health focus. The absolute power granted to the State undermines individual autonomy, liberty and privacy of the people (Rakesh P S, 2016).

The amendment brought about in 2020 during the COVID-19 pandemic increases the power of the Union Government to inspect other modes of travel such as bus, train, goods vehicle, aircraft in addition to ship/vessel under section 2A (Ministry of Law and Justice, 2020). It also provides protection to the health care providers considering the incidents of violence reported in the initial period of the COVID-19 pandemic in April 2020. The amendment prohibits violence against health care service personnel and damage or loss to property related to health facilities during an epidemic. Violation may be punished with imprisonment for three months to five years, and with fine of Rs. 50,000 to Rs. 200,000. In case of grievous injury caused to health care service personnel, the Court shall presume the accused to have committed the offence, unless proved otherwise, and the punishment constitutes six months to seven years imprisonment and fine of Rs. 100,000 to 500,000. In addition, any person convicted under the Act is also liable to pay monetary compensation for causing hurt or grievous hurt to any health care service personnel as well as in lieu of damage or loss to any property. However, some States such as Karnataka, Maharashtra, Rajasthan, Tamil Nadu, and West Bengal have their own laws to protect health care personnel with penal provisions different from the Epidemic Diseases

(Amendment) Act, 2020. It remains unclear how both the Union and the State Acts would be implemented simultaneously in these States, for example whether the fines would be collected in the State or the Central government exchequer (Boddupalli & Francis, 2020).

Disaster Management Act, 2005

The Disaster Management Act, 2005 (Act No. 53 of 2005) is a Union government Act enacted for the effective management of disasters in the country. Section 2 of the Act defines a disaster as a "catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man-made causes…" (Disaster Management Act, 2005). The Act provides for the formation of disaster management authorities at district, State and national levels and State and national plans for disaster management. It calls for setting up disaster response and mitigation funds at district, State and national levels, which can be used as per the provisions of the Act for response, prevention, mitigation, capacity building, etc. All the ministries and departments of the State and Union governments are required to allocate disaster management funds in their annual budgets and use them as per their disaster management plans. The Act permits immediate procurement of provisions and materials and use of other resources for the purpose of rescue and relief without following the due process of tendering etc. It lays down in detail the roles and responsibilities of the various government departments and the authorities during emergencies, what measures are to be taken at different levels, and how to coordinate and implement.

It has a provision for penalising anyone who obstructs an authorised officer or does not comply with the prescribed directions, with imprisonment up to two years or fine or both. The Act specifically states that there shall be no discrimination on the basis of sex, caste, community, descent or religion in matters of awarding compensation and relief to victims of disasters. It enables the Centre and States to enforce a lockdown and restrict public movement if so required, as was done during the COVID-19 pandemic (National Disaster Management Authority, 2020).

Integrated Disease Surveillance Programme (IDSP)

A decentralised State-based disease surveillance system for epidemic prone diseases was established in 2004 to detect and respond to disease outbreaks quickly. The integrated disease surveillance programme (IDSP) comprises a central surveillance unit (CSU) at Delhi, State surveillance units (SSU) at all State/UT headquarters and district surveillance units (DSU) in all districts in the country (Asaithambi et al., 2017). Under the Epidemic Diseases Act, 1897, all health facilities-government

hospitals, private hospitals, laboratories, and clinics are required to report cases of diseases classified as 'notifiable' by the government, to district/State government authorities. Diseases may be classified as 'notifiable' based on their infective nature, severity or frequency of occurrence. Such information is used by the authorities to monitor the diseases and provide early warning of possible outbreaks. On an average, IDSP reports 30-40 outbreaks every week in different States across the country (IDSP, 2021). The Centre has notified several diseases such as (1) cholera, (2) diphtheria, (3) encephalitis, (4) leprosy, (5) meningitis, (6) pertussis (whooping cough), (7) plague, (8) tuberculosis, (9) AIDS, (10) hepatitis, (11) measles, (11) yellow fever, (12) malaria, (13) dengue, etc. The onus of notifying any disease and the implementation lies with the State government. Any failure to report a notifiable disease is a criminal offence and the State government can take necessary action against defaulters (Saxena, 2019a; Saxena, 2019b).

Public Health Bill

Since independence, there have been multiple attempts by the Union Government to strengthen the legal framework for providing essential public health services and for better management of disease outbreaks/epidemics. First in 1955, and then in 1987, the Central Government developed Model Public Health legislation (e.g. Model Public Health Bill by the Central Bureau of Health Intelligence, 1987), but these were not adopted. A National Public Health Bill was drafted by the National Institute of Communicable Diseases in 2002-03 (currently the National Centre for Disease Control) but was not approved (Patro, Tripathy, & Kashyap, 2013; Rakesh PS, 2016).

The draft National Health Bill 2009 provided for "protection and fulfilment of rights in relation to health and wellbeing, health equity and justice, including those related to all the underlying determinants of health as well as health care; achieving the goal of health for all; and for matters connected therewith or incidental thereto" (Draft National Health Bill, 2009). It offered a legal framework to ensure essential public health services and adequate response to public health emergencies through effective collaboration between the Centre and the States. The Bill adopted a rights-based approach and upheld the right to treatment and care. The Bill provided for the formation of public health boards at the national and State levels for smooth implementation and effective coordination. It also had provisions for community-based monitoring and grievance redressal mechanisms to ensure transparency. However, the Bill was not passed (Rakesh P S, 2016).

The latest effort was the introduction of the Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism and Disasters) Bill, 2017 by GoI (Public Health (Prevention, Control and Management of Epidemics, Bio-Terrorism and Disasters) Bill, 2017). The Bill was prepared by the

National Centre for Disease Control (NCDC) and the DGHS jointly and was to repeal the Epidemics Diseases Act, 1897 (Verma, 2017). The Bill defined 'epidemic', 'outbreak', 'bioterrorism', 'public health emergency' and other related terms. It advised public health measures like social distancing, quarantine, isolation, diagnosis and guidelines for treatment, rather than only segregation and detention of people as is mentioned in the 1897 Act. It gave the list of diseases that may be categorised as epidemic-prone diseases, listed the potential bio-terrorism agents and was cognizant of public health emergencies of international concern, like the ongoing COVID-19. The punishment for contravention ranged from Rs. 10,000 to Rs.100,000 and imprisonment up to two years. The 2017 draft Bill provided for appeal before the State, district and local authorities unlike the 1897 Act which has no such provision (Goyal, 2020). Though it was a marked improvement over the Epidemics Diseases Act, 1897, the 2017 Bill combined varied events like epidemics, bio-terrorism and disasters which are very different from each other in nature and therefore need different preventive and management strategies.

Apart from the legislations mentioned above, India has other legal provisions which can be used to take public health measures to prevent and control epidemics. These include different provisions under the Indian Penal Code, 1860, the Livestock Importation Act, 1898, Indian Ports Act, 1908, Drugs and Cosmetics Act, 1940, Aircraft (Public Health) Rules, 1954, Essential Services Maintenance Act, 1968, Indian Aircraft (Public Health) Rules, 2015.

State Level Legislations

States may enact Regulations under the Epidemic Diseases Act, 1897 as per the prevailing situation, for example, The Himachal Pradesh Epidemic Disease (Dengue) Regulations, 2017, The Madhya Pradesh Epidemic Diseases, COVID-19 Regulations, 2020. States may also introduce amendments to the Union government Act as applicable to specific States, Epidemic Diseases (Punjab Amendment) Act, 1944 conferred powers on specific officials to execute various provisions of the Act in the State of Punjab. Similar amendments were passed by Madhya Pradesh, Haryana and Chandigarh while Himachal Pradesh included provisions for vaccination through the Epidemic Diseases (Himachal Pradesh Amendment) Act, 1984 (Rakesh P S, 2016). Some States have their own public health/epidemic diseases Acts, the oldest being the Madras Public Health Act, 1939 and the latest being the Rajasthan Epidemic Diseases Act, 2020. Gujarat drafted the Public Health Bill, 2009 that was not enacted.

Conclusion

It is widely recognised that the Epidemic Diseases Act, 1897 is obsolete and inadequate to address the present-day epidemics and pandemics. The IDSP may help in surveillance of small-scale outbreaks but is insufficient for managing large scale health crisis. The DMA, 2005 is a supportive legislation that cannot by itself address the challenges posed by public health emergencies. The newer and more potent infectious diseases, emerging and fast spreading across the world, warrant a contemporary, comprehensive, and relevant legislation that balances between the rights and responsibilities of both the government and the people. The several attempts discussed above to bring in a new legislation have not yielded results. Hence, there is a need to bring together the various draft legislations that exist at the State and Union government level for this purpose, assess their strengths and weaknesses, along with the reasons why they could not be enacted, and work towards bringing in an appropriate legislation for the management of outbreaks, epidemics and pandemics in the country.

CONCLUSION

The health sector in India is beset with complexities of multiple nature. There is a formal sector providing services both publicly and privately and there is an omnipresent informal sector, that has its loyal clientele. While the western system of medicine has a wide reach and acceptance, Indian systems of medicine and homoeopathy are popular too. Curiously, though yoga and naturopathy are not recognised as formal systems of care, they have become popular particularly in the last few decades. Manoeuvring the space in which all these systems and modalities of care operate is the country's governance and regulatory structure which too has its complexities. In the federal structure that India has, health is essentially a State subject with Centre having enough leeway by way of subjects such as family planning, medical education, vital statistics including registration of births and deaths, prevention of inter-state transmission of communicable diseases, that are on the concurrent list in the constitution. The Central and State institutions together, sometimes in harmony with each other and sometimes antagonistically have been instrumental in addressing the issues that often arise in the production, financing and delivery of health services. Despite the wide array of statutory and non-statutory mechanisms available to regulate the health system, the country’s people continue to face challenges of inadequate services, irrational treatment practices, lack of accountability, and concerns about quality, patient safety and cost of services. There are several reasons such as lack of resources and capacity to implement regulations, competing interests, Centre-State dichotomy, powerful private sector lobby etc. which are responsible for limited use of the available regulatory instruments. At the same time there is lack of regulation in certain critical areas, cost of services and standard treatment guidelines, being the most noteworthy. Time and again renewed efforts are made to address gaps in regulation, for instance the move to replace the various professional councils with commissions, widen the gamut of drugs and medical devices under price control, regulation of newer forms of service delivery like telemedicine etc. Health regulation is therefore a dynamic and evolving determinant of a strong health system that requires continuous engagement and balancing of interests of all the stakeholders involved.

This study is an attempt to lay down the landscape of regulation specific to health care delivery in India. More in depth studies to gauge the impact of specific legislations, efforts to strengthen their implementation, greater involvement of the patient/user community, regulating hitherto unregulated areas are some of the issues for further action in this field.

References

Abortion. (2003). Miller-Keane Encyclopaedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition. https://medical-dictionary.thefreedictionary.com/abortion Accessed on 3 June 2020.

Acharya, V. (1994). Status of Renal Transplant in India. *Journal of Postgraduate Medicine*, *40*(3), 158–161. https://www.jpgmonline.com/text.asp?1994/40/3/158/536.

AERB. (2014). Policies Governing Regulation of Nuclear and Radiation Safety. *GOI. AERB*

AERB. (2016). Compliance of Dental X-ray Facilities with Regulatory Requirements Stipulated in the Atomic Energy (Radiation Protection) Rules 2004. *GOI.*

AERB. (2018). Revised Guidelines for Obtaining Regulatory Consents from AERB for Medical Diagnostic X-Ray Equipment. *GOI.*

AERB. (2020). Guidelines for e-LORA Module of Dental Radiology Users. *GOI.*

Agrawal A. (2016). Medical Negligence: Indian Legal Perspective. *Annals of Indian Academy of Neurology, 19 (Suppl 1), S9–S14.* https://doi.org/10.4103/0972-2327.192889

Agrawal, D., & Goyal, P. (2011). Hospitals in Ancient India. *Ghadar Jari Hai*. 18-23. https://www.researchgate.net/publication/277817197_Hospitals_in_Ancient_India

Agarwal, S. K., Srivastava, R. K., Gupta, S., & Tripathi, S. (2012). Evolution of the Transplantation of Human Organ Act and Law in India. *Transplantation, 94(2), 110–113*.

Alavi, S. (2005). Unani Medicine in the Nineteenth-Century Public Sphere: Urdu Texts and the Oudh Akbar. *The Indian Economic and Social History Review*, *42(1), 101–129*. https://doi.org/10.1177/001946460504200104.

Ali, S. I. (2019, September 1). Rajasthan: Get Registered Before September 15 Under Clinical Establishment Act, Labs Told. *The Times of India E-paper*. https://timesofindia.indiatimes.com/city/jaipur/rajasthan-get-registered-before-september-15-under-clinical-establishment-act-labs-told/articleshow/70938102.cms.

All India Council for Technical Education. (2016). All India Board of Pharmaceutical Education. *GOI.*

Allied and Healthcare Professions Bill, 2018. *GOI.*

Andhra Pradesh Para Medical Board Act, 2006. *Government of Andhra Pradesh*.

Anshu, & Supe, A. (2016). Evolution of Medical Education in India: The Impact of Colonialism. *Journal of Postgraduate Medicine, 62(4), 255–259.* https://doi.org/10.4103/0022-3859.191011.

Aravind, B. S., Joy, E. T., Kiran, M. S., Sherubin, J. E., Sajesh, S., & Manchil, P. R. D. (2016). Attitude and Awareness of General Dental Practitioners Toward Radiation Hazards And Safety. *Journal of Pharmacy and Bioallied Sciences*. https://doi.org/10.4103/0975-7406.191969.

Asaithambi, A., Alagappan, U., Ragavendran, S., Ganesan, V., . S., . L., & Edwin, D. (2017). A Study on Notifiable Diseases Reported in a Tertiary Care Hospital. *International Journal Of Community Medicine And Public Health*, *4*(5), *1656–1660.* https://doi.org/10.18203/2394-6040.ijcmph20171779.

Ateriya, N., Saraf, A., Meshram, V., & Setia, P. (2018). Telemedicine and Virtual Consultation: The Indian perspective. *The National Medical Journal of India*, *31*(4), *215–218*. https://doi.org/10.4103/0970-258X.258220.

Atomic Energy Act, 1962. The Gazette of India Extraordinary. *GOI.*

Atomic Energy (Radiation Protection) Rules, 2004. The Gazette of India Extraordinary. *GOI.*

Avert. (2017). HIV Stigma and Discrimination. Avert. https://www.avert.org/professionals/hiv-social-issues/stigma-discrimination.

Avert. (2019). Human rights and HIV. Avert. https://www.avert.org/human-rights-and-hiv.

Avert. (2020). HIV and AIDS in India. Avert. https://www.avert.org/professionals/hiv-around-world/asia-pacific/india.

Bagga, R., Jaiswal, V., & Tiwari, R. (2015). Role of Directorates in Promoting Nursing and Midwifery Across the Various States of India: Call for Leadership for Reforms. *Indian Journal of Community Medicine*, *40(2), 90–96*. https://doi.org/10.4103/0970-0218.153870.

Bakshi, S. (2021). Parliamentary Committee Recommends Continuation of National Organ Transplant Program. *Medical Dialogues*. https://medicaldialogues.in/news/health/parliamentary-committee-recommends-continuation-of-national-organ-transplant-program-76264.

Balakrishnan, B., Kulkarni, K., Moirangthem, S., Kumar, C. N., Math, S. B., & Murthy, P. (2019). The Rights of Persons with Disabilities Act 2016: Mental Health Implications A. *Indian Journal of Psychological Medicine, 41(2), 119–125*. https://doi.org/10.4103/IJPSYM.IJPSYM_364_18.

Basak, S.C., & Sathyanarayana, D. (2010). Pharmacy Education in India. *American Journal of Pharmaceutical Education*, *74*(4). https://www.ajpe.org/content/74/4/68.

Basak, S.C., & Sathyanarayana, D. (2011). Pharmacy curriculum for practice in India: Needs and Gaps. *Pharma Review*, 9*(49), 53–55.* https://www.academia.edu/28858168/Pharmacy_curriculum_for_practice_in_India_needs_and_gaps.

Basak, S.C., Van Mil, J. W. F., & Sathyanarayana, D. (2009). The Changing Roles of Pharmacists in Community Pharmacies: Perception of Reality in India. *Pharmacy World and Science*, *31(6), 612–618.* https://doi.org/10.1007/s11096-009-9307-y.

Bathini, T. (2020, September 10). Two Years Since HIV & AIDS Act was Notified, Govts Have Done Little to Implement It. *The Wire*. https://thewire.in/government/hiv-aids-act-two-years-implementation.

BBC History Magazine. (2018). Collector's Edition: The Story of Medicine. *BBC History Magazine*.

Bell, R. C. (2012). The Ambulance: A History. *McFarland Incorporated Publishers.*

Benakatti, V., & Kanathila, H. (2018). Biomedical Waste Management in Dental Office - A Review. *World Journal of Advance Healthcare Research. 2 (4), 178-181.* https://www.wjahr.com/admin/assets/article_issue/8062018/1530615421.pdf

Bhatnagar, A. (2020, June 1). FIR Against Lab for 'Delaying Case Report''.' *The Indian Express*. https://indianexpress.com/article/cities/delhi/fir-against-lab-for-delaying-case-report-6436499/.

Bhuyan, A. (2018, January 18). Chhattisgarh's Sterilisation Deaths Have Changed Nothing for Family Planning Burden on Women. *The Wire*. https://thewire.in/health/sterilization-family-planning-women-burden.

Bloom, G., Henson, S., & Peters, D. H. (2014). Innovation in regulation of rapidly changing health markets. *Globalization and Health, 10(1), 53.* https://doi.org/10.1186/1744-8603-10-53

BMJ. (2020). Covid-19: India's Private Doctors and Government Clash Over Pandemic Response. *BMJ 2020*; 370: m3711 https://doi.org/10.1136/bmj.m3711

Board of Pharmaceutical Practice. (2021). Pharmacists. *International Pharmaceutical Federation.* https://www.fip.org/pharmaceutical-practice-and-the-fip-sections.

Boddupalli, R., & Francis, G. (2020). Epidemic Diseases (Amendment) Bill, 2020: A Missed Opportunity. *ILI Law Review. Special issue 2020, 302-315.*

Bombay High Court. (2017). In Case of Private Nursing Schools And ... vs The Union of India and Others dated 9 October 2017.

Bombay High Court. (2018). In the Case of Deepa Sanjeev Pawaskar vs The State of Maharashtra dated 25 July 2018. *Bombay High Court.*

British Dental Association. (2020a). Barber-Surgeons and Tooth Drawers. *British Dental Association*. https://bda.org/museum/the-story-of-dentistry/ancient-modern/barber-surgeons-and-toothdrawers. Accessed on 15 September 2020.

British Dental Association. (2020b). The First Dentists. *British Dental Association*. https://bda.org/museum/the-story-of-dentistry/ancient-modern/the-first-dentists. Accessed on 15 September 2020.

British Red Cross. (2018). British Red Cross Transport During the First World War. *The British Red Cross Society, 8.* https://vad.redcross.org.uk/.

Competition Commission of India. (2018). Policy Note: Making markets work for affordable healthcare. In *Competition Commission of India*.

Centers for Disease Control and Prevention. (2021). COVID-19 Overview and Infection Prevention and Control Priorities in non-US Healthcare Settings. *US Department of Health & Human Services*.

Central Bureau of Health Intelligence. (2019). National Health Profile of India- 2019 (14th Issue). *MoHFW, GOI.*

Central Motor Vehicles Rules, 1989. The Gazette of India Extraordinary. *GOI.*

Central Motor Vehicles (Ninth Amendment) Rules, 2016. The Gazette of India Extraordinary. *GOI.*

Centre for Law & Policy Research. (2021). Constitution of India, 1950. https://www.constitutionofindia.net/constitution_of_india Accessed on 8 September 2020.

Chanda, S., Dogra, V., Randhawa, S., Nagaraju, K., Hazarika, N., Shailendra Hegde, A. S., Varma, D., Deshmukh, A., & Phanse, V. (2019). The Design, Operations, and Feasibility of Primary Healthcare Service Delivery through Mobile Medical Units: A Way for Equitable Health Access and Achieving Universal Health Coverage in Low Resource Settings. *International Journal of Health Systems and Implementation Research, 3(2), 40–47*. https://ijhsir.ahsas-pgichd.org/index.php/ijhsir/article/view/43

Chandna, H. (2018, September 17). As India Struggles with Doctor Shortage, Govt Gives a Push to Nurse-Led Clinics. *The Print*. https://theprint.in/india/governance/as-india-struggles-with-doctor-shortage-govt-gives-a-push-to-nurse-led-clinics/118535/.

Chandrashekar, S., & Kantharaj, A. (2014). Legal and Ethical Issues in Safe Blood Transfusion. *Indian Journal of Anaesthesia*. https://doi.org/10.4103/0019-5049.144654.

Chari, B. (2020, December 2). Goa: A Year on, Rules to Appoint HIV Ombudsman Not Notified. *Times of India*. https://timesofindia.indiatimes.com/city/goa/a-yr-on-rules-for-appointing-hiv-ombudsman-yet-to-be-notified/articleshow/79519349.cms.

Chattopadhyay, S. (1974). Medical Termination of Pregnancy Act, 1971: A Study of the Legislative Process. *Journal of the Indian Law Institute, 16(4), 549–569.*

Chellaiyan, V., Nirupama, A., & Taneja, N. (2019). Telemedicine in India: Where Do We Stand? *Journal of Family Medicine and Primary Care, 8(6), 1872–1876.* https://doi.org/10.4103/jfmpc.jfmpc_264_19

Chhapia, H. (2017, September 15). SC Strips Indian Nursing Council of Power to Grant Colleges Recognition. *The Times of India.* http://timesofindia.indiatimes.com/articleshow/60521801.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Chhapia, H. (2020, January 3). Arts & Commerce Students May Get to Do BSc Nursing. *ETHealthworld.Com.* https://health.economictimes.indiatimes.com/news/policy/arts-commerce-students-may-get-to-do-bsc-nursing/73077444

Clinical Establishments (Central Government) Rules, 2012. The Gazette of India Extraordinary. *GOI.*

Clinical Establishments (Central Government) Amendment Rules, 2018. The Gazette of India Extraordinary. *GOI.*

Clinical Establishments (Central Government) Amendment Rules, 2020. The Gazette of India Extraordinary. *GOI.*

Clinical Establishments (Registration and Regulation) Act, 2010. The Gazette of India Extraordinary. *GOI.*

Coalition of Civil Society Organisations. (2020). Civil Society Recommendations on Making the Medical Termination of Pregnancy (Amendment) Bill 2020 A Rights Based Legislation.

Cock, K. M. De, Jaffe, H. W., & Curran, J. W. (2011). Reflections on 30 Years of AIDS. *Emerging Infectious Diseases*. https://doi.org/10.3201/eid1706.100184.

Consumer Protection Act, 2019. The Gazette of India Extraordinary. *GOI.*

Correspondent, H. (2019, May 15). Nursing Councils Write to PMO Demanding Removal of Indian Nursing Council President. *Hindustan Times*. https://www.hindustantimes.com/pune-news/nursing-councils-write-to-pmo-demanding-removal-of-indian-nursing-council-president/story-qmKzfMi2mVSTfI0EQEQpFJ.html.

Crane, J. (2013). 1774 Madhouses Act. *University of Warwick*. https://warwick.ac.uk/fac/arts/history/chm/outreach/trade_in_lunacy/research/1774madhousesact. Accessed on 12 February 2021.

Datta, D. (2014, October 9). Doctors in the Dock: Will Fuzzy Laws and Frivolous Cases Change the Way Medicine is Practiced in India? *India Today*. http://indiatoday.intoday.in/story/litigation-doctors-medicine-law-national-accreditation-board-for-hospitals/1/394983.html. Accessed on 17 October 2020.

Debnath, S. (2017). History of Pharmacy.

Deep, P. (2018). The Door Left Ajar: Evolution of Law of Torts in India. *International Journal of Law Management & Humanities*. 1(2).

Delhi Epidemic Diseases, COVID-19 Regulations, 2020. *Delhi Secretariat, Government of National Capital Territory of Delhi.* Delhi State Mental Health Authority. (2018). Minimum Standards for Mental Health Establishments as per Mental Healthcare Act 2017. *Government of National Capital Territory of Delhi.* Dental Council of India. (2017a). Dental Council of India. https://dciindia.gov.in/Home.aspx. Accessed on 18 September 2020.

Dental Council of India. (2017b). History of the Dental Council of India. https://dciindia.gov.in/History_DCI.aspx#. Accessed on 18 September 2020.

Dentists Act, 1948.The Gazette of India Extraordinary. *GOI.*

Dentists (Amendment) Act, 1993. The Gazette of India Extraordinary. *GOI.*

Dentists (Amendment) Act, 2016. The Gazette of India Extraordinary. *GOI.*

Department of Pharmaceuticals. (2013). National Pharmaceutical Pricing Authority. *GOI.*

Department Related Parliamentary Standing Committee on Health and Family Welfare. (2013). 73rd Report on the Indian Medical Council (Amendment) Bill, 2013. *MoHFW, GOI.*

Department-Related Parliamentary Standing Committee on Health and Family Welfare. (2015). 85th report of the Committee on the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Bill, 2014. *MoHFW, GOI.*

Department Related Parliamentary Standing Committee on Health and Family Welfare. (2016). 92nd Report on the Functioning of Medical Council of India. *MoHFW, GOI.*

Department Related Parliamentary Standing Committee on Health and Family Welfare. (2019). 115th report on the National Commission for Indian System of Medicine Bill, 2019. *MoHFW, GOI.*

Department Related Parliamentary Standing Committee on Health and Family Welfare. (2020). The 117th report on the Allied and Healthcare Professionals Bill, 2018. *MoHFW, GOI.*

DGHS. (2012). Indian Public Health Standards, Revised Guidelines. *MoHFW, GOI.*

DGHS. (2018). Minutes of 11th Meeting of the National Council for Clinical Establishments. *MoHFW, GOI.*

Dhot, P. S. (2005). Amendments to Indian Drugs and Cosmetics Act and Rules Pertaining to Blood Banks in Armed Forces. *Medical Journal Armed Forces India, 61(3), 264–266.* https://doi.org/10.1016/S0377-1237(05)80170-4.

Disaster Management Act, 2005. The Gazette of India Extraordinary. *GOI.*

Dixon, A., Harrison, T., & Mundle, C. (2011). Economic Regulation in Health Care: What Can We Learn from Other Regulators? *In The King's Fund 2011 (Issue Kings Fund, pp. 1–48).*

Dodgson, R., Lee, K., & Drager, N. (2002). Global Health Governance, A Conceptual Review. *World Health Organization, 1, 439–461.* https://doi.org/10.4324/9781315254227-33.

Draft Drugs and Cosmetics (Amendment) Rules, 2018. *GOI.*

Draft National Heath Bill, 2009. MoHFW, GoI Working Draft: Version January '09. *GOI.*

Drugs and Cosmetics Act, 1940. The Gazette of India Extraordinary. *GOI.*

Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

Drugs and Cosmetics (Eleventh Amendment) Rules, 2019. The Gazette of India Extraordinary. *GOI.*

Drugs and Cosmetics (Tenth Amendment) Rules, 2017. The Gazette of India Extraordinary. *GOI.*

Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. The Gazette of India Extraordinary. *GOI.*

Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955. The Gazette of India Extraordinary. *GOI.*

Drugs (Prices Control) Order, 2013. The Gazette of India Extraordinary. *GOI.*

Duffy, R. M., & Kelly, B. D. (2019). India's Mental Healthcare Act, 2017: Content, Context, Controversy. *International Journal of Law and Psychiatry, 62, 169–178.* https://doi.org/10.1016/j.ijlp.2018.08.002.

Duggal, R. (2007). Chapter one: Right to Health and Health Care- Theoretical Perspective. In M. Desai & K. B. Mahabal (Eds.), Health Care Case Law in India: A reader (p. 200). *Centre for Enquiry into Health and Allied Themes (CEHAT) and India Centre for Human Rights & Law (ICHRL).*

Duggal, R., & Ramachandran, V. (2004). The Abortion Assessment Project-India: Key findings and recommendations. *Reproductive Health Matters*, *12(24 SUPPL.), 122–129*. https://doi.org/10.1016/S0968-8080(04)24009-5

Dutt, A. (2019, September 30). Delhi Drafts Rules for Appointment of Officer to Keep a Check on Discrimination Against People with HIV. *Hindustan Times*. https://www.hindustantimes.com/cities/delhi-drafts-rules-for-appointment-of-officer-to-keep-a-check-on-discrimination-against-people-with-hiv/story-4iovGfpQK16az9UnCaOLeI.html

Dutta, A., Nagarajan, S., & Choudhary, P. (2020). Resetting Outcome Targets of Community Surgery Camps: The Case of the Chhattisgarh Tragedy. *Indian Journal of Medical Ethics, V(1), 45–48*. https://doi.org/10.20529/IJME.2020.018

Economic Times. (2014). IMA Opposes Government's Proposed Amendments to the MTP Act. *The Economic Times.* https://economictimes.indiatimes.com/news/politics-and-nation/ima-opposes-governments-proposed-amendments-to-the-mtp-act/articleshow/45060077.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Education Regulations, 1991. The Gazette of India Extraordinary. *GOI.*

EH News Bureau. (2019, August 23). No Rules to the Game. *Express Healthcare*. https://www.expresshealthcare.in/lab-diagnostics/no-rules-to-the-game/116862/

Ensor, T., & Weinzierl, S. (2006). A Review of Regulation in the Health Sector in Low and Middle Income Countries.

Epidemic Diseases Act, 1897. The Gazette of India Extraordinary. *GOI*.

Epidemic Diseases (Amendment) Act, 2020. The Gazette of India Extraordinary. *GOI.*

ET Bureau. (2020, April 1). Andhra Pradesh to take over private hospitals to tackle Covid-19. *The Economic Times.* https://economictimes.indiatimes.com/news/politics-and-nation/andhra-pradesh-to-take-over-private-hospitals-to-tackle-covid-19/articleshow/74922440.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Evolution of the Ambulance. (2010). *Fire History*. http://firehistory.weebly.com/evolution-of-the-ambulance.html Accessed on 2 March 2021.

Express News Service. (2018, November 2). Diagnostic Reports 'Have No Signature of Authorised Pathologist'; Police Case Against Lab. *The Indian Express*. https://indianexpress.com/article/cities/mumbai/diagnostic-reports-have-no-signature-of-authorised-pathologist-police-case-against-lab-5430262/

Express News Service. (2020, February 11). GPS Must for Ambulances from March. *The New Indian Express*. https://www.newindianexpress.com/states/kerala/2020/feb/11/gps-must-for-ambulances-from-march-2101725.htmlFamily Planning Division. (2013). Manual for Family Planning Indemnity Scheme. *MoHFW, GOI*.

Farreras, I. G. (2021). History of Mental Illness. In R. Biswas-Diener & E. Diener (Ed.), *Noba textbook series: Psychology. Champaign, IL: DEF publishers*.

Feigenbaum, E. (n.d.). Home Health Agency Regulatory Requirements. https://smallbusiness.chron.com/home-health-agency-regulatory-requirements-3025.html. Accessed on 27 January 2021.

Firdosi, M. M., & Ahmad, Z. Z. (2016). Mental Health Law in India: Origins and Proposed Reforms. *B J Psych. International*, *13*(3), 65–67. https://doi.org/10.1192/s2056474000001264.

Ganesh, M. (2020, February 17). How a Proper Regulatory Framework Can Help Home Healthcare Achieve Its Full Growth Potential. *The Economic Times.* https://economictimes.indiatimes.com/prime/pharma-and-healthcare/how-a-proper-regulatory-framework-can-help-home-healthcare-achieve-its-full-growth-potential/primearticleshow/74165231.cms?from=mdr.

Garg, K., Kumar, C. N., & Chandra, P. S. (2019). Number of Psychiatrists in India: Baby Steps Forward, But Long Way to Go. *Indian Journal of Psychiatry*, *61*(1), 104–105.

Garima. (2021, January 27). Health Ministry Orders Regulation of Online Health Service Aggregators. *Medical Dialogues*. https://medicaldialogues.in/news/health/hospital-diagnostics/health-ministry-ordes-regulation-of-online-health-service-aggregators-73957.

GBD 2017 Disease and Injury Incidence and Prevalence Collaborators. (2018). Global, regional, and national incidence, prevalence, and years lived with disability for 354 Diseases and Injuries for 195 countries and territories, 1990-2017: A systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*, *392*(10159), 1789–1858. https://doi.org/10.1016/S0140-6736(18)32279-7.

Genet, N., Boerma, W., Kroneman, M., Hutchinson, A., & Saltman, R. B. (2012). Home Care Across Europe - Current structure and future challenges. *European Observatory on Health Systems and Policies*.

Ghosh, A. K. (2010). A Short History of the Development of Homeopathy in India. *Homeopathy*, *99(2), 130–136*. https://doi.org/10.1016/j.homp.2009.10.001.

Gill, R. (2016). Scarcity of Nurses in India: A Myth or Reality? *Journal of Health Management*, *18*(4), *509–522*. https://doi.org/10.1177/0972063416665932.

Global Observatory on Donation and Transplantation. (2019). International Report on Organ donation and transplantation Activities, Executive Summary. *WHO*.

GoDental, A. (2020). History of Dentistry. *ADEA GoDental*. https://www.adea.org/GoDental/Health_Professions_Advisors/History_of_Dentistry.aspx.

Gopikumar, V. (2010). Comment on "The Mental Health Act 1987: Quo Vadimus"? *Indian Journal of Medical Ethics*, *7(4), 234–236*. https://doi.org/10.20529/ijme.2010.086.

GOI. (1946). Report of the Health Survey and Development Committee, Volume II, Recommendations. *The Manager of Publications, Delhi*.

GOI. (2006). Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure. *Planning Commission, GOI, 1–25.*

GOI. (2017). Lok Sabha Unstarred Question No. 137 answered on 15.12.2017. Demand to Prescribe Allopathic Medicines. *GOI.*

Government of Odisha. (2020). Directorate of Nursing, Department of Health and Family Welfare. http://nursingodisha.nic.in/ Accessed on 3 September 2020.

Government of Rajasthan. (2009). National Programme for Control of Blindness: Norms of Service delivery in Eye Camps. http://rajswasthya.nic.in/Norms of Service delivery in Eye Camps.pdf.

Government of Rajasthan. (2019). Indian Medicine Board, Jaipur. Rajasthan. https://health.rajasthan.gov.in/content/raj/medical/rajasthan-indian-medicine-board/en/about-us.html#. Accessed on 14 September 2020.

Government of Tamil Nadu. (2015). Health and Family Welfare Department: Registration of Indian System of Medicine & Homeopathy Practitioners. http://www.tnhealth.org/imh/imcouncil.html Accessed on 14 September 2020.

Goyal, P. (2020). The Epidemic Diseases Act, 1897 Needs An Urgent Overhaul. *Economic and Political Weekly*, *55*(45). https://www.epw.in/engage/article/epidemic-diseases-act-1897-needs-urgent-overhaul.

Graham, J. (2020). The History of the Ambulance. *History of Yesterday*. https://medium.com/history-of-yesterday/the-history-of-the-ambulance-ecc2d63fb1a6

Gupta, P. (2020, November 11). Much Awaited Draft Legislation on Nursing Does Little to Transform the Profession. Science, *The Wire*. https://science.thewire.in/health/national-nursing-midwifery-commission-bill-2020-public-feedback-shortcomings/.

Gupta, R. (2019, August 27). Abortion in India: Experts Call for Changes. *Down to Earth*. https://www.downtoearth.org.in/news/health/abortion-in-india-experts-call-for-changes-66369.

Gulati, R. (2020, December 1). E-Pharmacies V. Retail Pharmacies: The Honest Truth. *ETHealthworld.Com*. https://health.economictimes.indiatimes.com/news/pharma/e-pharmacies-v-retail-pharmacies-the-honest-truth/79502206

Hardas, A. P. (2012). Glimpse of Pharmacy Profession in India. *Journal of Drug Delivery and Therapeutics*. https://doi.org/10.22270/jddt.v2i2.123.

Havens, B. (1999). Home-Based and Long-Term Care: Home Care Issues and Evidence. *WHO*. https://www.who.int/chp/knowledge/publications/home_based_and_ltc_issues_evidence.pdf.

Health Sector Skill Council. (2013). Occupational Mapping Report: Allied Health and Paramedic Sector. *KPMG*.

High Court of Delhi. (2019). Order by the Justice Shankar in the High Court of Delhi dated 24 July 2019, New Delhi.

High Court of Delhi. (2020). Dr. Rohit Jain vs Govt Of NCT of Delhi and Ors dated 6 August 2020, New Delhi.

High Court of Karnataka. (2017). Order by the Justice Swamy, L. in the High Court of Karnataka dated 24 July 2017, Bangalore.

Highlights of Transfusion Medicine History. (2021). *AABB*. https://www.aabb.org/news-resources/resources/transfusion-medicine/highlights-of-transfusion-medicine-history. Accessed on 10 January 2021.

Himachal Pradesh Paramedical Council Act, 2003. *Himachal Pradesh Gazette.*

History of Blood Banking. (2021). Community Blood Center. https://givingblood.org/about-blood/history-of-blood-banking.aspx. Accessed on 12 January 2021.

History of the Knights of Malta. (2018). *The Way back Machine*. https://web.archive.org/web/20180827113117/http://www.knightsofmalta.com/history/history.html Accessed on 2 March 2021.

Homoeopathy Central Council Act, 1973. The Gazette of India Extraordinary. *GOI.*

Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982. The Gazette of India Extraordinary. *GOI.*

Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017. The Gazette of India Extraordinary. *GOI.*

Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Rules, 2018. The Gazette of India Extraordinary. *GOI.*

Human Rights Law Network. (2018). After HRLN's Files PIL, Health Ministry Issues Gazette Notification on Implementation of HIV & AIDS Act, 2017. *Human Rights Law Network*.

Hussain, A., & Khan, F. (2014). History of Dentistry Earlier Times: Period of Antiquity. *Archives of Medicine and Health Sciences*, *2*(1), 106–110. https://doi.org/10.4103/2321-4848.133850.

IANS. (2017, April 3). Home Healthcare Gaining Ground, But What About Regulations*? Financial Express*. https://www.financialexpress.com/lifestyle/health/home-healthcare-gaining-ground-but-what-about-regulations/612894/

IDSP. (2021). National Centre for Disease Control. *MoHFW, GOI*. https://www.idsp.nic.in/index4.php?lang=1&level=0&linkid=406&lid=3689. Accessed on 26 March 2021.

IMA. (2020). IMA White Paper: Every Pharmacist Must Know Certain MCI Rules. *Indian Medical Association*. https://www.ima-india.org/ima/left-side-bar.php?pid=231.

Indian Medicine Central Council Act, 1970. The Gazette of India Extraordinary. *GOI.*

Indian Medical Council Act, 1956. The Gazette of India Extraordinary. *GOI.*

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. The Gazette of India Extraordinary. *GOI.*

Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2020. The Gazette of India Extraordinary. *GOI.*

Indian Nursing Council. (2016). Nurse Practitioner in Critical Care (Postgraduate-Residency Program). *GOI.*

Indian Nursing Council. (2019a). Notification: Integration of Middle Level Health Provider (MLHP). *Indian Nursing Council*.

Indian Nursing Council. (2019b). Notification on Single Entry Level for Nursing-Phasing out of GNM Programme, dated 14 March 2019. *Indian Nursing Council*.

Indian Nursing Council Act, 1947. The Gazette of India Extraordinary. *GOI.*

Indian Nursing Council (Amendment) Act, 1957. The Gazette of India Extraordinary. *GOI.*

Indian Nursing Council (Conduct of Business) Regulations, 2009. The Gazette of India Extraordinary. *GOI.*

Indian Nursing Council Regulations, (n.d.). The Gazette of India Extraordinary. *GOI.*

Information Technology Act, 2000. The Gazette of India Extraordinary. *GOI.*

Insurance Regulatory and Development Authority of India. (2020). Circular on Disclosure of Underwriting Philosophy of Offering Insurance Coverage to Persons with Disability (PWD) and People Affected with HIV/AIDS and Mental Illness Diseases. *IRDAI*.

International Institute for Population Sciences. (2017). National Family Health Survey (NFHS -4), 2015-16: India. *Mumbai: IIPS*.

Jacob, A. (1974). Abortion Law Reform: A Study of the Medical Termination of Pregnancy Act, 1971. *Journal of the Indian Law Institute*, *16*(4), 570–592.

Jain, A., Nundy, S., & Abbasi, K. (2014). Corruption: Medicine's Dirty Open Secret. *BMJ*; *348*: g4184 doi:10.1136/bmj.g4184.

Jain, D. (2019). Time to Rethink Criminalisation of Abortion? Towards A Gender Justice Approach. *NUJS Law Review*, *1*.

Jain, D. (2020, March 15). Proposed Changes to Abortion Law Continue to Sideline Pregnant Persons. *The Wire Science.* https://science.thewire.in/health/proposed-changes-to-abortion-law-continue-to-sideline-pregnant-persons/.

Jain, D., & Tronic, B. (2019). Conflicting Abortion Laws in India: Unintended Barriers to Safe Abortion for Adolescent Girls. *Indian Journal of Medical Ethics*, *IV (4), 310–317.* https://doi.org/10.20529/IJME.2019.059.

Jain, R., & Rao, B. (2016). India's Focus on Medical Diagnostic Laboratories: Indian planning and programmes. *In 22 March 2016: 22nd International Academic Conference, Lisbon*. https://doi.org/10.20472/IAC.2016.022.026.

Jejeebhoy, S. J., Kalyanwala, S., Mundle, S., Tank, J., Zavier Francis, A. J., Kumar, R., Acharya, R., & Jha, N. (2012). Feasibility of Expanding the Medication Abortion Provider Base in India to Include Ayurvedic Physicians and Nurses. *International Perspectives on Sexual and Reproductive Health*, *38(3), 133–142.* https://doi.org/10.1363/3813312.

Joelving, F. (2015). India's "Health Camps": The Drug Rep Will See You Now. *BMJ (Online)*, *351*(December), 1–8. https://doi.org/10.1136/bmj.h6413.

Johns Hopkins Medicine. (2021). Haematology. *The Johns Hopkins University*. https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/hematology. Accessed on 25 February 2021.

Kannan, R. (2016, June 8). More People Opting For Private Healthcare. *The Hindu*. https://www.thehindu.com/sci-tech/health/more-people-opting-for-private-healthcare/article4967288.ece.

Karan, A., Negandhi, H., Nair, R., Sharma, A., Tiwari, R., & Zodpey, S. (2019). Size, Composition and Distribution of Human Resource for Health in India: New Estimates Using National Sample Survey and Registry Data. *BMJ Open*, *9*(4). https://doi.org/10.1136/bmjopen-2018-025979.

Karimi, H., & Masoudi Alavi, N. (2015). Florence Nightingale: The Mother of Nursing. *Nursing and Midwifery Studies*. https://doi.org/10.17795/nmsjournal29475.

Kaur, H. (2020). Can the Indian legal framework deal with the COVID-19 pandemic? A review of the Epidemic Diseases Act. *Bar & Bench.* https://www.barandbench.com/columns/can-the-indian-legal-framework-deal-with-the-covid-19-pandemic-a-review-of-the-epidemics-diseases-act

Kaur, H., Paleja, A., & Srivastava, S. (2020). Legal and Regulatory Framework for Laboratory Testing in India: A Case Study for Covid-19. *The Leap Blog*. https://blog.theleapjournal.org/2020/07/legal-and-regulatory-framework-for.html.

Kedia, R. (2016). HIV/AIDS Legislation in India - A Primer. *Indian Law Journal*. https://indialawjournal.org/hiv-aids-legislation-in-india-a-primer.php.

Kelkar, R. V. (1974). Impact of the Medical Termination of Pregnancy Act, 1971: A Case Study. *Journal of the Indian Law Institute*, *16*(4), 593–625.

Kelly, H. (2011). The Classical Definition of a Pandemic is Not Elusive. *Bulletin of the World Health Organization. 89:540-541*. doi: 10.2471/BLT.11.088815

Kerala Clinical Establishments (Registration and Regulation) Act, 2018. *Government of Kerala.*

Keshri, V. R. (2018). Government Stewardship for Health Care: A Scoping Review of Regulatory Frameworks for Health Care Providers. Working Paper 03/2018. *The Centre for Health Policy*.

Khadria, B. (2007). International Nurse Recruitment in India. *Health Services Research*, *42(3 II), 1429–1436.* https://doi.org/10.1111/j.1475-6773.2007.00718.x.

Khakurel, B., Shrestha, R., Joshi, S., & Thomas, D. (2019). Chapter 2: Evolution of the Pharmacy Profession and Public Health. In *D. Thomas (Ed.), Clinical Pharmacy Education, Practice and Research (pp. 13–30). Elsevier.*

Khanna, A. B., & Narula, S. A. (2016). Mobile Health Units: Mobilizing Healthcare to Reach Unreachable. *International Journal of Healthcare Management*, *9*(1), 58–66. https://doi.org/10.1080/20479700.2015.1101915.

Kieny, M. P., Bekedam, H., Dovlo, D., Fitzgerald, J., Habicht, J., Harrison, G., Kluge, H., Lin, V., Menabde, N., Mirza, Z., Siddiqi, S., & Travis, P. (2017). Strengthening health systems for universal health coverage and sustainable development. *Bulletin of the World Health Organization*. https://doi.org/10.2471/BLT.16.187476.

Kiersey, R. A., & Coleman, A. (2017). Approaches to the Regulation and Financing of Home Care Services in Four European Countries. An Evidence Review. *Health Research Board.*

Koop, C., & Lodge, M. (2017). What is Regulation? An Interdisciplinary Concept Analysis. *Regulation and Governance, 11(1), 95–108.* https://doi.org/10.1111/rego.12094

Krishnan, S. (2015). MTP Amendment Bill, 2014: Towards Re-Imagining Abortion care. *Indian Journal of Medical Ethics, XII (1), 43–46*. https://ijme.in/wp-content/uploads/2016/11/2028-5.pdf .

Kumar, M. S. (2020, March 10). PIL Seeks to Make Private Hospitals Accountable. *The Times of India E-paper*.http://timesofindia.indiatimes.com/articleshow/74558240.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Kumar, V. (2020, July 1). Punjab Blinks Again on Clinical Establishment Ordinance. *The Times of India E-paper*. https://timesofindia.indiatimes.com/city/chandigarh/pb-blinks-again-on-clinical-establishment-ordinance/articleshow/76721192.cms

Kumari, A. (2019). Careers in Audiology and Speech-Language Pathology. *Employment News*. http://employmentnews.gov.in/newemp/MoreContentNew.aspx?n=InDepthJobs&k=30172

Kumari, S., Mishra, S., & Mishra, P. (2018). An Evidence-Based Review on Quackery in Dentistry. *BLDE Univ J Health Sci*, *3(2), 75–78*.

Kunnathoor, P. (2019). PCI Imposes Moratorium on Fresh D Pharm & B Pharm Courses for 5 years from 2020-21; North East Region Exempted. *PharmaBiz.Com*. http://www.pharmabiz.com/NewsDetails.aspx?aid=117096&sid=1.

Lalchandani, K. (2020, July 27). Should Healthcare be Covered Under Consumer Protection Act, 2019? *Mint*. https://www.livemint.com/opinion/online-views/opinion-should-healthcare-be-covered-under-consumer-protection-act-2019-11595840683770.html. Accessed on 17 October 2020.

LOCOST. (2006). A Lay Person's Guide to Medicines. *LOCOST*.

Loudon, I. (2006). A Brief History of Homeopathy. *Journal of the Royal Society of Medicine*, *99(12), 607–610*. https://doi.org/10.1258/jrsm.99.12.607.

M.P. Paramedical Council (Maintenance, Publication and Revision of Register and Appeal) Rules, 2001. *Government of Madhya Pradesh*.

M.P. Sah Chikitsiy Parishad Adhiniyam, 2000. *Government of Madhya Pradesh*.

Maharashtra Paramedical Council Act, 2011. *Maharashtra Government Gazette*.

Manchester Specialty Programs. (2021). State Licensure and Inspection Requirements for Home Care Firms. https://www.manchesterspecialty.com/home-health-care-requirements/ Accessed on 27 January 2021.

Mandal, D. (2012). Recent Trends in Pharmacy Education in India. *PharmaBiz.Com*. http://pharmabiz.com/NewsDetails.aspx?aid=72517&sid=21.

Mangine, D. (2017). The History of Allied Health Professions. *SIMTAIK BLOG.* https://blog.simtalkblog.com/blog/2017/11/02/history-allied-health-professions Accessed on 5 December 2020.

Mann, G. (2019). The Allied and Healthcare Professions Bill, 2018: Bill Summary. *PRS Legislative Research*.

Manorama Online. (2019, January 31). Nurses Can Work Anywhere in India, Rules Supreme Court. *Manorama*. https://www.onmanorama.com/news/india/2019/01/31/nurses-can-work-anywhere-in-india-rules-supreme-court.html

Marwaha, N. (2015). Voluntary Blood Donation in India: Achievements, Expectations and Challenges. *Asian Journal of Transfusion Science*. https://doi.org/10.4103/0973-6247.157011

Math, S. B., Vinay Basavaraju, S. N. H., Gowda, G. S., Manjunatha, N., Kumar, C. N., & Gowda, M. (2019). Mental Healthcare Act 2017 – Aspiration to Action. *Indian Journal of Psychiatry*, *61(10).*

Mathrubhumi. (2011, November 18). Nursing Concern. *Mathrubhumi.Com*. https://english.mathrubhumi.com/features/women/nursing-concern-1.32505.

Medical Devices Rules, 2017. The Gazette of India Extraordinary. *GOI.*

Medical Dialogues Bureau. (2021, February 8). Notified Minimum Standards for Different Categories of Mental Health Establishments: Center to Delhi HC. *Medical Dialogues*. https://medicaldialogues.in/news/health/notified-minimum-standards-for-different-categories-of-mental-health-establishments-center-to-delhi-hc-74337.

Medical Termination of Pregnancy Act, 1971. The Gazette of India Extraordinary. *GOI.*

Medical Termination of Pregnancy (Amendment) Act, 2002. The Gazette of India Extraordinary. *GOI.*

Medical Termination of Pregnancy (Amendment) Act, 2021. The Gazette of India Extraordinary. *GOI.*

Medical Termination of Pregnancy Regulations, 1975. The Gazette of India Extraordinary. *GOI.*

Medical Termination of Pregnancy Regulations, 2003. The Gazette of India Extraordinary. *GOI.*

Medical Termination of Pregnancy Rules, 1975. The Gazette of India Extraordinary. *GOI.*

Medical Termination of Pregnancy Rules, 2003. The Gazette of India Extraordinary. *GOI.*

Meningitis Research Foundation. (April 2020). Outbreak, Epidemic, Pandemic-What's the Difference? https://www.meningitis.org/blogs/outbreak-epidemic-pandemic-difference. Accessed on 21 March 2020.

Mental Health Act, 1987. The Gazette of India Extraordinary. *GOI.*

Mental Healthcare Act, 2017. The Gazette of India Extraordinary. *GOI.*

Mental Healthcare (Central Mental Health Authority and Mental Health Review Boards) Rules, 2018. The Gazette of India Extraordinary. *GOI.*

Mental Healthcare (State Mental Health Authority) Rules, 2018. The Gazette of India Extraordinary. *GOI.*

Merriam-Webster. (2021). Nurse. *Merriam-Webster.* https://www.merriam-webster.com/dictionary/nurse. Accessed on 12 August 2020.

Ministry of AYUSH. (2020a). Annexure-I Administrative Set-up (Organograms) of Indian System of Medicine and Homoeopathy (AYUSH) in States / Union Territories. *GOI, 214-240.*

Ministry of AYUSH. (2020b). Introduction. *GOI, 1-58.*

Ministry of AYUSH. (2020c). List of State Boards / Councils of Indian System of Medicine & Homoeopathy. *GOI, 1, 346–347.*

Ministry of AYUSH. (2021). *GOI*. https://main.ayush.gov.in/.

Ministry of Education. (2019). Graduate Pharmacy Aptitude Test (GPAT). *GOI*.

Ministry of Health. (1961). Report of the Health Survey and Planning Committee (August 1959-october1961). *GOI.*

Ministry of Health and Family Planning. (1966). Report of the Committee to Study the Question of Legalisation of Abortion. *GOI.*

Mishra, A., & Galhotra, A. (2018). Mental Healthcare Act 2017: Need to Wait and Watch. *International Journal of Applied and Basic Medical Research*, *8(2), 67–70*.

MoHFW. (2005). Report of the National Commission on Macroeconomics and Health. *GOI*.

MoHFW. (2010a). Clinical Establishments (Registration and Regulation) Act, 2010: Minimum Standards. *GOI*.

MoHFW. (2010b). Clinical Establishments (Registration and Regulation) Act, 2010: Standard Treatment Guidelines (Speciality/Super Speciality wise). *GOI*.

MoHFW. (2014). Guidelines on Processing Charges for Blood and Blood Components. *GOI*.

MoHFW. (2015a). Highlights of National Organ and Tissue Transplant Programme and Operational Guidelines for its Implementation. *GOI*.

MoHFW. (2015b). Operational Guidelines for Mobile Medical Units. *GOI*.

MoHFW. (2018). Guidelines on Midwifery Services in India. *GOI*.

MoHFW. (2019). Status of Applicability of Transplantation of Human Organs and Tissues Act (THOTA). *GOI*.

MoHFW. (2020a). Central Drugs Standard Control Organisation (CDSCO). *GOI*. https://cdsco.gov.in/opencms/opencms/en/Home/ Accessed on 23 November 2020.

MoHFW. (2020b). Coronavirus Disease 2019 (COVID-19): Standard Operating Procedure (SOP) for Transporting a Suspect/Confirmed Case of COVID-19. *GOI*.

MoHFW. (2021a). National Blood Transfusion Council. *GOI.*

MoHFW. (2021b). National Mental Health Programme. *GOI.*

MoHFW. (n.d.). Guidelines for the Management of Common Mental Disorders. *GOI*.

Moore, L. (1999). Measuring Quality and Effectiveness of Prehospital EMS. *Prehospital Emergency Care*. https://doi.org/10.1080/10903129908958963.

Motor Vehicles Act, 1988. The Gazette of India Extraordinary. *GOI.*

Motor Vehicles (Amendment) Act, 2019. The Gazette of India Extraordinary. *GOI.*

Motor Vehicles (Driving) Regulations, 2017. The Gazette of India Extraordinary. *GOI.*

Mudur, G. (2004). Inadequate Regulations Undermine India's Health Care. *BMJ, 328(124).* https://doi.org/10.1136/bmj.328.7432.124-a

Murthy, P., Malathesh, B., Kumar, C., & Math, S. (2016). Mental Health and The Law: An overview and Need to Develop and Strengthen the Discipline of Forensic Psychiatry in India. *Indian Journal of Psychiatry*, *58(6), 181–186.* https://doi.org/10.4103/0019-5545.196828.

NACO. (2007a). Antiretroviral Therapy Guidelines for HIV-Infected Adults and Adolescents Including Post-Exposure Prophylaxis. *MoHFW, GOI.*

NACO. (2007b). National Blood Policy. *MoHFW, GOI*

NACO. (2007c). Voluntary Blood Donation Programme - An Operational Guideline. *MoHFW, GOI.*

NACO. (2012). Operational Guidelines for ART Services. *MoHFW, GOI.*

NACO. (2013). National Guidelines on Second line and Alternative First-line ART for Adults and Adolescents. *MoHFW, GOI.*

NACO. (2014). National AIDS Control Programme: Phase IV (2012-2017)- Strategy Document. *MoHFW, GOI.*

NACO. (2015a). Data Protection Guideline of National Aids Control Programme. *MoHFW, GOI.*

NACO. (2015b). National Guidelines for HIV Testing. *MoHFW, GOI.*

NACO. (2016a). A Report on the Assessment of Blood Banks in India. *MoHFW, GOI.*

NACO. (2016). National AIDS Control Organization, Annual Report 2015-16. *MoHFW, GOI.*

NACO. (2018). Data Sharing Guidelines. *MoHFW, GOI.*

NACO. (2019). India HIV Estimates 2019 Report. *MoHFW, GOI.*

NACO. (2020). Reply to RTI Application. *MoHFW, GOI.*

Nagar, D. (2019, September 23). An Opt-Out Model for Organ Donation. *Deccan Herald*. https://www.deccanherald.com/opinion/panorama/an-opt-out-model-for-organ-donation-763526.html

Nandraj, S. (2012). Unregulated and Unaccountable: Private Health Providers. *Economic & Political Weekly*, *XLVII* (4).

Nandraj, S. (2018). Chapter 26, Regulating Healthcare Establishments: The Case of the Clinical Establishments Act, 2010. In S. Nundy, K. Desiraju, & S. Nagral (Eds.), *Healers or Predators? Healthcare Corruption in India.* Oxford University Press.

Nandraj, S. (2019). Regulation for Better Governance. *Seminar*, *714* (February), *57–60*.

Nandraj, S., & Khot, A. (2003). Accreditation System for Health Facilities: Challenges and Opportunities. *Economic and Political Weekly, 38(50), 5251–5255.* https://doi.org/10.2307/4414398

Narasimhan, G., Kota, V., & Rela, M. (2016). Liver Transplantation in India. *Liver Transplantation*, *22*(7), 1019–1024.

Narayan, C. L., & John, T. (2017). The Rights of Persons with Disabilities Act, 2016: Does it Address the Needs of the Persons with Mental Illness and Their Families. *Indian Journal of Psychiatry*, *59(1), 17–20.*

Narayan, C. L., & Shikha, D. (2013). Indian Legal System and Mental Health. *Indian Journal of Psychiatry*, *55(6), 177–181.*

Narayan, P. (2019, June 29). Tamil Nadu: 20,000 Clinical Establishments Face Closure Over Registration. *The Times of India Epaper*. https://timesofindia.indiatimes.com/city/chennai/tamil-nadu-20000-clinical-establishments-face-closure-over-registration/articleshow/69997193.cms.

Narcotic Drugs and Psychotropic Substances Act, 1985. The Gazette of India Extraordinary. *GOI.*

Narcotic Drugs and Psychotropic Substances Rules, 1985. The Gazette of India Extraordinary. *GOI.*

National Accreditation Board for Hospitals & Health care Providers. (n.d.). *Quality Council of India*. https://nabh.co/introduction.aspx. Accessed on 30 December 2020.

National Ambulance Code. (2013). Automotive Industry Standard: Constructional and Functional Requirements for Road Ambulances. *Ministry of Road Transport and Highways, GOI*.

National Commission for Allied and Healthcare Professions Act, 2021. The Gazette of India Extraordinary. *GOI.*

National Commission for Homoeopathy Act, 2020. The Gazette of India Extraordinary. *GOI.*

National Commission for Indian System of Medicine, 2020. The Gazette of India Extraordinary. *GOI.*

National Dental Commission Bill 2020, Public Notice. *GOI*.

National Disaster Management Authority. (2020). Order No. 1-29/2020-PP (Pt.II) dated 24 Mar 2020. *GOI*.

National Health Mission. (2020). ERS/ Patient Transport Service. *MoHFW, GOI*.

National Health Mission. (2021a). Free Drugs & Diagnostics Service Initiative. *MoHFW, GOI*.

National Health Mission. (2021b). Mobile medical units (MMUs). *MoHFW, GOI*.

National Medical Commission. (2019). Rules and Regulations, NMC. *GOI*. https://www.nmc.org.in/rules-regulations-nmc Accessed on 12 October 2020.

National Medical Commission Act, 2019. The Gazette of India Extraordinary. *GOI.*

National Organ and Tissue Transplant Organization. (2013). History of Renal Transplantation. *MoHFW, GOI*.

National Organ and Tissue Transplant Organization. (2018). Transplantation Trends. *MoHFW, GOI*. https://www.notto.gov.in/transplant-trends.html.

National Organ and Tissue Transplant Organization. (2019). Organ Report. *MoHFW*, GOI. https://notto.gov.in/organreport.html.

National Programme for Control of Blindness & Visual Impairment. (2018). State Wise Targets & Achievement for Various Eye Diseases During 2018-19. *MoHFW, GOI*.

National Rural Health Mission. (2010). Guidelines for Antenatal Care and Skilled Attendance at Birth by ANMs/LHVs/SNs. *MoHFW, GOI.*

Nautiyal, S. (2020). Maharashtra FDA Receives Complaints about 543 Medical Stores Running Without Pharmacists. *PharmaBiz.Com*. http://www.pharmabiz.com/NewsDetails.aspx?aid=131035&sid=1

Newsroom. (2020). Crazy Ambulance Charges in India: COVID Patients Delivery Costs More Than A Flight. *Emergency Live.* https://www.emergency-live.com/ambulance/crazy-ambulance-charges-in-india-for-covid-patients-delivery/

NHSRC. (2010). Emergency Medical Service (EMS) in India: A Concept Paper. *MoHFW, GOI*.

NHSRC. (2017). Guidelines and Request for Proposal for AERB Compliance for Public Health Facilities. *MoHFW, GOI*.

Niti Aayog. (2016). A Preliminary Report of the Committee on the Reform of the Indian Medical Council Act, 1956. *GOI.*

Niti Aayog. (2017). A Preliminary Report of the Committee on the Reform of the IMCC Act, 1970 and HCC Act, 1973. *GOI.*

Nizamie, S. H., & Goyal, N. (2010). History of Psychiatry in India. *Indian Journal of Psychiatry*, *52(1).* https://doi.org/10.4103/0019-5545.69195

Noha. (2016, November 6). MP Medical Council Opposes Appointment of ISM Practitioners to Health Posts. *Medical Dialogues.* https://medicaldialogues.in/mp-medical-council-opposes-appointment-of-ism-practitioners-to-health-posts.

Nursing Section. (2020). Order dated 20 July 2020: Constitution of a Committee of Experts for Examining the Draft of the National Nursing and Midwifery Commission Bill, 2020- Reg. *MoHFW, GOI.*

Ortiz, J. M. (1998). The Revolutionary Flying Ambulance of Napoleon's Surgeon. *The Wayback Machine*. https://web.archive.org/web/20080514091424/http://www.napoleonic-literature.com/Flying_Ambulance.htm

Pallikadavath, S., Irudaya Rajan, S., & Wilson, C. (2016). Impact of low fertility and early age at sterilisation on women's formal education and skill development in South India. *Journal of Population Research*, 33(3), 199–220. https://doi.org/10.1007/s12546-016-9167-y.

Pandya, S. K. (2016). The Functioning of the Medical Council of India Analysed by the Parliamentary Standing Committee of Health and Family Welfare. *Indian J Med Ethics, 1(2), 68–71*. https://doi.org/10.20529/IJME.2016.020

Patel, V., Saxena, S., Lund, C., Thornicroft, G., Baingana, F., Bolton, P., Chisholm, D., Collins, P. Y., Cooper, J. L., Eaton, J., Herrman, H., Herzallah, M. M., Huang, Y., Jordans, M. J. D., Kleinman, A., Medina-Mora, M. E., Morgan, E., Niaz, U., Omigbodun, O., UnÜtzer, Jü. (2018). The Lancet Commission on Global Mental Health and Sustainable Development. *The Lancet*, *392(10157), 1553–1598.* https://doi.org/10.1016/S0140-6736(18)31612-X

Patnaik, L. (2019, October 1). Orissa High Court Asks State to Give Report on Clinical Act. *The Times of India E-paper*. http://timesofindia.indiatimes.com/articleshow/71381638.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst&pcode=461

Patro, B.K., Tripathy, J.P., & Kashyap, R. (2013). Epidemic Diseases Act 1897, India: Whether Sufficient to Address the Current Challenges? *Journal of Mahatma Gandhi Institute of Medical Sciences. 18:109-11.*

Paul, J., Govindan, R., Manjunatha, N., Kumar, Cn., & Math, S. (2019). Mental Healthcare Act 2017 – Role of Nurse in Enabling Person with Mental Illness. *Indian Journal of Psychiatric Nursing, 16(2), 114–117*. https://doi.org/10.4103/iopn.iopn_29_19

Pearson, G. J. (2007). Evolution in the Practice of Pharmacy - Not A Revolution! *Cmaj*, *176(9), 1295–1296*. Https://Doi.Org/10.1503/Cmaj.070041

Perappadan, B. S. (2019, April 19). Chemists and Druggists Are Passé; from now, All Will Be Pharmacies. *The Hindu*. https://www.thehindu.com/news/national/chemists-and-druggists-are-pass-from-now-all-will-be-pharmacies/article26891032.ece.

Perappadan, B. S. (2020, March 11). Coronavirus: States to be Asked to Invoke Epidemic Disease Act: Centre. *The Hindu.* https://www.thehindu.com/news/national/coronavirus-states-to-be-asked-to-invoke-epidemic-disease-act-centre/article31043653.ece.

PharmaBiz Bureau. (2020). HC Seeks Responses of Govt & NMC on Repeal of CEA Rules, Allowing Non-Pathologists to Certify Medical Reports. *PharmaBiz.Com*. http://www.pharmabiz.com/NewsDetails.aspx?aid=134289&sid=1

Pharmaceutical Jurisprudence. (2018). In *Pharmacy College*.

Pharmacy Act, 1948. The Gazette of India Extraordinary. *GOI.*

Pharmacy Council of India. (2018a). http://www.pci.nic.in/GenInfo_About_Introduction.html Accessed on 10 November 2020

Pharmacy Council of India. (2018b). State Pharmacy Council. https://pci.nic.in/pharmaact_chapter3.html Accessed on 10 November 2020

Pharmacy Council of India. (2019). Moratorium for new D.Pharm and B.Pharm Institutions from 2020-2021 Academic Session.

Pharmacy Practice Regulations, 2015. The Gazette of India Extraordinary. *GOI.*

Pharmapproach. (2020). History of Pharmacy. https://www.pharmapproach.com/history-of-pharmacy/ Accessed on 20 November 2020.

Pinto, S. (2019, April 14). Telephonic Medical Consultation Cannot Be Criminalised. *Deccan Chronicle.* https://www.deccanchronicle.com/nation/current-affairs/140419/telephonic-medical-consultation-cannot-be-criminalised.html.

Planning Commission. (n.d.). Chapter 5.4: Health and Family Welfare. *GOI*. https://niti.gov.in/planningcommission.gov.in/docs/plans/annualplan/ap2021pdf/ap2021ch5-4-2.pdf

Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982. The Gazette of India Extraordinary. *GOI.*

Prakash, G. (2015). Steering Healthcare Service Delivery: A Regulatory Perspective. *International Journal of Health Care Quality Assurance, 28(2), 173–192.* https://doi.org/10.1108/IJHCQA-03-2014-003.

Prakash, S. (2018). A Comparative Analysis of Various Indian Legal Systems Regarding Medical Negligence: Criminal, Consumer Protection and Tort Laws. *Legal Service India.com*. http://www.legalserviceindia.com/medicolegal/mlegal.html. Accessed on 23 March 2021.

Prashanth, N. R., Abraham, S. E., Hongally, C., & S. Madhusudan. (2019). Dealing with Statutory Bodies Under the Mental Healthcare Act 2017. *Indian Journal of Psychiatry*, *61*(*10), 717–723.* https://doi.org/10.4103/psychiatry.IndianJPsychiatry.

Priyanka, V., & Ashok, B. (2016). E-pharmacies Regulation in India: Bringing New Dimensions to Pharma Sector. *Pharmaceutical Regulatory Affairs: Open Access*, *05(02), 1–7.* https://doi.org/10.4172/2167-7689.1000175.

Protection of Children from Sexual Offences Act, 2012. The Gazette of India Extraordinary. *GOI.*

PTI. (2015, January 19). Odisha Issues Guidelines for Holding Health Camps. *The Economic Times*. https://health.economictimes.indiatimes.com/news/policy/odisha-issues-guidelines-for-holding-health-camps/45939204

Public Health Foundation of India. (2012). From 'Paramedics' to Allied Health Professionals: Landscaping the Journey and Way Forward. *MoHFW, GOI*.

Public Health (Prevention, Control and Management of Epidemics, Bioterrorism and Disasters) Bill, 2017. *GOI*.

Raha, S., Berman, P., & Bhatnagar, A. (2009). Some Priority Challenges of the Nursing Sector in India. *India Health Beat. World Bank*, *1(5).* https://openknowledge.worldbank.org/handle/10986/12820

Rajendran, S. (2020, September 14). Consumer Protection Act 2019 and Health Care Services. *The Hindu Centre for Politics and Public Policy*. https://www.thehinducentre.com/the-arena/current-issues/article32599186.ece.

Rajiv, G. (2015, February 2). Eye camps without permission will invite penal action. *Times of India*. https://timesofindia.indiatimes.com/city/thiruvananthapuram/eye-camps-without-permission-will-invite-penal-action/articleshow/46093064.cms.

Raju, R. S., & Maurya, D. S. (2018). 108 in Crisis: Complacency and Compromise Undermine Emergency Services' Potential. *Economic & Political Weekly*.

Rakesh P.S., (2016). The Epidemic Diseases Act of 1897: Public Health Relevance in The Current Scenario. *Indian Journal of Medical Ethics, 1 (3 (NS)), 156-160.* https://ijme.in/articles/the-epidemic-diseases-act-of-1897-public-health-relevance-in-the-current-scenario/.

Raktim Pratim Tamuli, S. S., & Saikia, B. (2019). Organ Donation – Attitude and Awareness Among Undergraduates and Postgraduates of North-East India. *Journal of Family Medicine and Primary Care*, *8*(1), *130–136.* https://doi.org/10.4103/jfmpc.jfmpc.

Randhawa S. (2021, February 10). Indian Dentistry is in Crisis - the New Dental Commission Bill Should Step Up. *The Wire Science.* https://science.thewire.in/health/indian-dentistry-is-in-crisis-the-new-dental-commission-bill-should-step-up/ .

Rao, B., & Jain, R. (2015). Medical Diagnostic Laboratories Provisioning of Services in India. *CHRISMED Journal of Health and Research*, *2*(1), 19. https://doi.org/10.4103/2348-3334.149340.

Rastogi, A., & Chandrashekar, R. (2019). Assessing the Judiciary's Role in Access to Safe Abortion: An Analysis of Supreme Court and High Court Judgements in India from June 2016-April 2019. A Pratigya Campaign for Gender Equality and Safe Abortion Report.

Ravichandran, V. (2019). Retail Pharmacy Market Scenario in India. *A Journal of Composition Theory*, *XII*(Xi), *908–911*.

Ravindran, S. T., Balasubramanian, P., & Bhate-Deosthali, P. (2019). Availability of Safe Abortion Services and the Perspectives of Actors on the Right to Safe Abortion in the States of Bihar and Tamil Nadu, India: A Rapid Assessment. *SAHAJ on behalf of CommonHealth.*

Ravishankar, B., & Shukla, V. (2007). Indian Systems of Medicine: A Brief Profile. *African Journal of Traditional, Complementary and Alternative Medicines*, *4(3), 319–337*. https://doi.org/10.4314/ajtcam.v4i3.31226.

Ray, P., & Sen, S. (2014). Chapter I: Colonial Constructions of the Indian Nurse. *Working Lives Women in Nursing (pp. 42–76).*

Rehabilitation Council of India Act, 1992. The Gazette of India Extraordinary. *GOI.*

Rehabilitation Council of India Regulations, 1997. The Gazette of India Extraordinary. *GOI.*

Rehabilitation Council of India. (2000). Zonal Coordination's Committees of Rehabilitation Council of India. http://www.rehabcouncil.nic.in/forms/Sublink1.aspx?lid=801 Accessed on 25 December 2020

Rehabilitation Council of India (2018). Continuing Rehabilitation Education (CRE) programmes. http://rehabcouncil.nic.in/forms/Sublink1.aspx?lid=1034. Accessed on 24 December 2020.

Rehabilitation Council of India. (2020). http://www.rehabcouncil.nic.in/forms/list.aspx?id=41. Accessed on 24 December 2020.

Revised Dentists (Code of Ethics) Regulations, 2014. The Gazette of India Extraordinary. *GOI.*

Rights of Persons with Disabilities Act, 2016. The Gazette of India Extraordinary. *GOI.*

Ritchie, H., & Roser, M. (2018). Mental Health. *Our World in Data*. https://ourworldindata.org/mental-health Accessed on 12 March 2021.

Sagar, R., Dandona, R., Gururaj, G., Dhaliwal, R. S., Singh, A., Ferrari, A., Dua, T., Ganguli, A., Varghese, M., Chakma, J. K., Kumar, G. A., Shaji, K. S., Ambekar, A., Rangaswamy, T., Vijayakumar, L., Agarwal, V., Krishnankutty, R. P., Bhatia, R., Charlson, F., Dandona, L. (2020). The Burden of Mental Disorders Across the States of India: The Global Burden of Disease Study 1990–2017. *The Lancet Psychiatry*, *7(2), 148–161*. https://doi.org/10.1016/S2215-0366(19)30475-4

Sahay, M. (2018). Transplantation of Human Organs and Tissues Act- "Simplified." *Indian Journal of Transplantation*, *12, 84–89.*

Saikia, D. (2017). Human Resource Challenges in the Public Health Sector in Rural India. *The Journal of Institute of Public Enterprise*, *40*(1). https://doi.org/10.2139/ssrn.2985393

Saikia, D. (2018). Nursing Shortages in the Rural Public Health Sector of India. *Journal of Population and Social Studies*. https://doi.org/10.25133/JPSSv26n2.008

Saini, A. (2016). Physicians of Colonial India (1757-1900). *Journal of Family Medicine and Primary Care*, *5(3), 528*. https://doi.org/10.4103/2249-4863.197257

Sairam, R. (2013, January 13). Health Dept. Frames Norms for Free Medical Camps. *The Hindu.* https://www.thehindu.com/news/cities/Coimbatore/health-dept-frames-norms-for-free-medical-camps/article4319109.ece

Saltman, R. B., & Busse, R. (2002). Balancing Regulation and Entrepreneurialism in Europe's Health Sector: Theory and Practice. *In Regulating Entrepreneurial Behaviour in European Health Care Systems*.

Saxena, A. (2019a, August 14). Delhi: South Body to Make Malaria a Notifiable Disease by Next Week. *The Indian Express.* https://indianexpress.com/article/cities/delhi/delhi-south-body-to-make-malaria-a-notifiable-disease-by-next-week-5902887/

Saxena, A. (2019b, August 15). Explained: What is a Notifiable Disease? *The Indian Express.* https://indianexpress.com/article/explained/notifiable-disease-malaria-who-notifies-a-disease-and-how-does-it-help-5906376/

Schedule F: Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

Schedule H: Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

Schedule H1: Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

Schedule K: Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

Schedule N: Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

Schedule X: Drugs and Cosmetics Rules, 1945. The Gazette of India Extraordinary. *GOI.*

ScienceDirect. (2021). Clinical Microbiology. *Elsevier*. https://www.sciencedirect.com/topics/immunology-and-microbiology/clinical-microbiology

Services: Quality Accreditations, NABL. (2021). *ACME Consulting*. http://www.acmeconsulting.in/services.html Accessed on 11 March 2021.

Shankar, R. (2020). Give Wings to E-Pharmacy Sector. *PharmaBiz.Com*. http://www.pharmabiz.com/NewsDetails.aspx?aid=130621&sid=3

Sharma, B. (2014). Preparing Midwives as a Human Resource for Maternal Health: Pre-Service Education and Scope of Practice in Gujarat, India. *Karolinska Institutet, Stockholm, Sweden*.

Sharma, K., & Chandna, H. (2019, November 12). Hundreds of Colleges Came Up Amid India's Pharma Boom. Here's Why Govt Wants No More. *The Print*. https://theprint.in/india/education/hundreds-of-colleges-came-up-amid-indias-pharma-boom-heres-why-govt-wants-no-more/317076/

Sharma, M., & Brandler, E. S. (2014). Emergency Medical Services in India: The Present and Future. *Prehospital and Disaster Medicine*, *29(3).* https://doi.org/10.1017/S1049023X14000296

Sharma, S., Kumar, K., & Singh, G. (2017). An Overview on Narcotic Drugs and Psychotropic Substances Act, 1985. *Journal of Forensic Sciences & Criminal Investigation*, *4*(*4), 1–4*. https://doi.org/10.19080/jfsci.2017.04.555644

Sharma, S. K. (2017). Nursing Practice Act: Current Scenario and Future Needs of India. *Nursing Journal of India*, *CVIII (6), 250–254.*

Sharma, Suresh K., & Rani, R. (2020). Nurse-to-Patient Ratio and Nurse Staffing Norms for Hospitals in India: A Critical Analysis of National Benchmarks. *Journal of Family Medicine and Primary Care*. https://doi.org/10.4103/jfmpc.jfmpc_248_20.

Sharp, P. M., & Hahn, B. H. (2011). Origins of HIV and the AIDS Pandemic. *Cold Spring Harbor Perspectives in Medicine*, *1*(*1), 1–22.* https://doi.org/10.1101/cshperspect.a006841.

Sheikh, S., Pallagatti, S., Singla, I., Gupta, R., Aggarwal, A., Singh, R., & Gupta, D. (2014). Survey of Dental Radiographical Practice in States of Punjab and Haryana in India. *Journal of Investigative and Clinical Dentistry*, *5*(1), *72–77*. https://doi.org/10.1111/jicd.12016.

Shin, H. Y., Kim, K. Y., & Kang, P. (2020). Concept Analysis of Community Health Outreach. *BMC Health Services Research*, *20*(1), 417. https://doi.org/10.1186/s12913-020-05266-7.

Shrivastav, S. (2019, February 22). Nursing Council Letter on Power of Recognition Illegal. *The Times of India*. https://timesofindia.indiatimes.com/city/nagpur/nursing-council-letter-on-power-of-recognition-illegal/articleshow/68102530.cms.

Shroff, S. (2009). Legal and Ethical Aspects of Organ Donation and Transplantation. *Indian Journal of Urology*, *25*(3), 348–355.

Siddiqi, S., Masud, T. I., Nishtar, S., Peters, D. H., Sabri, B., Bile, K. M., & Jama, M. A. (2009). Framework for Assessing Governance of the Health System in Developing Countries: Gateway to Good Governance. *Health Policy, 90(1), 13–25.* https://doi.org/10.1016/j.healthpol.2008.08.005

Singh A.R., & Gupta, S.K. (2014). Review of the Centralized Accident and Trauma Services (Cats) in New Delhi, India. *Cibtech Journal of Bio-Protocols ISSN*, *3*(1), 2319–384045.

Singh, J., Desai, M. S., Pandav, C. S., & Desai, S. P. (2012). Contributions of Ancient Indian Physicians - Implications for Modern Times. *Journal of Postgraduate Medicine, 58, 73–78*. https://doi.org/10.4103/0022-3859.93259.

Singh, R., Gupta, N., Vanathi, M., & Tandon, R. (2019). Corneal Transplantation in the Modern Era. *Indian Journal of Medical Research, July, 7–22520.*

Singh, S. (2015). Status of Clinical Psychology in India – (A Retrospective Analysis of Review). *International Journal of Indian Psychology*, *2*(4). https://doi.org/10.25215/0204.076.

Smith, Y. (2019). Types of Pharmacy. *News-Medical*. https://www.news-medical.net/health/Types-of-Pharmacy.aspx. Accessed on 20 December 2020.

Solomon, S., Solomon, S. S., & Ganesh, A. K. (2006). AIDS in India. *Postgraduate Medical Journal*, *82*(*971), 545–547.* https://doi.org/10.1136/pgmj.2006.044966.

Special Correspondent. (2017, July 24). INC not Authorised to Recognise Nursing Colleges: High Court. *The Hindu*. https://www.thehindu.com/news/national/karnataka/inc-not-authorised-to-recognise-nursing-colleges-high-court/article19347984.ece.

Srinivasan, S. (2018). Ch. 11 The Unholy Nexus: Medical Profession, Pharmaceutical Companies, and Regulatory Authorities. In S. Nundy, K. Desiraju, & S. Nagral (Eds.), *Healers or Predators? Healthcare Corruption in India. Oxford University Press.*

Sriram, V., Baru, R., & Bennett, S. (2018). Regulating Recognition and Training for New Medical Specialties in India: The Case of Emergency Medicine. *Health Policy and Planning*, *33*(7), *840–852*. https://doi.org/10.1093/heapol/czy055.

Steingart, K. R., Ramsay, A., Dowdy, D. W., & Madhukar, P. (2012). Serological tests for the diagnosis of active tuberculosis: relevance for India. *The Indian Journal of Medical Research*, *135(5), 695–702.*

Sulania, A., Sachdeva, S., Jha, D., Kaur, G., & Sachdeva, R. (2016). Organ Donation and Transplantation: An Updated Overview. *MAMC Journal of Medical Sciences*, *2(1), 18–27.* https://doi.org/10.4103/2394-7438.174832

Sundararaman, T., Chakraborty, G., Nair, A., Mokashi, T., & Ved, R. (2012). Publically Financed Emergency Response and Patient Transport Systems Under NRHM. *National Health Systems Resource Centre*.

Supreme Court of India. (1992). Judgement in the Case of Civil Extraordinary Jurisdiction writ petition (civil) no. 91 of 1992.

Supreme Court of India. (2008). Judgement in case of Suman Kapur vs Sudhir Kapur dated *7 November 2008*.

Supreme Court of India. (2016). Writ Petition (Civil) No. 95 of 2012 in case of Devika Biswas vs Union of India & Ors dated 14 September 2016.

Supreme Court of India. (2019). Daily Orders Private Nursing Schools and ... vs The Indian Nursing Council dated 22 January 2019.

Supreme Court of India. (2020). Judgement in case of Pharmacy Council of India v. Dr. S.K. Toshniwal Educational Trusts Vidarbha Institute of Pharmacy dated 5 March 2020.

Tandon, P., Gupta, V., Ranjan, A., Gandhi, P., Kotiyal, A., & Kapoor, A. (2017). A Review on the Current Classification and Regulatory Provisions for Medicines in Drug & Cosmetic Act, in the light of Present-Day Context. *Int Arch BioMed Clin Res*. https://doi.org/10.21276/iabcr.2017.3.3.26

Thavarajah, R., Saranya, V., & Priya, B. (2019). The Indian Dental Litigation Landscape: An Analysis of Judgments on Dental Negligence Claims n Indian Consumer Redressal Forums. *Journal of Forensic and Legal Medicine*, *68* (*August*), *101863*. https://doi.org/10.1016/j.jflm.2019.101863.

Protection of Children from Sexual Offences Act, 2012.The Gazette of India Extraordinary. *GOI.*

Tiwari, R. R., Sharma, K., & Zodpey, S. P. (2013). Situational Analysis of Nursing Education and Work Force in India. *Nursing Outlook, 61(3), 129–136*. https://doi.org/10.1016/j.outlook.2012.07.012.

TNN. (2019, July 3). Not Easy to Adopt Clinical Establishments Act: Vishwajit Rane. *The Times of India E-paper*. https://timesofindia.indiatimes.com/city/goa/not-easy-to-adopt-clinical-establishments-act-rane/articleshow/70048634.cms.

TNN. (2020, June 17). IMA Holds Protest, Burns Copies of Clinical Establishment Act. *The Times of India*. https://timesofindia.indiatimes.com/city/ludhiana/ima-holds-protest-burns-copies-of-clinical-establishment-act/articleshow/76413507.cms

Tribune News Service. (2014, December 9). Strict Norms for Medical Camps. *The Tribune*. https://www.tribuneindia.com/news/archive/bathinda/strict-norms-for-medical-camps-15857

Transplantation of Human Organs and Tissues Act, 1994. The Gazette of India Extraordinary. *GOI.*

Transplantation of Human Organs (Amendment) Act, 2011. The Gazette of India Extraordinary. *GOI.*

Transplantation of Human Organs Rules, 1995. The Gazette of India Extraordinary. *GOI.*

Transplantation of Human Organs (Amendment) Rules, 2008. The Gazette of India Extraordinary. *GOI.*

Transplantation of Human Organs and Tissues Rules, 2014. The Gazette of India Extraordinary. *GOI.*

Trivedi, I. (2017, March 15). Lack of Regulations Still a Concern for Diagnostic Laboratories Industry. *LIVE Mint*. https://www.livemint.com/Politics/VJVWRi9DaVtPJrMdV5IOKP/Lack-of-regulations-still-a-concern-for-diagnostic-laborator.html.

UNDP. (2016). HIV and the Law in India. *UNDP*.

Urick, B. Y., & Meggs, E. V. (2019). Towards a Greater Professional Standing: Evolution of Pharmacy Practice and Education, 1920–2020. *Pharmacy*, *7(3), 98*. https://doi.org/10.3390/pharmacy7030098

Vashist, A., Parhar, S., Gambhir, R. S., Sohi, R. K., & Talwar, P. S. (2014). Legal Modalities in Dental Patient Management and Professional Misconduct. *SRM J Res Dent Sci 5(2), 91–96*. https://doi.org/10.4103/0976-433X.132079.

Verma, A. (2020). What is the State of 'Emergency Ambulance Services' in India? *FACTLY*. https://factly.in/what-is-the-state-of-emergency-ambulance-services-in-india/#:~:text=.

Verma, R. (2017, March 22). Draft Public Health Bill Restrictive, Unclear: Experts. *Down To Earth.* https://www.downtoearth.org.in/news/health/draft-public-health-bill-riddled-with-issues-say-experts-57430.

Walton-Roberts, Runnels, M., Rajan, V., Sood, S. I., Nair, A., Thomas, S., Packer, P., MacKenzie, C., Murphy, A. T., Labonté, G., Bourgeault, R., & Lynn, I. (2017). Causes, Consequences, and Policy Responses to the Migration of Health Workers: Key Findings from India. *Human Resources for Health*, *15(28), 1–18*. https://doi.org/10.1186/s12960-017-0199-y

Western Cape Government. (n.d.). National Guideline on Home-Base Care / Community-Based Care. *Western Cape Government.*

West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017. *Government of West Bengal.*

WHO Regional Office for South-East Asia. (2000). Allied Health (Paramedical) Services and Education, Report of an Intercountry Consultation. *WHO Regional Office for South-East Asia* (Issue March).

WHO Western Pacific Region. (2016). Health workforce regulation in the Western Pacific Region. In *World Health Organization*.

Wire Staff. (2020, March 15). Delhi Govt Exercises Powers Under Epidemic Diseases Act to Battle Coronavirus. *The Wire Science*. https://science.thewire.in/health/coronavirus-delhi-government-epidemic-diseases-act/.

Word History. (2020a). The History of 'Doctor'. *Merriam-Webster*. https://www.merriam-webster.com/words-at-play/the-history-of-doctor. Accessed on 8 October 2020.

World Health Organization. (2002). Community Home Based Care in Resource Limited Settings: A Framework for Action. *WHO.*

World Health Organization. (2007). Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action. *WHO.*

World Health Organization. (2008). Mental Health Gap Action Programme - Scaling up care For Mental, Neurological, And Substance Use Disorders. *WHO*.

World Health Organization. (2009). Global Glossary of Terms and Definitions on Donation and Transplantation. *WHO.*

World Health Organization. (2010). Telemedicine: Opportunities and Developments in Member States: Report on the Second Global Survey on e-health 2009 (Global Observatory for eHealth Series, 2). *WHO.*

World Health Organization. (2012a). Information Sheet: Safe and Unsafe Induced Abortion- Global and Regional Levels In 2008, And Trends During 1995 – 2008. *Information Sheet WHO.*

World Health Organization. (2012b). Safe Abortion: Technical and Policy Guidance for Health Systems, 2nd ed. *WHO*.

World Health Organization. (2018). India: Mental Health ATLAS 2017 - Member State Profile. *WHO*.

World Health Organization. (2020a). Classifying Health Workers: Mapping Occupations to the International Standard Classification: International Labour Organization, International Standard Classification of Occupations: ISCO-08. *WHO.*

World Health Organization. (2020b). Global Health Observatory Data Repository: Nursing and Midwifery Personnel. *WHO*.

World Health Organization. (2020c). HIV/AIDS Factsheets. *WHO*. https://www.who.int/news-room/fact-sheets/detail/hiv-aids Accessed on 23 March 2021.

World Health Organization. (2020d). Nursing and Midwifery. *WHO*. https://www.who.int/health-topics/nursing#tab=tab_1 Accessed on 10 September 2020.

World Health Organization. (2020e). World Health Statistics 2020: Monitoring Health for the SDGs, Annex 2 Tables of Health Statistics by Country, WHO Region and Globally. *WHO*.

World Health Organization. (2021a). "Epidemic". Definitions: Emergencies. Humanitarian Health Action. WHO. https://www.who.int/hac/about/definitions/en Accessed on 30 March 2021

World Health Organization. (2021b). Mobile Clinics. *WHO*. https://www.who.int/emergencies/partners/mobile-clinics Accessed on 2 March 2021.

World Health Organization. (2021c). Transplantation of Human Cells, Tissues and Organs. *WHO*. https://www.who.int/transplantation/en/ Accessed on 2 February 2021.

World Health Organization. (2021d). WHO Coronavirus (COVID-19) Dashboard. *WHO.* https://covid19.who.int/ Accessed on 6 May 2021.Yadav L. (2018). PCI Launches Pharmacist Registration and Tracking System to Capture Pharmacist Data Pan India. *PharmaBiz.Com*. http://www.pharmabiz.com/NewsDetails.aspx?aid=112343&sid=1.

Yadav, M., & Rastogi, P. (2015). A Study of Medical Negligence Cases Decided by the District Consumer Courts of Delhi. *Journal of Indian Academy of Forensic Medicine*, *37(1), 50*. https://doi.org/10.5958/0974-0848.2015.00011.1.

Yadla, M. (2019). Legal Policies of Organ Transplantation in India: Basics and Beyond. *Saudi Journal of Kidney Diseases and Transplantation*, *30(4), 943–952.*

Yasmeen, A. (2019, May 14). KMC Warns Doctors Against Online Consultations. *The Hindu*. https://www.thehindu.com/news/national/karnataka/kmc-warns-doctors-against-online-consultations/article27130640.ece.

Yenepoya University. (2020). Historical Background and Development of Profession of Pharmacy. *Yenepoya University.*

ZIQITZA Blogs. (2017). What are the Different Types of Ambulances and the Benefits Associated with it*? ZIQITZA Healthcare Limited*. https://www.zhl.org.in/blog/different-types-ambulances-benefits-associated/.

Zodpey, S., & Hasan, H. (2015). Supply Constraints in Human Resources for Health May Limit Progress Towards Universal Health Coverage in India: An Exploratory Study. *South-East Asian Journal of Medical Education*, *9*(2). https://doi.org/10.4038/seajme.v9i2.88.

Annexure I

Definitions of Select Legal Terms

Act (i, ii): A law passed by a legislature and approved by the President of India in case of a Central Act and by the Governor of the state in case of a state Act. A "bill", after being enacted, becomes an 'Act'. In case of the Central Government, Parliament constitutes the legislature and in case of the state government, the state legislative assembly is the legislature. After being approved, the Act is published in the Gazette of India/State Gazette (government's official public journal) by which the public at large is informed about the Act, after which nobody can plead ignorance of that Act.

Appeal (iii): Legal proceedings in which a case is brought before a higher court for the reconsideration of the decision of a lower court.

Appellant (iii): A person who appeals to a higher court for the review of the decision made by a lower court.

Appellate (iii): Those applications in a court that are concerned with the decisions made by a lower court.

Appellate Court (iv): A court which hears the appeals for review of decisions made by a lower court.

Autonomous Bodies (v): Such bodies as are established by the government to discharge the activities which are related to governmental functions. Such bodies are given autonomy to discharge their functions in accordance with the Memorandum of Associations (e.g., Indian Military Academy, National Institute of Fashion Technology, Indian Institute of Technology, Central Silk Board etc.).

Bill (vi): A legislative proposal for enactment of a law. It is called a Bill until it is passed and signed, at which time it is an Act and is no longer referred to as a Bill.

Bye-law (vii): Subordinate legislation made by the local government or statutory authority by exercising its statutory power and accompanied by some sanction or penalty for non-observance.

Case Law (viii): Legally binding and commonly accepted rules or principles developed over time through the gradual accumulation of rulings by judges. These are laws made by court cases rather than legislation.

Civil Law (iii): That part of the law that encompasses business, contracts, estates, domestic (family) relations, accidents, negligence, and everything related to legal issues, statutes, and lawsuits, that is not criminal law.

Citizen's/Client's Charter (v): is required to be maintained by all the Ministries/Departments/Offices of the Government of India and the State/Union Territory Governments and to be prominently displayed on their website/ notice board of the Information Facilitation Centre. Citizen's Charter is a document which represents a systematic effort to focus on the commitments of the Organisation

towards its citizens/clients in respect of the standards of services, information, choice and consultation, non-discrimination and accessibility, redress courtesy and value for money. It acts as a tool for facilitating delivery of services to citizens with specified standards, quality and time frame etc.

Commission (iii): A Commission is appointed by a court to ascertain or investigate facts needed to decide a case. A Commission is usually given specific terms of reference. Members of a Commission can be academics, social activists/workers, advocates, or judges.

Constitutional Bodies (v): Such bodies as are established under the provisions of the Constitution of India (e.g., Union Public Service Commission, Election Commission, Comptroller and Auditor General of India, National Commission for Women etc.).

Defendant (viii): In a civil suit, the person complained against; in a criminal case, the person accused of the crime.

Executive (iii): The Executive is one of the three main organs of the government. It is the part of the government that has sole authority and responsibility for effecting and enforcing laws. It comprises the President, Vice-President, Prime Minister and the Cabinet/Union Council of Ministers.

File (v): A collection of papers on a specific subject, assigned a number and consisting of one or more of the following parts- (a) Notes (b) Correspondence (c) Appendices to Notes/ Correspondence.

Habeus Corpus (viii): Legal term for the right to petition a court to decide whether confinement has been undertaken with due process of law.

Injunction (viii): A court order that prohibits a party from doing something (restrictive injunction) or compels them to do something (mandatory injunction).

Judiciary (iii): The judiciary is one of the three main organs of the government (also known as the judicial system or court system). It is the system of courts that interprets and applies the law in the name of the state.

Judicial review (viii): A procedure where the court can review the administrative decisions of the government.

Jurisdiction (iii, viii): The defined area of authority, power or right granted to a court to make pronouncements on legal matters and administer justice.

Law (i, ix): The system of authoritative materials for guiding judicial and administrative action recognised or established in a politically organised society. Law is a system of principles and rules which governs the affairs of the society and can be enforced by the concerned authority. An Act is more specific.

Legislation: The enactments of a legislator or a legislative body.

Legislature (iii): A branch of the government having the power to make laws in a country. It is one of the three main organs of the government.

Legislative Assembly (iii): The name given in some countries to either a legislature, or to one of its branches. In India, legislative assembly refers to the state government branch of the legislature.

Litigant (iii): A party to a lawsuit in a court.

Lok Adalat (iii): A system of alternative dispute resolution developed in India. It roughly means "people's court".

Notice (iii): The legal notification by which a party or person is made aware of a legal process affecting their rights, obligations, or duties.

Notification (v): Mostly used in notifying promulgation of statutory rules and orders, appointments and promotions of gazetted officers etc. through publications in the Gazette of India.

Order (iii): Direction of a court or judge normally made or entered in writing during the proceedings of a case.

Order (v): Generally used for issuing certain types of financial sanctions and for communicating government orders in disciplinary cases, etc., to the officials concerned.

Ordinance (x): Law promulgated by the President of India or the Governor of any State on the recommendation of the Union/State Cabinet respectively when the legislature is not in session. The legislature has to approve the ordinance within six weeks of its reassembly.

Petition (iii): A formal written request presented to a court of law.

Petitioner (iii): The party who presents a petition in court of law.

Plaintiff (iii, viii): The party who initiates a lawsuit (also known as an action) before a court of law. May also be referred to as a petitioner/applicant/claimant.

Precedent (viii): A precedent is a previous decision used as a justification for deciding a subsequent case in the same way.

Procedural (iii): Procedural law comprises the rules by which a court prescribes the steps for having a right or duty that is judicially enforced, and determines what happens in civil lawsuit, criminal or administrative proceedings.

Prosecutor (viii): A lawyer representing the government in a criminal case.

Resolution (v): This form of communication is used for making public announcement of decisions of government in important matters of policy in e.g., the policy of industrial licensing, appointment of committees or commissions of enquiry. Resolutions are also published in the Gazette of India.

Rules (i): Rules help in governing law. They are secondary. They are in place to make the parent Act work effectively. Rules provide the details which have not been provided for in the Act. However, Rules by no means can go beyond the power conferred by the Act or extend the same.

Special Courts (iii): Bodies within the judicial branch of government that generally address only one area of law or have specifically defined powers.

Statute (iii): A statute is a formal written enactment of a legislative authority that governs a state, city, or country. Typically, statutes command or prohibit something, or declare policy.

Statutory Bodies (v): Such bodies as are established under a statute or an Act of Parliament (e.g., Central Vigilance Commission, Central Information Commission, Central Board of Film Certification, National Commission for Backward Class etc.).

Suit (iii): A civil action brought by a party/parties against another in a court of law.

Tribunal (viii): A special court outside the civil and criminal judicial system that examines special problems and makes judgements, e.g., an industrial tribunal, which resolves disputes between employers and employees.

Undertaking (viii): A promise, reduced to writing, which is legally enforceable.

---

i. https://legodesk.com/legopedia/difference-between-act-and-law/ Accessed 5 June 2020
ii. http://voice4india.org/act-becomes-law-when-notified-in-gazette-of-india/781/ Accessed 5 June 2020
iii. https://dakshindia.org/common-legal-terms/ Accessed 5 June 2020
iv. https://www.advocatekhoj.com/library/glossary/a.php Accessed 5 June 2020
v. Ministry of Personnel, Public Grievances and Pensions, Department of Administrative Reforms and Public Grievances, May 2015. Central Secretariat Manual of Office Procedure. Fourteenth Edition. Government of India. https://darpg.gov.in/sites/default/files/CSMOP_0_0.pdf Accessed 5 June 2020
vi. https://www.advocatekhoj.com/library/glossary/b.php Accessed 5 June 2020
vii. https://indiankanoon.org/docfragment/1773071/?forminput=bye%20law%20definition Accessed 5 June 2020
viii. Desai, M., Mahabal, K.B. (Ed.), 2007. Health Care Case Law in India-A Reader. Cehat. https://www.escr-net.org/sites/default/files/desai%20and%20mahabal_0.pdf Accessed 23 May 2020.
ix. http://legislative.gov.in/sites/default/files/legal-glossary/h%20to%20l.pdf Accessed 5 June 2020.
x. https://legislative.gov.in/sites/default/files/legal-glossary/m%20to%20o.pdf Accessed 5 June 2020.

Annexure II

Categories of Health Legislations in India

The repository of health legislations in India has been complied for easy access to the Acts, Rules, Regulations, Schedules, and Notifications issued by the Government of India. Most of the documents provided in the database are collected over a period from various sources. The legislations governing the various issues related to health have been divided into the following categories to highlight the range of resources available in the area of health regulation. The Repository of Health Legislations in India may be accessed at https://www.hstp.org.in/health-systems-governance/.

1. Allied Health Care Professionals
2. Ambulances
3. Blood Banks
4. Dentists
5. Doctors (Allopathy)
6. Doctors (Homoeopathy)
7. Doctors (Indian Systems of Medicine)
8. Environment Protection
9. Food Safety
10. Health Facilities
11. Health Information
12. Health Insurance
13. Medical and Research Institutes
14. Medical Devices
15. Medical Services
16. Mental Health
17. Narcotic Drugs and Substance abuse
18. Nurses
19. Occupational Health
20. Patient Rights and Ethics
21. Persons with Disabilities
22. Pharmaceuticals & Vaccines
23. Pharmacies
24. Pharmacists
25. Public Health, Epidemics, Pandemics and Outbreaks
26. Social Security
27. Tobacco Control

Health Systems Transformation Platform (HSTP)
C1 Block, ISID, 4, Institutional Area, Phase II, Vasant Kunj,
New Delhi – 110070, India
hstp@hstp.org.in
Phone +91-11-61326500