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REGULATION OF CLINICAL ESTABLISHMENTS IN INDIA

UNDER THE GUIDANCE AND SUPERVISION OF

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DECLARATION

I declare that this Dissertation titled **"REGULATION OF CLINICAL ESTABLISHMENTS IN INDIA"** is researched and submitted by me to the National University of Advanced Legal Studies, Kochi, in partial fulfilment of the requirement for the award of Degree of Master of Laws in Public Health Law, under the guidance and supervision of Dr. Ambily Perayil, Assistant Professor, NUALS, and is an original, bona fide and legitimate work and it has been pursued for an academic interest. This work or any type thereof has not been submitted by me or anyone else for the award of another degree of either this University or any other University.

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ABBREVIATIONS

1. ASQua: Asian Society for Quality in HealthCare
2. CEA: Clinical Establishments (Registration and Regulation) Act
3. CHC: Community Health Centre
4. CPA: Consumer Protection Act
5. CRISIL: Credit Rating Information Services of India Ltd.
6. HC: High Court
7. ICCPR: International Covenant on Civil and Political Rights
8. ICESCR: International Covenant on Economic, Cultural and Social Rights
9. ICHA: Indian Confederation for Healthcare Accreditation
10. ICU: Intensive Care Unit
11. IMA: Indian Medical Association
12. IMC: Indian Medical Council
13. MoH&FW: Ministry of Health and Family Welfare
14. MCI: Medical Council of India
15. NABH: National Accreditation Board for Hospitals and Healthcare providers
16. NMC: National Medical Commission
17. NHA: National Health Authority
18. NHP: National Health Policy
19. NRHM: National Rural Health Mission
20. PHC: Primary Health Care Centers
21. QCI: Quality Council of India
22. SHC: Secondary Health Centre
23. SC: Supreme Court
24. UN : United Nations
25. UDHR: Universal Declaration of Human Rights
26. WB: World Bank
27. WHO: World Health Organisation

LIST OF CASES

1. Common Cause v. Union of India and Others, AIR 1996 SC 929.
2. Consumer Education & Research Centre v. Union of India and Others, AIR 1995 SC 922
3. Francis Coralie Mullin V. The Administration, Union Territory Of Delhi, AIR 1981 SC 746
4. Indian Medical Association v. V. P. Shantha and Ors, (1995) 6 SCC 651
5. Parmanand Katara v. Union of India, AIR 1989 SC 2039
6. Paschim Banga Khet Mazdoor Samiti v. State of West Bengal, AIR 1996 SC 2426
7. Sheela Barse v. Union of India, 1986 3 SCC 596
8. State of Punjab v. Mohinder Singh Chawla, (1997) 2 SCC 83
9. S. Lal v. State of Bihar, 1994 SCC [Cri] 506
10. S. Mittal v. State of UP ,AIR 1989 SC 1570
11. TN In re v. Union of India, AIR 1988 SC 1782
12. TN In re v. Union of India, 2002 3 SCC 31
13. Vincent v. Union of India, AIR 1987 SC 990.

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CHAPTER 1

INTRODUCTION

Health is not simply the absence of disease or abnormalities; it is a state of complete physical, social, and mental well-being.[1] Thus, health is viewed as a function of biological function and the overall state of the human mind, body, and spirit, implying that it is free of illness, injury, and pain. There is a proverb that states, "Life is Wealth." If children remain healthy, it aids in the proper growth and development of the mind and body, as they require concentration in the classroom and full participation in field activities. Medical testing enables experts to comprehend and learn about children's physical condition and growth in terms of height and weight, which has a substantial impact on their overall function and well-being. When a person is strong and healthy, it demonstrates the person's overall functioning and can also serve as a good example to others, teaching them how to achieve good health.[2]

Today's healthcare consumers have greater expectations than ever. They are not simply in control; they are looking for options that are tailored to their specific needs and within their budget. To improve overall health care, it is critical to prioritise customised data, real-time data, and block chain technology that optimise patient outcomes. It guarantees life democratically and increases efficiency and durability, thereby influencing health care purchasing decisions. India is the world's second most populous country and one of the fastest growing economies in modern times, owing to India's unique public health challenges and unprecedented opportunities.[3]

The Constitution contains provisions ensuring everyone's right to the best possible physical and mental health. Article 21 of the Constitution[4] ensures that all citizens have access to health care and personal freedom. The Supreme Court held that Article 21's right to human dignity is founded on the guiding principles of national policy and thus encompasses health protection. Failure to treat a patient in a timely manner constitutes a violation of the patient's right to life. Likewise, the Court has upheld the government's obligation to maintain essential

[1] Constitution – WHO, available at https://www.who.int/about/who-we-are/constitution (last visited September 12, 2021)
[2]George J Annas, "Reviewd works – Ethics, Equality and Health for All", Health and Human Rights, Volume 5, Number 1, 2000, page 185.
[3]HEALTH CARE IN INDIA - VISION 2020ISSUES AND PROSPECTS, available at https://niti.gov.in/planningcommission.gov.in/docs/reports/genrep/bkpap2020/26_bg2020.pdf (last visited September 12, 2021)
[4]Article 21 Constitution of India Available at, https://legislative.gov.in/constitution-of-india (last visited September 12, 2021)

health services. According to the World Health Organization (WHO)[5], health is not simply the absence of disease but a state of complete physical, mental, and social well-being. The WHO clarifies further that it is the government's legal obligation to ensure equal access to "timely, acceptable, affordable, and high-quality health care and to provide health services, such as safe drinking water, sanitation, food, housing, health and education information, and sexual equality, to all its members". In India, this right, which serves as a natural foundation for the development of public health, is safeguarded in numerous ways by the Indian Constitution.

The situation as it stands in India is worrisome as for every 10,189 people there is only 1 doctor available and also statistics show that 2,046 people fight for a single bed[6]. No doubt, India is suffering from a major health crisis[7]. In this power hierarchy prevailing in the private sector, the informal sector has the least authority and does not come under the ambit of any regulation. Evidences suggest that more than 80% of the population is dependent on this sector for out-patient care.[8]The services provided by these practitioners are often of variable quality and in some cases even dangerous.[9] Thus, due to this multi-layered framework of private hospitals in India, it has become difficult to manage their functioning through proper set of regulations by the State

Patients were forced to choose between expensive private care and a "inadequate" public health system, putting their fundamental right to health on hold.[10] In order to ensure the affordable and quality healthcare guaranteed under the constitution, The Central Government enacted the Clinical Establishments (Registration and Regulation) Act, 2010[11] to allow for the registration and regulation of all clinical establishments in the country with the objective of prescribing the minimum standards of facilities and services supplied by them. The Clinical Establishments Act (Registration and Regulation) was promulgated by the Parliament of India

[5]WHO World Health Organization, availale at https://www.who.int/ (last visited September 12, 2021)
[6] India's public health system in crisis: Too many patients, not enough doctors https://www.hindustantimes.com/india-news/public-health-system-in-crisis-too-many-patients-not-enough-doctors/story-39XAtFSWGfO0e4qRKcd8fO.html (last visited on September 12, 2021)
[7]Public Vs Private Healthcare in India, available at https://docmode.org/public-vs-private-healthcare-in-india/.(last visited September 12, 2021)
[8] Narayana K. V., The Unqualified Medical Practitioners: Methods of Practice and Nexus with Qualified Doctors. Working Paper No. 70. Hyderabad: Centre for Economic and Social Studies; 2006.
[9]Damodaran H. India's New Capitalists: Caste, Business, and Industry in a Modern Nation. Ranikhet: Permanent Black in Association with The New India Foundation; 2008.
[10]Sengupta, Amit, and SamiranNundy. "The private health sector in India." BMJ (Clinical research ed.), 2005, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1285083/ (last visited September 12, 2021)
[11] Clinical Establishments (Registration and Regulation) Act, 2010, Available at https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf (last visited September 12, 2021)

in 2010 corresponding to that. The program consists of 7 Chapters and 56 sections. The Act came into force on 1st March 2012 in four states, namely Arunachal Pradesh, Himachal Pradesh, Mizoram, and Sikkim, as well as all Union Territories excluding the National Capital Territory of Delhi, pursuant to a Gazette notification of 28th February 2012.[12] The states of Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Assam, Haryana and Kerala have enacted the Act pursuant to the provisions of Article 252 (1) of the Constitution.[13]

The purpose of this Act is to register all medical institutions in India to facilitate self-regulation and standard practice. With the exception of military bases, all public and private institutions, including AYUSH centers, are required to register. Regulation of clinical establishment is still in papers by the improper implementation of the act and also it is required to control the quality and cost of health care in various public and private institutions in India.[14]Because after eleven years from the date of establishment of this act, still it is laid down as an unsuccessfull legislation. Hence there is an urgent need of ensuring standardised and quality health care especially to the poor and vulnerable section.

1.1 SCOPE OF THE STUDY

It is a fundamental human right as well as a fundamental constitutional right that each and every citizen has access to health and health care. Health is not confined to the concept of being free of illness, but rather refers to a person's whole state of well-being and wellbeing. Every state owes it to its citizens to provide them with health-care facilities of a minimum standard of quality. India is a country with a sophisticated health-care system that extends over its whole territory. It is necessary to have an unified regulatory framework for health care providers because of the complicated structure of the healthcare system as it is currently configured. As a result, India requires a uniform type of legislation to regulate the health-care industry. However, despite the fact that the Clinical Establishment Act has been in effect for 11 years, it continues to be regarded as a failure. It is imperative that the legislation be implemented as soon as possible in order to address the issues now facing the health care system. The united government needed to devote more attention to standardised medical

[12] Revised+Schedule+of+Notification.pdf - Delhi Govt. Available at, http://web.delhi.gov.in/wps/wcm/connect (last visited September 12, 2021)
[13] Article 252 (1) Constitution of India Available at, https://legislative.gov.in/constitution-of-india (last visited September 12, 2021)
[14] *Supra* note 8

training and oversight of doctors, as well as health care insurance. Assuring everyone, especially the poor and vulnerable, access to inexpensive and high-quality health care is a top priority.

1.2 RESEARCH PROBLEM

The problem highlighted here is determining the efficiency of the Clinical Establishment Act of 2010, which regulates the registration of clinical establishments and establishes minimum standards for their operation. The researcher's objective is to provide an overview of the Act and to identify the challenges and shortcomings associated with its implementation.

1.3 RESEARCH OBJECTIVES

1. To analyse whether registration is mandatory under the Clinical Establishment Act.

2. To ascertain the efforts taken by the government toward standard of treatment regulation.

3. To analyse the criteria of both professional and ethical conduct necessary to preserve the medical profession's dignity in relation to the clinical establishment act.

4. To determine if the clinical establishment offers appropriate medical care and therapy to stabilise any individual brought to the clinical establishment in an emergency medical situation.

5. To determine whether the clinical setting is adequate to accomplish its objective.

6. To study about the clinical establishment authorities constituted under the Clinical Establishment Act and the constraints they encounter.

7. To ascertain whether the act is sufficient to ensure that poor people receive inexpensive care at a reasonable and fair price.

1.4 RESEARCH QUESTIONS

1. Whether Clinical Establishment Act is providing better healthcare facilities in our society?

2. What are the steps taken by the government for regulating the medical treatment in India?

3. Whether there is any medical and ethical standards prescribed by this act for ensuring the dignity of medical profession?

4. Whether this act is sufficient to provide necessary treatment to any individuals in case of medical emergency?

5. Whether the authority under act are sufficient to maintain the objectives and aims prescribed under this act?

1.5 HYPOTHESIS

The Clinical Establishment Act has shown to be a successful method for maintaining a minimum standard of treatment and healthcare facilities. To implement this system, a far more systematic and thorough approach should be established due to the act's lack of affordable health care facilities and quality treatment.

1.6 RESEARCH METHODOLOGY

This research methodology used in this work is of the doctrinal method. Analytical and critical methods of study are used throughout the research to find the effectiveness of the Clinical Establishment Act 2010. The study attempts to analyse the legislations, rules, regulations and orders. The secondary survey used in the study are mainly articles, books and websites.

1.7 LITERATURE REVIEW

The research has depended on the primary sources including the Constitution of India, WHO constitution, various legislations, executive orders, judgements of Supreme Court and High Courts, International treaties etc. The research has also used secondary resources like books, commentaries for the proper understanding of the subject and analysing the various topics. The research has extensively depended the electronic resources like online databases, websites for gathering resources.

- **Phadke, A., 2010. The Indian Medical Association and the Clinical Establishment Act, 2010: irrational opposition to regulation. Indian Journal of Medical Ethics, (4).**

The 'statement of objects and reasons' from the Clinical establishment Act 2010 Central, summarising its background, rationale and main provisions. In this Artcile the author discuss here mainly on the doctors' opposition to the legislation and the irrational opposition to the bill. Also he discusses about, other unresolved problems of this act in detailed manner.

- **Kannabiran K. The Clinical Establishments (Registration and Regulation)Bill, 2007: a brief review. Indian J Med Ethics. 2008 Jul-Sep;5(3):108-9**

The Clinical Establishment Act was passed by the Lok Sabha in May in the year 2010 The Bill was to be passed in 2007; it lapsed and was reintroduced in the year 2008. Some important aspects of the implications of this Bill have been covered in this Article. Like what are the objections for 2007 bill, what are the reasaons for lapsing 2007 bill, What are the changes in 2010 act.

- **SANDHYA SRINIVASAN Regulation and the Medical Profession: Clinical Establishments Act, 2010, Vol. 48, No. 3 (2013), pp. 14-16**

This Article deals with The Clinical Establishments (Registration and Regulation) Act, 2010 which is in force in a few states is being sought to be placed before the state legislature in Maharashtra amidst vehement protest from the medical fraternity. This legislation, which

the Indian Medical Association claims will lead to doctors being harassed, was born of a long patients' rights movement against abysmal infrastructure conditions and poorly qualified staff in small clinics, hospitals, and diagnostic and pathology laboratories.

- **Sinha, A., 2019. Clinical Establishments Act, 2010: Improving clinical standards or proscribing physiotherapy. Physiotherapy - The Journal of Indian Association of Physiotherapists, 13(2), p.53.**

This article describes the relevance of the utilization of health and rehabilitation services in India, in an effective manner in order to ensure access to rehab services in India in addition to availability and affordability of services. This article also states that, The Clinical Establishments Act of 2010 applies to all types of clinical establishments in the public and private sectors, as well as single-doctor clinics, in all recognised medical systems. Armed forces-run establishments are the lone exception. So, The clinical establishment of physiotherapy, dietetics, and integrated counselling centre is included under the general category of allopathy clinical establishment.

- **Singh, M., 2017. Clinical Establishments Registration and Regulation System (CERRS) in India. International Journal of Healthcare Education & Medical Informatics, 04(02), pp.15-19.**

The online application used by the Ministry of Health and Family Welfare of the Government of India for the National Clinical Establishment Program is discussed in this article. The Clinical Establishments Registration and Regulation System (CERRS) Project allows clinical establishments in India to register and be approved online. Some restrictions have been noted regarding online registration and renewal of Clinical Establishments, as well as the necessity for technological upgrades, among other suggested reforms.

- **PrabhalChakraborty:Effects Of Demonetization, Clinical Establishment Act, And Media News On Medical Tourism: An Exploratary Study In West Bengal**

The Indian hospital sector has created a global footprint through low-cost conventional medical treatment and has sought out patients from outside. According to a 2015 report by KPMG, "India delivered health services through the provision of medical care to international patients and the mobility of experienced specialists." Medical Tourism, sometimes referred to as Wellness Tourism or Health Tourism, is the term used to describe the movement of individuals from one country to another. The medical tourism sector has developed innovative medical packages that include pre- and post-surgical recreational activities. West Bengal has historically made considerable strides in providing medical and health care services. West Bengal is one of the regions in India with the most advanced medical technology, diagnostics, and hospital facilities.

- **Joseph, S., 2021. Impact assessment of accreditation in primary and secondary public health-care institutions in Kerala, India. Indian Journal of Public Health, 65(2), p.110.**

This Article assess the impact of accreditation on the quality of public health care delivery in primary and secondary health care settings in the state of Kerala. It stresses that in order for the accreditation to bring the embodied quality, structural, and procedural aspects of health care facilities must be improved.

- **Shaikh, A., 2020. Understanding of the Right to Health and Health Care in India With the Strategy at Governmental Level. SSRN Electronic Journal.**

This Article describes in detail the core relation between the right to health and health care in India. It elaborates on the multiple references in the Constitution of India to public health and on the role of the state in the provisions of health care to citizens. It also discusses the strategy adopted by the Government in order to ensure right to health in health care institutions in India.

- **Priebe, G., 2016. Micro Level Impact of the Right to Health – A Qualitative Study of Patient Perceptions. Diversity & Equality in Health and Care, 13(5).**

This article articulates that, in addition to providing functioning health care facilities, securing empowering care interactions is an important aspect of health care quality work. It

also adds that, while human rights-based state rules and health-care policies are critical, particular strategies to ensure their implementation on a micro level in health care are required.

- **Garg P, Nagpal J. A review of literature to understand the complexity of equity, ethics and management for achieving public health goals in India. J ClinDiagn Res. 2014;8(2):1-6.**

This Article systematically reviewed the evidence base regarding regulation of private hospitals, applicability of private-public mix, state of health insurance and effective policy development for India, while seeking lessons on regulation of private health systems, from South African (a developing country) and Australian (a developed country) health care systems.

1.8 CHAPTERISATION

Chapter 1- Introduction

This chapter provides an overview of the research project by outlining the purpose of the study and the topic's relevance. It contains the research questions and the research hypothesis. Additionally, the chapter discusses the research method and provides a brief overview of the literature reviewed.

Chapter 2- Health care System in India: Need for Regulation

This chapter discusses the principles of right to health and how right tohealth is being interpreted by various international documents as well as legislations and judgements in india. This chapter mainly deals with the indian health care sector in India. It then discusses on the relevance of regulating and monitoring health care citizens of health care institutions inorder to secure and safeguard the right to health of citizen by providing quality health care services.

Chapter 3- Over view of Clinical Establishment (Registration and Regulation) Act,2010.

This Chapter discusses the objective of the Clinical Establishment (Registration and Regulation) Act,2010 and also deals with the provisions concerning the registration and regulation of clinical establishments in India.

Chapter 4- Impact and consequences of Clinical Establishment (Registration and Regulation) Act,2010.

This chapter discusses the changes or consequences that have occurred in India since the Act's inception. That is, it discusses the problems that exist in the healthcare system and how they can be resolved, as well as the solutions to the problems. This chapter provides a detailed analysis of the changes and benefits that the act has brought about, as well as a clear indication of whether the act is a boon or a bane.

Chapter 5- Conclusion and Suggestions

This chapter concludes the analysis of the act's establishment, the changes it has brought in the field of healthcare, and the act's necessity, advantages, and disadvantages. Additionally, it makes suggestions for expanding the act's applicability and for properly regulating it to ensure that the public receives high-quality care.

CHAPTER 2

HEALTHCARE SYSTEM IN INDIA: NEED FOR REGULATION

2.1 INTRODUCTION

Health is a barometer of human development, and human development is the bedrock of economic and social progress. Since independence, India has recognised the right to health care and protection. Since then, Independent India has viewed the public as the primary owner of the right to health care and the state as the primary provider of health care for all. Our country, as a founding member of the United Nations, has ratified a number of international treaties that guarantee the protection of people's health care rights. The Indian Constitution does not expressly recognise the fundamental right to health. On the other hand, Article 21 of India's Constitution protects a fundamental right to life and personal liberty. The term "life" in article 21 refers to a dignified human existence, not to mere survival or animal existence. It encompasses a broad range of rights, including the right to subsistence, a higher standard of living, and safe working and recreational environments. Article 21 should be read in conjunction with Articles 38, 42, 43, and 47 to grasp the nature of the state's commitment to ensuring the effective implementation of this right. The World Health Organization defines health care as "preventive, curative, and palliative interventions, whether directed at individuals or populations." The structured provision of such services may result in the formation of a health care system. The primary goal of a healthcare system is to improve people's health.

In the majority of countries, the quality of care delivered by the health-care delivery system has become a primary concern. Due to the critical nature of quality in health care, quality-of-care programmes have become a global phenomenon. Numerous countries are examining various strategies for improving the quality of their health-care systems. In India, the quality of public and private sector services provided to the populace is largely disregarded. The current health-care delivery system lacks sufficient incentives for efficiency improvements. In India, mechanisms for improving hospital efficiency, accountability, and responsible governance that have been implemented in other countries have yet to be implemented. Although the for-profit private sector accounts for a sizable portion of India's health care (50% of inpatient care and 60%–70% of outpatient care), it has received less

attention from policymakers than the public sector. As a result, India's private-sector health-care delivery system has largely remained unmanaged and fragmented, with clear evidence of serious quality-of-care issues in a number of practises. Inadequate and inappropriate treatments, excessive use of advanced technologies, and resource waste are just a few of the issues, as are significant issues of medical malpractice and carelessness. Current health-care policies and procedures fall short of ensuring high-quality care and preventing malpractice. Entities and methods for monitoring the clinical and non-clinical effectiveness of services provided in public and private facilities are required in the current environment. Concerns about how to improve the quality of health care have been expressed in India by the general public and a diverse range of stakeholders, including the government, professional organisations, private providers, and health-care finance organisations. Additionally, initiatives have been launched to establish systems and processes to ensure that health care providers deliver high-quality care.

The Central Government enacted the Clinical Establishments (Registration and Regulation) Act, 2010 ("Act") to regulate and register all clinical establishments in the country, with the objective of establishing minimum standards for the facilities and services provided by them.

2.2 HEALTH: RIGHT TO HEALTH

Health and well-being of a person are considered to be two personal matters, but it is then, when we or the person close to us fall ill that we recognize that Health is in fact a public issue and there is the chronic importance of Health Rights in our day today life. Access to quality health is not only a human need, a right of citizenship and a public good, but it is also a prerequisite to good health, which is essential to enjoy and achieve fruits of equitable development. While the right to health would be the ultimate aim, the right to health care would be a first step, a tangible and feasible demand of today’s society.

Health is one of the most difficult terms to define. Health can mean different things to different people. A strict understanding of right to health implies that everyone has the guarantee of perfect health. Access to quality health care is not only a human need, a right of citizenship and a public good, but it is also a pre-requisite to good health, which is essential to

enjoy and achieve fruits of equitable development.[15] Health does not mean merely physical health or the absence of disease, disability or infirmity. It is a state of complete physical mental, emotional, social, and spiritual well-being both of the individual and of the nation. Every woman, man, child, and adolescent has the human right to the best possible physical and mental health without regard for any form of discrimination. The human right to health is critical for all aspects of a person's life and well-being, as well as for the realisation of a number of other fundamental rights and freedoms.[16] A strict understanding of a right to health implies, somewhat absurdly, that everyone has the guarantee of perfect health.

Not only health care is included in the right to health, but also the underlying determinants of health, such as safe drinking water, adequate sanitation, and access to health information. The right encompasses fundamental liberties such as the right to be free of discrimination and coerced medical treatment. Additionally, it encompasses entitlements such as the right to adequate primary health care. The right encompasses a variety of facets, including child health, eternal health, and access to life-saving medications. As with other human rights, it is particularly concerned with the disadvantaged, vulnerable, and impoverished. The right to health requires an effective, inclusive, and high-quality health system. The World Health Organization[17] uses a holistic definition of Health according to which health does not merely consist of the absence of disease or handicaps but refers to the highest attainable standard of physical, mental and social well-being. While this definition is more inclusive and allows various aspects of life to be taken into account in health issues, this wide understanding of health can be a double-edged sword. On the one hand, if appears to avoid restricted, paternalist of imperialist interpretations of the concept, but on the other hand, it leaves plenty of room for relativist interpretations of what is to be included in health and what it means to be Healthy. After all, even when we think about Health merely in terms of lack of disease of handicap, there might be differences in interpretations of its meaning across cultural, national and generational borders.

[15] Health and Right to health, Available at http://findarticles.com (last visited September 20, 2021).
[16] *Ibid.*
[17] WHO World Health Organisation Available at https://www.who.int/ last visited (September 20, 2021)

2.2.1 Right to Health at International Level

The right to health is entrenched in a series of international treaties as well as numerous national constitutions. Among the most important instrument at the international level guarantying right to health is the Universal Declaration of Human Rights (UDHR)[18] although the UDHR is a General Assembly declaration instead of a treaty, it may be legally binding on the countries as either customary international law or as authoritative interpretation of the U.N. Charter.[19]

A major international standard-setting instrument is the International Covenant on Economic, Social and Cultural Rights.[20] Notably Article 12 of this Covenant lays down the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health". A General Comment[21] attempts to circum-scribe the content of this article in greater detail. Yet such a commentary or any effort, for that matter, to give concrete substance to contractual provisions at international level will always be infused with the need to affect a compromise between representatives of highly differing countries.

Furthermore, numerous international instruments recognise the right to health, including article 5 (e) (iv) of the 1965 International Convention on the Elimination of All Forms of Racial Discrimination, articles 11.1 (f) and 12 of the 1979 Convention on the Elimination of All Forms of Discrimination Against Women, and article 24 of the 1989 Convention on the Rights of the Child. Numerous regional human rights instruments recognise the right to health, including the European Social Charter as revised in 1961 (art. 11), the African Charter on Human and Peoples' Rights as revised in 1981 (art. 16), and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social, and Cultural Rights as revised in 1988. (art. 10). Similarly, the Human Rights Commission has recognised the right to health.[22]

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[18] Universal Declaration of Human Rights, U.N.G.A. res. 217A (III), U.N. Doc A/810 at 71 (1948).
[19] Henry J. Steiner & Philip Alston, International Human Rights in Context: Law, Politics, Morals, 2nd edition (Oxford: OUP, 2000), p. 143.
[20] IArt.12. ICESCR Available at https://www.who.int/hhr/Economic_social_cultural.pdf (last visited September 20, 2021)
Also see B. Toebes, The Right to Health as a Human Right in International Law
(Amsterdam: Hart, 1998).
[21] U.N. Committee on Economic, Social and Cultural Rights [hereinafter "CESCR"], General Comment 14, The right to the highest attainable standard of health, CESCR, 22nd Sess., Para.
[22] Committee on Economic, Social & Cultural Rights resolution 1989/11, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments. The United Nations General Assembly in 1991 resolution 46/119

Health is inextricably linked to and dependent on the fulfilment of other human rights enshrined in the International Bill of Rights, including the rights to food, housing, work, education, human dignity, life, non-discrimination, equality, the prohibition of torture, privacy, and access to information, as well as the freedoms of association, assembly, and movement. These and other fundamental rights and liberties pertain to critical facets of the right to health.

The General Comment on Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), adopted in 2000, sheds critical light on the conceptualization of the right to health. It demonstrates that the right to health does not have to be synonymous with the right to be healthy. Rather than that, when the goal of enabling individuals to enjoy the highest possible standard of health is stated, a dual condition is implied: the right to health is first and foremost contingent on the individual's biological and socioeconomic circumstances, and secondly, on the government's financial resources. This limitation was reflected in the Covenant's formulation, which rejected the WHO definition of health. According to the World Health Organization, health is "a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity."[23].

Accordingly, elements of the right to health within the meaning of the Covenant include availability, i.e. the existence of a sufficient number of health facilities; attainability, i.e. non-discriminatory access in physical, economic and informational terms; acceptability, i.e. respect for ethnic and cultural distinctions; as well as the necessary quality of healthcare benefits. The second paragraph of Article 12 ICESCR specifies the obligations of the state as follows: reduction of infant mortality; improvement of environmental and industrial hygiene; prevention, treatment and control of epidemic, endemic, occupational and other diseases; and creation of conditions which enable all persons to obtain medical service and medical attention in the event of sickness. Systematically speaking, the state is responsible for respecting and protecting its inhabitants, and for granting access to benefits and services.[24]

Governments are obliged to enforce the human right to health fall in three distinct ways: they must respect the right, they must protect the right, and they must fulfill the right. To respect means a government itself must not to violate the right to health, as it would by cutting funding for doctors working in underserved areas, for example. To protect entails that a government is

[23] U.N. Committee on Economic, Social and Cultural Rights, General Comment 14, the right to the highest attainable standard of health, note 13.
[24] Committee on Economic, Social and Cultural Rights, General Comment 14, The right to the highest attainable standard of health, note 13.

responsible for preventing third parties from violating the right to health. Eviscerating environmental regulations arguably violates the right to health, as does allowing price gouging by monopolistic pharmaceutical companies. And the obligation to fulfil emphasizes that a government must ensure that all citizens have access to basic health services.

World Health Organization and The Right to Health

The WHO Constitution was the first international instrument to enshrine the pursuit of the highest possible standard of health as a fundamental human right ("the right to health").[25]

The WHO Constitution's Preamble is a masterfully coherent statement claiming ownership of the entire field of contemporary international public health. In a similar vein to the United Nations Charter, the Preamble asserts that the principles set forth are necessary for the happiness, harmonious relations, and security of all peoples, thereby expressing a contemporary set of universal aspirations. It states that health is a necessary condition for their attainment, and that the highest possible level of health is a fundamental right of every human being without exception. The preamble defines health positively, as total physical, mental, and social well-being, rather than exclusively negatively, as the absence of disease or infirmity. While the concept of public health is contemporary, the Preamble's rhetorical cadences echo those of the Age of Reason in the late 18th century. Certain rights, such as the right to health or the right to life, liberty, and the pursuit of happiness, according to this view, cannot be granted or denied by any government because they are fundamental, inalienable human rights that all humans already possess.[26]

The Preamble then discusses nations' responsibilities to contribute to their citizens' health. This obligation is not imposed from the outside, but stems from every human being's fundamental right, and thus from humanity as a whole. The Preamble then discusses nations' responsibilities to contribute to their citizens' health. This obligation is not imposed from the outside, but stems from every human being's fundamental right, and thus from humanity as a

[25] In February 1946 the Economic and Social Council of the United Nations established a Technical Preparatory Committee of Experts to prepare an agenda for the International Health Conference in New York, to be held from 19 to 22 July 1946. The agenda included the preparation of a constitution for a World Health Organization (WHO) . The Conference eventually approved the WHO Constitution on 22 July, and designated an Interim Commission to carry out essential public health activities until the new organization was established. Representatives of sixty-one states signed the WHO Constitution on July 22, 1946, after which it remained open for signature until it came into force on April 7, 1948.

[26] Frank P Grad, "The preamble of the Constitution of the World Health Organization", Bulletin of the World Health Organization. 2002; 80(12):981-982.

whole. The Preamble begins with each human being's fundamental right to health and progresses to the health of all peoples, noting that this is critical to their accomplishment of peace and security and requires the complete collaboration of individuals and states. When sickness, poverty, and other social problems combine to destabilise governments and societies, the connection between health, peace, and security becomes self-evident.

The Preamble notes that the achievement of any state in the promotion and protection of health is of value to all. It follows that unequal development in the promotion of health in different countries, and particularly in the control of disease, is a common danger. Additionally, the Preamble emphasises the fundamental necessity of a child's healthy growth, stating that it is critical for a child's development to live happily in an ever-changing environment. To achieve optimal health, all peoples must benefit from medical, psychological, and associated knowledge. This concept serves as a reminder that access to important knowledge and medicines should not be restricted at any national boundary, and that such restrictions should not be accepted for political or commercial reasons..[27]. The Preamble recognises another prerequisite for completing the WHO's mission: governments' responsibility for their citizens' health can be satisfied only via the provision of suitable health and social measures. This suggests that not only government action is required, but also social and economic measures if states are to fulfil their commitment to their citizens' health. This implies a knowledge of the importance of flexibility in the formulation of health policies.[28]

Recognizing the magnitude of the challenge ahead, the Preamble emphasises the importance of educated public opinion and active participation on the side of the public in order to enhance the public's health. The Preamble recognises another prerequisite for completing the WHO's mission: governments' responsibility for their citizens' health can be satisfied only via the provision of suitable health and social measures. This suggests that not only government action is required, but also social and economic measures if states are to fulfil their commitment to their citizens' health. The Preamble requires member states to promote not only their own people's health, but also to support WHO's cooperative activities to advance the health of all people worldwide. Because health is widely seen as a fundamental human right, it may possibly be deemed to transcend limiting national and sovereign restrictions.[29]

[27] *Ibid.*
[28] *Ibid.*
[29] *Ibid.*

One must agree that this preamble language of the WHO Constitution would codify far-reaching human rights norms commensurate with contemporary public health discourse – creating what would be referred to as a "Magna Carta of health,"[30] "represent[ing] the broadest and most liberal concept of international responsibility for health ever officially promulgated,"[31] and encompassing the aspirations of WHO's mandate following the ravages of the Second World War.[32]

As the United Nations' (UN's) principal specialized agency with purview over the conditions necessary for health, WHO possesses a unique institutional responsibility to implement the right to health through its directing and coordinating authority in international health. The participation of United Nations organisations and programmes, particularly the critical role designated to the WHO in implementing the right to health at the international, regional, and national levels, is critical. States parties should seek technical help and collaboration from the WHO when developing and implementing national plans on the right to health. Additionally, States parties should make use of the WHO's wide information and advice services while drafting their reports, particularly with regard to data collection, disaggregation, and the formulation of right to health indicators and benchmarks.[33]

The Universal Declaration of Human Rights

The United Nations' first catalogue of human rights and fundamental freedoms was the UDHR, a declaration adopted by the United Nations General Assembly (UNGA) on 10 December 1948 in Paris, France.[34] The UDHR represents a watershed moment in human rights history. The UDHR was the first time an organised community of states adopted a Declaration of human rights and basic freedoms. It was envisioned as a universal benchmark of achievement for all peoples and nations. The UDHR has evolved into a gauge for assessing the extent to which international human rights principles are respected and adhered to.

Its preamble includes the "four freedoms" enumerated in Franklin D. Roosevelt's famous speech to the U.S. Congress, and its adoption marked the first time that international law protected the individual rights of citizens within their own countries[35]. The catalogue of

[30] Parran T. Remarks at concluding meeting of International Health Conference. UN Doc. E/H/VP/18. 2. Reprinted in Parran T. Chapter for world health. Public Health Reports. 1946;61:1265-1268.
[31] Allen CE. "World health and world politics", International Organization. 1950;4(1):27- 43, 30.
[32] Bok S., "Rethinking the WHO definition of health", Harvard Center for Population and Development Studies, Working Paper Series. 2004;17(7):1-14.
[33] Available at http://www.who.int (last Visited September 20, 2021)
[34] Paul Sieghart, The International Law Of Human Rights (Oxford: Clarendon Press, 1993), p- 24.
[35] Available at http://www1.umn.edu/humanrts/instree/l1viedec.html (last visited September 20, 2021)

human rights and fundamental freedoms set out in UDHR contains special provision relating to health under article 25.[36] In fact this provision laid down the foundations for the international legal framework for the right to health, which is pre-condition for the enjoyment of all other human rights. The provisions contained in article 25 were expanded and flourished in the ICESCR and many other international legal instruments.

It affirms in article 25 that everyone has the right to a standard of living adequate for his or her health and well-being, including food, clothing, housing, medical care, and necessary social services, as well as the right to security in the event of unemployment, sickness, disability, widowhood, or old age, or other inability to earn a living due to circumstances beyond their control. Motherhood and childhood deserve special consideration and attention. All children, whether born within or outside of marriage, will be entitled to the same level of social support..[37] Since the adoption of the UDHR, the right to health has become widely accepted as a fundamental human right, explicitly recognised in various international and regional human-rights treaties, as well as in national constitutions, domestic laws, policies, and programmes.

The International Covenant on Economic Social and Cultural Rights

The UDHR's provision on the right to health is complemented by the provision in the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which is meant to elaborate on its meaning. This covenant was the first human rights treaty to require states to recognize and realize progressively the Right to Health, and it provides key provisions for the protection of Right to Health in International law.[38] Article 12 of the Covenant is the most comprehensive article in international human rights legislation on the right to health. Article 12.1 of the Covenant recognises "the right of everyone to the highest achievable quality of physical and mental health," while article 12.2 outlines a series of "measures to be taken by States parties... to fully realise this right." These steps include the following: Providing for the reduction of stillbirths and infant mortality, as well as for the child's healthy development; Improving all aspects of environmental and industrial hygiene; Preventing, treating, and controlling epidemic, endemic, occupational, and other diseases; and Establishing conditions that ensure access to all medical services and attention in the event of illness.

[36] Paul Sieghart, The International Law of Human Rights, note 29, p- 24.
[37] See Article 25 of Universal Declaration of Human Rights Available at https://www.un.org/en/about-us/universal-declaration-of-human-rights (last visited September 20, 2021)
[38] See Amnesty International Report 2007.

The Third Committee of the United Nations General Assembly did not endorse the WHO's preamble to the WHO Constitution's definition of health, which defines health as "a condition of complete bodily, mental, and social well-being, not only the absence of sickness or infirmity." However, the reference to "the best possible quality of physical and mental health" in article 12.1 of the Covenant is not limited to the right to health care. On the contrary, the drafting history and express language of article 12.2 recognise that the right to health encompasses a broad range of socioeconomic factors that contribute to the conditions necessary for people to live a healthy life, including underlying determinants of health such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.[39]

In 2000, the UN Committee on Economic, Social, and Cultural Rights, which monitors conformity with the ICESCR, adopted a General Comment on the Right to Health to clarify and operationalize the preceding provisions..[40] The Committee was cognizant of the fact that, for millions of people worldwide, full enjoyment of the right to health remained a distant objective. Furthermore, this aim is growing increasingly distant in many circumstances, particularly for those living in poverty. The Committee recognises the considerable structural and other impediments imposed by international and other forces beyond the control of States that prevent many States Parties from fully implementing article 12. To assist States parties in implementing the Covenant and meeting their reporting obligations, the General Comment focuses primarily on the normative content of article 12 (Part I), the obligations of States parties (Part II), violations (Part III), and national implementation (Part IV), while Part V addresses the obligations of actors other than States parties. The General Comment is based on the Committee's many years of experience analysing States parties' reports.

The General Comment states that the right to health also contains a "core content" that refers to the right's bare minimal essential level. Although this level cannot be determined abstractly because it is a national activity, significant factors are identified to aid the process of prioritisation. The fundamental content includes essential primary health care; minimum essential and nutritious food; sanitation; safe and potable water; and essential medications. Adoption and implementation of a national public health strategy and action plan is another critical task. This must address the health issues of the entire population; be developed and revised on a participatory and transparent basis; include indicators and benchmarks that allow

[39] Committee on Economic, Social and Cultural Rights, General Comment 14, note 13.
[40] *Ibid.*

for close monitoring of progress; and pay special attention to all vulnerable or marginalised groups..[41] The General Comment clarifies that the right to health encompasses not only timely and appropriate health care but also the underlying determinants of health, such as access to safe drinking water and adequate sanitation, an adequate supply of safe food, nutrition, and housing, safe occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health..[42]

2.2.2 Right to Health in India

India has ratified a number of international accords aimed at ensuring the protection of people's rights to health care. While Article 21 of the Indian Constitution safeguards a fundamental right to life and personal liberty, it does not expressly recognise it.

Over time, the judiciary has determined that Article 21's right to life is incomplete without the right to live in dignity, which encompasses a variety of other rights such as the right to education, livelihood, health, and housing. Thus, the right to health became a part of fundamental rights and was incorporated into Article 21 of the Indian Constitution. The provisions of the Indian Constitution that define the right to health are as follows: The Indian constitution's Article 21 addresses the protection of life and personal liberty. It expressly states that no one's life or personal liberty may be taken away unless and until the proper legal procedure is followed. The purpose of Article 21's fundamental right is to prohibit the violation of personal liberty and the impairment of life unless and until legal procedures are followed. The right to life is inherent in our nature; without it, we would be unable to live as human beings, and it encompasses all aspects of life that contribute to the meaning, completion, and worth of a human being's life.[43]

The right to live with human dignity enshrined in Article 21 derives itself from the Directive Principles of State Policy and in particular Clauses (e) and (f) of Article 39 and Articles 41 and 42 and must therefore at least include the protection of children's health, incentives and facilities for safe, fair and humane working conditions, etc.[44] These are the minimum requirements that must exist in order to allow an individual to live with human

[41] *Ibid.*
[42] *Ibid.*
[43] V. Maheshwari, India - The Expanding Horizons, 5th January 2011. http://www.legalserviceindia.com/articles/art222.htm.
[44] Indian, Law: Judicial Interpretation Of Article 21 Of The Indian Constitution,(7th December 2020 10:00), https://guide2lawyers.blogspot.com/2012/06/judicial-interpretation-of-article-21.html.

dignity and no Government, neither the central government nor any government of any State, has the right to take any action that would deprive a person of these fundamental elements.[45]

Role of State in ensuring Right to Health

According to Article 47 of the Indian Constitution, the state's primary responsibility is to raise citizens' nutritional and living standards and to improve public health. It also prohibits the consumption of intoxicating beverages and harmful medicinal items, except for medical purposes. Nonetheless, it is not enforceable in a court of law, and it may not be necessary to compel the State, through the judicial process, to enact legislation providing for this essential element of a life of human dignity, but where the State has already enacted legislation providing for these fundamental requirements, the State is unquestionably obligated to ensure that the State's failure to comply with such legislation results in a violation of the Constitution.[46]

In comparison to some of the other social rights, the Supreme Court of India has only recently formulated and accepted the right to health as an integral part of the right to life. The Supreme Court has recognised the right to health as a result of a variety of petitions and public interest litigations, ranging from PILs relating to workplace health hazards to petitions filed by individuals seeking health security rights, as well as incentives and facilities for children to grow in a safe, healthy, and humane manner.[47]

In India, the right to healthcare has been recognised since ancient times. It was recognised in a variety of post-independence Indian constitutional provisions. According to Article 19(6), public health is a limiting factor in relation to Article 19(1)(g), which guaranteed all Indian citizens the right to practise any profession or to engage in any occupation, trade, or business. The Supreme Court and the High Courts have interpreted Article 21 in numerous cases in light of various international instruments with the goal of broadening its scope and purpose and effectively incorporating the right to health care as a necessary component of life protection.[48]

These covenants are codified in The Protection of Human Rights Act, 1993's Statement of Objects and Reasons. Additionally, human rights commissions have the authority to examine

[45] Abhay, Judicial Interpretation Of Article 21 Of The Indian Constitution, 2011 http://www.legalservicesindia.com/law/article/1105/10/Judicial-Interpretation-in-Right-to-Life-and-Personal-Liberty/. (last visited September 20, 2021)
[46] *Ibid.*
[47] Jayna Kothari, Social Rights And The Indian Constitution, EPW https://www.epw.in/tags/constitution-india. (last visited September 20, 2021)
[48] Francis Coralie Mullin V. The Administration, Union Territory Of Delhi, AIR 1981 SC 746 (India).

human rights treaties and other international instruments and make recommendations on how to effectively enforce them.[49] Several complaints have been filed recently with national or state human rights commissions alleging medical negligence and inadequacy of care by private and public hospitals and medical professionals. The Constitution contains clauses ensuring citizens' right to the best physical and mental health possible. Article 21 of the Constitution ensures that every individual's life and personal liberty are protected. The Supreme Court held that Article 21's right to a dignified life is derived from the values embodied in the directive principles of state policy and includes the guarantee of health. Additionally, the right to health is a component of the right to life, and the government is obligated by law to provide healthcare services.

Further, in *State of Punjab v. Mohinder Singh*,[50] the Supreme Court ruled that the right to health is now a settled law and is an integral part of the right to life. If a government hospital fails to provide a patient with timely medical care, the patient's right to health is violated and then his right to life is violated as in *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*[51]. Likewise, the Court has upheld the responsibility of the State to provide health care facilities in *State of Punjab v. Ram Lubhaya Bagga*.[52] In addition to violations of the right to health, public interest petitions have been filed pursuant to Article 21. They were applied for special care for children in prison in *Sheela Barse v. Union of India*[53] and against hazardous drugs in *Vincent v. Union of India*[54]; against inhuman conditions in after-care homes in *Vikram v. State of Bihar*.[55] The supreme court ruled on the health rights of mentally ill patients, *TN In re v. Union of India*[56] which resulted in the death of 25 chained inmates. The rights of patients in cataract surgery camps in *S. Mittal v. State of UP*[57] and for immediate medical aid to injured persons in *Parmanand Kataria v. Union of India*[58] and about conditions in tuberculosis hospitals in *S. Lal v. State of Bihar*[59]; The regulation of blood banks and availability of blood products in *Common Cause v. Union of India and Others*[60]. In *Consumer Education and*

[49] The Protection of Human Rights Act, 1993, Chapter III, Section 12 (f).
[50] State of Punjab v. Mohinder Singh, AIR 1997 SC 1225.
[51] Paschim Banga Khet Mazdoor Samity v. State of West Bengal, AIR 1996 SC 2426 at 2429 para 9.
[52] State of Punjab v. Ram Lubhaya Bagga ,1998 4 SCC 117.
[53] Sheela Barse v. Union of India ,1986 3 SCC 596.
[54] Vincent v. Union of India, AIR 1987 SC 990.
[55] TN In re v. Union of India, AIR 1988 SC 1782
[56] TN In re v. Union of India, 2002 3 SCC 31.
[57] S. Mittal v. State of UP ,AIR 1989 SC 1570.
[58] Parmanand Kataria v. Union of India ,1989 4 SCC 286.
[59] S. Lal v. State of Bihar, 1994 SCC [Cri] 506.
[60] Common Cause v. Union of India and Others, AIR 1996 SC 929.

Research Centre v. Union of India[61], the Supreme Court held that according to Articles 39(e), 41, 43, 48A, the right to health, medical assistance to protect health and vigour of worker while on duty or after retirement is a fundamental right, and this recognition would help to make the life of the worker meaningful and meaningful enough for society.

2.3 HEALTH CARE SYSTEMS IN INDIA

The term "health care system" refers to the organisation of people, institutions, and resources for the purpose of delivering health care services that fulfil the target population's health needs. The WHO defines it as "All the activities whose primary purpose is to promote, restore, or maintain health." World Bank (WB) has given a broader definition for the health system by including factors interrelated to health, such as poverty, education, infrastructure, and social and political environment.

According to WHO, the goals for health systems are good health, responsiveness to the population's expectations, and fair financial contribution. Progress towards these goals depends on how systems carry out four vital functions of providing health care services, resource generation, financing, and stewardship. Further, other dimensions for evaluating health care systems include quality, efficiency, acceptability, and equity. These dimensions have also been described in the United States as "the five C's": Cost, Coverage, Consistency, Complexity, and Chronic illness.

Worldwide, there are as many health care systems as there are nations, each with its own history and organisational structure. In certain nations, planning for the health care system is decentralised among market participants. In others, governments, labour unions, charities, religious organisations, and other coordinated groups work cooperatively to give planned health care services to the community they serve.

However, in India health care system is characterized by a pattern of mixed ownership and different systems of medicine - Allopathy, Ayurveda, Yoga, Unani, Siddha, Naturopathy and Homoeopathy (AYUSH).[62]

[61] Consumer Education and Research Centre v. Union of India 1995, AIR 922, 1995
[62] Ministry of Ayush, available at https://www.ayush.gov.in/ (last visited September 20, 2021)

The Ayurvedic system[63] (meaning life science) deals with causes, symptoms, diagnosis, and treatment based on all aspects of well-being (mental, physical, and spiritual). These experts, traditionally, have been acquiring skills from their ancestors. However, with the advent of education, various institutions offer traditional medical training.

The Siddha[64] system describes diseases as a condition in which the general loss of five aspects of human beings is lost, leading to various types of malnutrition. Diagnostic methods in the Siddha medical system are mainly based on the acumen of physician clinics after patient observation, heart rate and diagnosis, and clinical history.

Yoga[65] is both a science and an art of physical, mental, moral, and spiritual well-being. Yoga is thought to have been invented a few thousand years ago by Indian saints and sages. Yoga derives from the Vedas, and its philosophy is the art and science of coexistence with the universe. Yogis presented a rational interpretation of their experiences with Yoga and infused each individual with a sound and scientifically prepared approach.

Naturopathy[66] has many references to the Vedas and other ancient writings, indicating that these practices were widely practiced in ancient India. Naturopathy believes that all diseases arise due to the accumulation of harmful substances in the body, and when given the extent of their removal, it provides treatment or relief. It also believes that the human body has the natural ability to build and sustain itself. Naturopathy differs slightly from other medical systems, as it does not believe in a specific cause of the disease and its treatment but focuses on the underlying causes of diseases such as unnatural behaviors in life, thinking, function, and sleep, or rest, and natural factors that interfere with normal body function.

The Unani[67] medical system believes that the body comprises four essential elements: earth, air, water, and fire, which have different winds: cold, hot, wet, and dry. After mixing and blending the four ingredients, a new compound with a new shape emerges hot, hot-dry, cold-wet, and cold-dry. The body has integrated and straightforward organs, which have received

[63] GUIDELINES for AYURVEDA PRACTITIONERS, available at https://www.ayush.gov.in/docs/ayurved-guidlines.pdf (last visited September 20, 2021)
[64] GUIDELINES for Siddha PRACTITIONERS, available at https://www.ayush.gov.in/docs/siddha-guidlines.pdf (last visited September 20, 2021)
[65] GUIDELINES for YOGA PRACTITIONERS, available at https://www.ayush.gov.in/docs/yoga-guidlines.pdf (last visited September 20, 2021)
[66] GUIDELINES for NATUROPATHY PRACTITIONERS, available at https://www.ayush.gov.in/docs/Naturopathy-guidlines.pdf (last visited September 20, 2021)
[67] GUIDELINES for UNANI PRACTITIONERS, available at https://www.ayush.gov.in/docs/unani-guidlines.pdf (last visited September 20, 2021)

nourishment by four humors, viz. blood, phlegm, yellow bile, black bile. The Unani medical program believes in health promotion, disease prevention, and treatment. In addition to such health care programs, there are also faith / spiritual healers found mainly in rural India.

Some spiritual leaders use one or more of the traditional remedies, viz, Ayurveda, Yoga, or Naturopathy as alternative therapies for their clients.

2.4 INDIAN HEALTHCARE SECTOR

With a mixed healthcare system consisting of public and private healthcare service providers, it has been observed that a majority of the private healthcare providers are in urban India, largely servicing the needs for secondary and tertiary care. The government healthcare system in India seeks to provide primary, secondary and tertiary care in an affordable and accessible manner in both rural and urban areas.

National Rural Health Mission, launched in 2005[68], seeks to provide affordable, accessible and quality healthcare to the rural population, especially to those belonging to vulnerable groups. Special focus will be accorded to the empowered action group states, namely - Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Rajasthan, Uttaranchal and Uttar Pradesh, as well as the north-eastern states, Jammu & Kashmir and Himachal Pradesh. Set up in a decentralised manner, the primary healthcare system in rural India has been established as a three-tier system based on the following norms:

Sub-centres: A subcentre (SC) is established in a plain area with a population of 5,000 people and in hilly/difficult-to-reach/tribal areas with a population of 3,000 people as the peripheral and first point of contact for healthcare in rural areas. Based on factors such as catchment area, care seeking behaviours, case load, among others, sub-centres have been classified into two types. Type A sub-centres provide all mandated services except facilities for childbirth. Type B sub-centres provide all recommended services, as well as facilities for delivery. The staffing recommendations for both facilities are different but require at least one ANM/female health worker and one male health worker. The minimum assured services offered include preventive, promotive, few curative and referral services (Government of India, 2012).

[68] NATIONAL RURAL HEALTH MISSION Meeting people's health needs in rural areas. Available at https://nhm.gov.in/WriteReadData/l892s/nrhm-framework-latest.pdf (last visited September 20, 2021)

Primary health centres:. In a plain area with a population of 30,000 people and in hilly/difficult-to-reach/tribal areas with a population of 20,000 people, a primary health care centre (PHC) with six indoor/observation beds is created. It serves as the cornerstone of rural health. It is the first port of call between patients from the village community and a medical officer, and serves as a referral unit for six sub-centres. PHCs were designed to provide integrated preventive, promotive and curative healthcare to the rural population. A PHC must have a medical officer and other staff members as a minimum requirement (Government of India, 2012).

Community health centres: Community health centres (CHCs) are set up by state governments in an area with a population of 1,20,000 people and in hilly/difficult to reach/ tribal areas with a population of 80,000. They aim to provide optimised and specialised care to the community. Considering the current shortage with regards to clinical manpower, doctors in PHCs may also have to take over shift duties to provide emergency services at CHCs. An anaesthetist and public health specialist will be required in addition to specialists for surgery, medicine, obstetrics and gynaecology, and paediatrics. A district / sub-divisional hospital or CHC can be declared a first referral unit if it can provide round-the-clock emergency obstetric and new born care as well as for blood storage. District hospitals serve as secondary level care providers for rural areas. National Urban Health Mission (NUHM)[69] was launched as a sub-mission of the National Health Mission[70] in 2013. It seeks to cover all state capitals, district headquarters and cities/towns with a population of more than 50,000 with a primary focus on care for vulnerable groups and reducing out-of-pocket expenditures. Inter-sectoral convergence that focuses on all determinants of public health is one of the key objectives of the NUHM.

2.4.1 Private Healthcare System

The situation as it stands in India is worrisome as for every 10,189 people there is only 1 doctor available and also statistics show that 2,046 people fight for a single bed. No doubt, India is suffering from a major health crisis[71]. With an aim to bring in quality and affordable healthcare, several private players have entered the healthcare sector in the past two decades.

[69] NATIONAL URBAN HEALTH MISSION FRAMEWORK FOR IMPLEMENTATION, Available at http://nrhmchd.gov.in/sites/default/files/nuhm.pdf (last visited September 20, 2021)
[70] National Health Mission, Available at https://nhm.gov.in/ (last visited September 20, 2021)
[71] Public Vs Private Healthcare in India, Available at https://docmode.org/public-vs-private-healthcare-in-india/.(last visited September 20, 2021)

However, much of these facilities are limited to urban areas. While India's economy continues to grow, the health-seeking habits of its citizens have changed with increasing health awareness. Healthcare has achieved more political will in the past few years, and more so in the current year in light of the COVID-19 pandemic. As much as 70% of new hospital beds added to the country's healthcare capacity in the last ten years has come in from the private sector. Since the hospital business is capital intensive with a long gestation period, several of the current hospital assets are not delivering expected investor returns. Capital and operating efficiency are therefore critical for keeping the business of healthcare healthy for investors (EY and FICCI, 2016).[72] Going by data from the past decade, the hospital bed density per 1,000 people has risen from 2.26 to 2.77 for urban areas in India. However, at the national level, the number of beds remains nearly 1.31 beds per 1,000 people.

In this power hierarchy prevailing in the private sector, the informal sector has the least authority and does not come under the ambit of any regulation. Evidences suggest that more than 80% of the population is dependent on this sector for out-patient care.[73] The informal sector mainly provides treatment for things like minor ailments, ante-natal and delivery services. The urban and rural poor are dependent on them for first level of care. The services provided by these practitioners are often of variable quality and in some cases even dangerous.[74] Thus, due to this multi-layered framework of private hospitals in India, it has become difficult to manage their functioning through proper set of regulations by the State

A recent report (Singh, 2018)[75] in the Business Standard describes the evolution of the India's organised healthcare industry. Earlier, private healthcare was provided largely by trust-run hospitals or private facilities. Branded for-profit hospitals and corporate caregiver chains have also entered the market today. Growth in this industry has clocked in at 12-17%. Apollo Hospitals was the first corporate group to enter the for-profit healthcare business in the 1980s. Several other entities, including Max Healthcare, Fortis, Narayana Hrudayalaya, Medanta and Paras entered the fray in the coming years to varying levels of success.

[72] FICCI KPMG – Indian Media and Entertainment Industry Report 2016, available at https://ficci.in/spdocument/20723/Executive-summary-FICCI_KPMG-report-2016.pdf (last visited September 20, 2021)
[73] Narayana K. V., The Unqualified Medical Practitioners: Methods of Practice and Nexus with Qualified Doctors. Working Paper No. 70. Hyderabad: Centre for Economic and Social Studies; 2006.
[74] Damodaran H. India's New Capitalists: Caste, Business, and Industry in a Modern Nation. Ranikhet: Permanent Black in Association with The New India Foundation; 2008.
[75] Raman Singh eyes bigger victory in 2018 state polls, Available at https://www.business-standard.com/article/news-ani/raman-singh-eyes-bigger-victory-in-2018-state-polls-117121000631_1.html (last visited on September 20, 2021)

Tier-2 and tier-3 cities have seen the entry of several private hospital chains as well. Niche facilities in maternal health and neonatal care have also emerged with chains like Cloud 9 and CK Birla Women's hospital setting up shop. With the epidemiological transition that India has seen and the rising cases of NCDs, lifestyle diseases, infections and geriatric health conditions, opportunities for healthcare businesses are significant (Singh, 2018).[76]

2.5 ROLE OF HEALTHCARE SYSTEM IN PROMOTING AND PROTECTING PUBLIC HEALTH

The quality of a society's health care system and services is viewed as a critical aspect in defining a state's government. Health care systems and services differ per country, depending on the state's health care policies. In highly industrialised countries, health care systems have advanced significantly and the breadth of services available to their citizens is widely acknowledged. Health care is a critical aspect in determining a person's physical and mental well-being. That is why it is also widely regarded as a significant economic contributor to a country. Health care services, whether public or private, include the diagnosis, prevention, and treatment of illnesses, injuries, and other health impairments affecting people worldwide. Health care is provided by a variety of providers and experts, including dentists, physicians, ophthalmologists, midwives, nurses, and pharmacists. They are the ones who are largely responsible for meeting the patient's health-related requests and wants.

Not only do health systems have a responsibility to enhance people's health, they also have a responsibility to protect them from the financial costs of disease - and to treat them with dignity. Thus, health systems have three primary goals. These include enhancing the population's health, meeting people's expectations, and providing financial protection against the costs of illness.

The mission of public health is to improve population health outcomes through the prevention of disease and the health consequences of environmental hazards and natural or man-made disasters; the promotion of behaviours that reduce the risk of communicable and non-communicable diseases and injuries; and the provision of high-quality health care to the general public. A properly operating health care system can make a considerable contribution

[76] *Ibid.*

to the economics, development, and industrialisation of a country. Health care is frequently seen as a vital component in promoting people's total physical and emotional well-being.

2.6 REGULATION OF HEALTH CARE PROVIDERS.

The Indian Constitution's preamble, in conjunction with the Directive Principles of State Policy, strives to establish a welfare state based on socialist social patterns. It directs the government to prioritise "public health improvement." Additionally, Articles 38, 42, 43, and 47 of the Constitution[77] ensure the promotion of individual health as well as health care. The Union List[78], the State List[79], and the Concurrent List[80] are three distinct lists in the Indian Constitution that detail the legislative powers of Parliament and state legislatures separately and in combination. The Concurrent List discusses criminal law and procedure, marriage, divorce, and all other personal law issues, economic and social planning, population control and family planning, social security and social insurance, employment, education, the legal and medical professions, and the prevention of infectious or contagious disease transmission. Parliamentary legislation supersedes state legislature legislation on matters on the Concurrent List. Parliament lacks legislative authority over the State List, which encompasses public health, hospitals, and sanitation. Two-thirds of the Rajya Sabha can vote to authorise parliament to pass binding legislation on any state matter if it is "necessary or expedient in the national interest." Additionally, two or more States may petition the legislature to legislate on a subject traditionally designated for the state. Other states may choose to adopt the resulting legislation.

In India, health regulation is complicated by a diverse array of actors and obstacles. These include legislation governing health care facilities and services, disease control and medical care, human power (education, licensure, and professional responsibility), ethics and patients' rights, pharmaceuticals and medical devices, radiation protection, poisons and hazardous substances, occupational health and accident prevention, family, women, and child

[77] Articles 38, 42, 43 and 47, Constitution of India, Available at https://legislative.gov.in/constitution-of-india (last visited September 20, 2021)
[78] Union List, Constitution of India, Available at https://legislative.gov.in/constitution-of-india (last visited September 20, 2021)
[79] State List, Constitution of India, Available at https://legislative.gov.in/constitution-of-india (last visited September 20, 2021)
[80]Concurrent List, Constitution of India, Available at https://legislative.gov.in/constitution-of-india (last visited September 20, 2021)

health, mental health, smoking/tobacco control, social security and health insurance, and the environment.

Legislation regulates the licensure of medical professions such as physicians, nurses, dentists, and pharmacists in order to regulate their market access. Statutory regulatory councils have been established to oversee the education, registration, and professional conduct of physicians, dentists, nurses, pharmacists, and practitioners of alternative systems of medicine such as Ayurveda, Yoga, Unani, Siddha, and Homeopathy[81], as well as to monitor the standards of medical education, promote medical training and research, and monitor the education, registration, and professional conduct of physicians, dentists, nurses, pharmacists, and practitioners of alternative systems of medicine such as Ayurveda Among the most significant pieces of law are the National Medical Commission Act, 2019[82], the Indian Nursing Council Act, 1947[83], the Indian Medicine Central Council Act, 1970[84], the Homeopathy Central Council Act, 1973[85], and the Pharmacy Act, 1948[86]. Almost all of these regulations establish bodies to establish uniform educational and qualification standards. Additionally, each rule establishes a centralised registry for individuals qualified to practise the regulated profession of medicine. Finally, councils usually develop regulations governing professional conduct and determine what constitutes professional misconduct.

Regulations governing the prevention and treatment of disease

Numerous laws have been enacted to combat sickness and improve medical care. The first laws date all the way back to British rule. The 1897 Epidemic Disease Act[87], which regulates the control of lethal epidemic diseases, the 1898 Lepers Act[88], are just a few examples. Numerous further legislation were adopted in the years that followed, notably the

[81] Ministry of Ayush, available at https://www.ayush.gov.in/ (last visited September 20, 2021)
[82] National Medical Commission Act, 2019 available at https://www.nmc.org.in/nmc-act/ (last visited September 20, 2020)
[83] Indian Nursing Council Act, 1947 available at https://www.indiannursingcouncil.org/uploads/files/16141575032256.pdf (last visited September 20, 2020)
[84] Indian Medicine Central Council Act, 1970 available at https://legislative.gov.in/sites/default/files/A1970-48_0.pdf (last visited September 20, 2020)
[85] Homeopathy Central Council Act, 1973 available at https://legislative.gov.in/sites/default/files/A1973-59.pdf (last visited September 20, 2020)
[86] Pharmacy Act, 1948 available at https://legislative.gov.in/sites/default/files/A1948-8.pdf (last visited September 20, 2020)
[87] The Epidemic Disease Act 1897 available at https://legislative.gov.in/sites/default/files/A1897-03.pdf (last visited September 20, 2020)
[88] The Lepers Act 1898 available at http://www.indianlegislation.in/BA/BaActToc.aspx?actid=1904 (last visited September 20, 2020)

Medical Termination of Pregnancy Act of 1971[89] and its revisions. This enables a licenced physician to perform MTP in a variety of conditions. Similarly, the 1994 Pre-natal Diagnostic Procedures (Regulation and Prevention of Misuse) Act[90] and its 2002 amendment regulate the use of pre-natal diagnostic techniques. The Act prohibits the use of prenatal diagnostic testing for the aim of ascertaining foetal sex, as well as the practise of "sex selection." Such tests are permitted only in registered facilities and for specific objectives, including the diagnosis of chromosomal abnormalities, genetic metabolic diseases, sex-related genetic disorders, and congenital deformities. The Transplantation of Human Organs Act of 1994[91] regulates the removal, storage, and transplantation of human organs, as well as the ban of commercial deals in human organs.

Regulations relating to Drugs & Pharmaceuticals

The 1940 Drugs and Cosmetics Act[92] is the primary core statute regulating the import, manufacturing, distribution, and sale of pharmaceuticals and cosmetics. The Drug Act established organisations – such as the Medications Technical Advisory Board and the Central Drugs Laboratory – to carry out certain provisions of the Act, enabling the Central Government to regulate the import, manufacture, distribution, and sale of drugs in India. The Central Drugs Standard Control Organization,[93] which reports to the Ministry of Health and Family Welfare[94], is responsible for enforcing this Act's provisions. Among other things, this authority is responsible for approving novel medications and creating uniform drug standards. Apart from

[89] Medical Termination of Pregnancy Act of 1971 available at https://main.mohfw.gov.in/acts-rules-and-standards-health-sector/acts/mtp-act-1971 https://www.indiacode.nic.in/bitstream/123456789/8399/1/pre-conception-pre-natal-diagnostic-techniques-act-1994.pdf (last visited September 20, 2020)
[90] Pre-natal Diagnostic Procedures (Regulation and Prevention of Misuse) Act 1994 available at https://www.indiacode.nic.in/bitstream/123456789/8399/1/pre-conception-pre-natal-diagnostic-techniques-act-1994.pdf (last visited September 20, 2020)
[91] The Transplantation of Human Organs Act of 1994 available at https://main.mohfw.gov.in/sites/default/files/Act%201994.pdf (last visited September 20, 2020)
[92] Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[93] CDSCO Central Drugs Standard Control Organization available at https://cdsco.gov.in/opencms/opencms/en/Home/ (last visited September 20, 2020)
[94] Ministry of Health and Family Welfare available at https://www.mohfw.gov.in/ (last visited September 20, 2020)

vaccines[95], prescription drugs[96], disinfectant fluids,[97] drug life periods[98], condoms,[99] cosmetics,[100] GMP for Ayurvedic drugs,[101] and clinical trials for the import and manufacture of new drugs[102], to name a few.

Blood safety and transfusion services are also subject to a variety of statutory requirements. In 1993, amendments to the Drugs and Cosmetics Act and accompanying recommendations required blood testing for five transmissible diseases, including HIV/AIDS. Blood banks must obtain a licence from the proper authorities, and these licences must be renewed on a regular basis. Additionally, a 1996 Supreme Court decision resulted in significant changes to the country's blood supply administration. In *Common Cause v. Union of India*[103] and others, the court mandated licensure of blood banks, a prohibition on professional blood donations, and stringent criteria for conducting blood donation camps.

Regulations of the private institutional providers of health care

According to studies on utilisation and household health expenditures, 50 percent of those seeking indoor care and 60 to 70% of those seeking ambulatory care (or out-patient care) in the country visit private health facilities. The 'not-for-profit' and 'for-profit' health sectors make up the private health sector. Despite their widespread presence in the country, data on the quantity, role, nature, structure, operation, kind, and quality of care provided by private hospitals is clearly lacking. The quality of care offered by India's private health-care services has also been questioned. This occurs in a setting where there are minimal quality assurance

[95] Schedule G Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[96] Schedule H Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[97] Schedule O Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[98] Schedule P Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[99] Schedule R Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[100] Schedule S Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[101] Schedule T Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited September 20, 2020)
[102] Schedule Y Drugs and Cosmetics Act 1940 available at, https://legislative.gov.in/sites/default/files/A1940-23.pdf (last visited O September 20, 2020)
[103] Common Cause v. Union of India AIR 2018 SC 1665

measures in place, and the majority of the population uses the formal health sector but has no control over the quality of care.[104]

Furthermore, private-sector laws and accountability mechanisms are few and far between. Clinical establishments are not supervised or overseen in the vast majority of Indian states. Only a few states require private facilities, such as hospitals and nursing homes, to be registered.

2.7 ACCREDITATION OF HEALTHCARE

Accreditation is defined as public recognition of a healthcare organization's compliance with accreditation standards, as determined by an independent external assessment of the organization's performance in relation to the standard. Accreditation assessment is based on establishing an organization's technical competence in accordance with accreditation standards when it comes to providing services within its scope. It transcends compliance. It necessitates continued excellence. This characteristic distinguishes it as a market-driven process that involves all stakeholders, including consumers, empaneling agencies, regulators, and other third parties. Accreditation is also a well-established mechanism used globally to promote acceptance conformity assessment results on a national and international level.[105]

In other words, accreditation is based on the presence or absence of such standards as determined by qualitative indicators (evidence of performance) observed by an expert panel. Accreditation is an optional process. It emphasises education, self-development, increased performance, and risk reduction. Accreditation is based on the highest standards of performance and professional accountability, and it motivates healthcare organisations to strive for continuous excellence. Accreditation as a concept. Accreditation in healthcare services refers to the evaluation process by which an accrediting body verifies that a healthcare organisation complies with certain standards established by subject-matter experts. Accreditation is typically conducted by a multidisciplinary team of health professionals and compares the environment in which clinical care is delivered to published standards. National standards are frequently the result of a synthesis of national statutes, government guidance,

[104] Bhat, Ramesh. (1996). Regulation of the Private Health Care Sector in India.
[105] Quality and accreditation in health care services A global review, Available at https://www.who.int/hrh/documents/en/quality_accreditation.pdf (last visited September 20, 2021)

independent reports, international accreditation standards, and biomedical and health services research. The accreditation process entails the establishment of standards for all services provided by a general hospital, for example, in accordance with universally/nationally recognised quality standards. The optimal country-specific approach, however, is determined by the accreditation system's desired outcomes. The fundamental expectations for an accreditation system are that it will provide an independent, objective evaluation process; will be highly credible and unbiased; will represent the broadest possible consensus among users and stakeholders; will promote improvement in healthcare delivery; and will be trusted by key users and stakeholders.[106]

The accreditation evaluation process is guided by the following principles:[107]Hospital operations are based on sound system-based organisational principles; they are transparent and objective, Accreditation standards are integrated into hospital operations and institutionalised, Patient safety and core quality, as management and staff in all functions and at all levels establish and own core values, There is a structured quality improvement programme in place that is based on continuous monitoring of patient care services, including feedback, Interviews with patients, residents, and staff are conducted as part of the evaluation process. It requires on-site visits to patient care areas and departments to address issues related to the physical assessment of infrastructure, medical equipment, security, and infection control, among other things, as required by accreditation standards. In a nutshell, accreditation is a thorough examination of a hospital's facility and clinical competence to provide services within its scope.[108]

With the rapid expansion of the private sector's cutting-edge technology in healthcare, the accreditation programme is gaining traction on the regulatory agenda. In the majority of developed economies, there are substantial financial incentives to seek accreditation. Governments recognize the critical nature of encouraging independent assessment programmes

[106] Alkhenizan A, Shaw C. Impact of accreditation on the quality of healthcare services: a systematic review of the literature. Ann Saudi Med. 2011;31(4):407-416.
Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3156520/ (last visited September 20, 2021)
[107] Universitary evaluation. From the program's accreditation to the institutional evaluation, 5th World Conference on Educational Sciences - WCES 2013
[108] Chuang S, Howley PH, Gonzales SS. An international systems-theoretic comparison of hospital accreditation: developing an implementation typology. Int J Qual Health Care. 2019;31(5):371-7

through accreditation, particularly at the secondary/tertiary level of hospitals, to attract the best in terms of Patient Safety and Quality of Care.[109]

While the accreditation body operates in regulatory areas such as healthcare and food safety, it will have some sort of relationship, possibly with the regulator. For instance, regulation may provide that if a healthcare organisation is accredited by a recognised national accreditation body, it is automatically deemed to be registered. Similarly, when granting accreditation, the accreditation body will take into account applicable regulatory requirements.

Patient safety has long been a central tenet of healthcare implementation worldwide. Globally, awareness of this issue is growing, accelerating the need to improve the quality of healthcare in terms of actual patient care and patient safety. India, too, has stepped up and demonstrated an unwavering commitment to improving the quality of healthcare services by obtaining accreditation from organisations such as NABH, JCI, ISO, ISQua, and CRISIL Rating. ISO is primarily concerned with back office operations, whereas NABH and JCI are more concerned with clinical outcomes and patient satisfaction.[110]

Accreditation has altered the landscape of healthcare; it is essentially a framework that enables healthcare organisations to establish objective systems aimed at patient safety and quality care that are developed using a holistic approach to Total Quality Management. Standardization is a dynamic process that results in continuous quality improvement. A robust healthcare infrastructure is critical for any country's growth, and accreditation demonstrates that the hospital is capable of ensuring that patients receive excellent care. Hospitals are now under constant pressure to maintain and improve their quality, and are pursuing accreditation in order to be recognised for providing high-quality services that result in increased patient satisfaction.[111]

In healthcare, the term "quality" refers to the influence of services on the recipient's health and safety. Quality is the consequence of continuous efforts and an unshakable dedication to perfection. Healthcare personnel in India have consistently demonstrated an appalling lack of awareness and concern for the quality of care they give. This disregard for

[109] Dastur, F. (2012). Hospital accreditation: a certificate of proficiency for healthcare institutions. J Assoc Physicians India, 60, 12-13

[110] Shaikh, Z. M. (2019) The Impact of Hospital Accreditation on the Patients' Experience of Hemodialysis Department: A Case Study. Research Review : International Journal of Multidisciplinary

[111] Pomey, M.P., Contandriopoulos, A.P., François P. and Bertrand, D., (2004) Accreditation: A Tool for Organisational Change in Hospitals? International Journal of Health Care Quality Assurance, 17 (3), 113-124.

quality has manifested itself in substandard treatment, safety breaches, and cases of medical malpractice, all of which end in disease, disability, and death.

As global demand for high-quality healthcare has increased significantly over the last decade, market forces such as medical tourism, insurance, corporate growth, and empanelment have emerged, necessitating the need to standardize care quality in healthcare settings. As a result of these factors, national and international accreditation bodies have been established to serve as a mechanism for quality assurance.[112]In general, there are two types of hospital accreditation: Hospital and healthcare accreditation that occurs inside national borders and Accreditation by an international healthcare organization.

Global demand for high-quality healthcare has expanded dramatically over the last decade, resulting in the emergence of market pressures such as medical tourism, insurance, corporate expansion, and empanelment, necessitating the need to standardise treatment quality in healthcare settings. As a result of these reasons, national and international accreditation agencies have been developed to provide a method for ensuring the quality of products and services. In general, there are two types of hospital accreditation: internal accreditation of hospitals and healthcare facilities, and external accreditation by an international healthcare organisation.

2.7.1 Healthcare Accreditation Bodies in India:

RATINGS OF HOSPITAL/NURSING HOMES BY CRISIL (Credit Rating Information Services of India Ltd.): It is a multinational analytical organisation that specialises in credit ratings, market research, and risk and policy consulting. Its ranking of healthcare institutions indicates a view about the relative quality of care provided to patients by the facility. The grading scale is composed of two components: a hospital classification and a four-point scale for rating the hospital's service quality (Grade A – Excellent quality, Grade B – Excellent but less than Grade A quality, Grade C – Average quality, Grade D – Poor quality).[113].

[112] Rawlins, R. (2001). Hospital accreditation is important. Bmj, 322(7287), 674.
[113] Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan, available at https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp11/wg11_hclinic.doc (last visited September 20,2021)

The ICHA (Indian Confederation for Healthcare Accreditation) was founded in 2002 and incorporated as a not-for-profit organisation in 2004 under section 25 (now 8) of the companies act. ICHA is a self-governing body that is globally recognised as the most effective and credible platform. ICHA's values and guiding principles are enshrined in three excellence pillars: TRUST, TRANSPARENCY, and TRANSACTIONS (communication)[114].

India's leading accreditation bodies are the Quality Council of India, an autonomous body, and its constituent organisation, the National Accreditation Board for Hospitals and Health Care Providers (NABH). QCI operates under the auspices of the Ministry of Commerce. NABH was added as a constituent to QCI in 2006. The NABH guidelines are broken down into ten sections. These chapters detail the procedures that should be followed by all hospital departments in order to provide standard care. Five of the ten chapters focus on patients, while the remaining five focus on organisations. Each chapter contains a collection of specific standards guidelines referred to as 'Standards,' totaling 105 standards (IVth Edition, December, 2015). Each standard contains a number of 'Objective elements,'683 collectively referred to as 'Objective elements.' All hospital operations, beginning with the patient's admission and continuing through discharge, are streamlined by objective elements[115].

A standard is a statement that details the structures and processes that must be in place for an organization's quality of care to significantly improve. A standard's objective element is a quantifiable component. Acceptable conformity with objective aspects is what determines a standard's overall compliance.

NABH is a nationally recognised organisation that engages its members in a number of high-quality forums. It is an institutional member, a board member, and a member of the ISQua Accreditation Council, as well as a member of the Asian Society for Quality in Healthcare's (ASQua) board of directors.[116].

In India, the healthcare sector is currently undergoing rapid social, economic, and technological change. These changes raise concerns about the healthcare system's quality. Hospitals are an essential component of the healthcare system. Accreditation is the single most effective strategy for enhancing hospital quality. Accreditation serves as a motivator for national hospitals to improve their capacity to provide high-quality care. National accreditation

[114] *Ibid*
[115] *Ibid*
[116] *Ibid*

standards ensure that hospitals, whether public or private, national or international, perform their assigned functions in the national health system.

2.8 CONCLUSION

Accreditation has not been successfully implemented in all nations. These must be adopted and practised successfully in conformity with the principles, policies, and organisations of the original country. The healthcare business has changed dramatically over the last few years, shifting from a physician-centered to a patient-centered strategy, owing to the growing demand for high-quality healthcare services. This has resulted in the strengthening of quality assurance processes and the pursuit of accreditation. Accreditation establishes a high level of technical competence within healthcare institutions in terms of particular service delivery requirements.

Globalisation and the increasing demand for high-quality services have required the establishment of a national health care system. Globally, greater emphasis on patient outcomes, safety, and quality of care has driven stakeholders, legislators, and healthcare provider organisations to establish standardised systems for evaluating healthcare organisations. Accreditation and certification have been suggested as strategies to improve patient safety and care quality.

Accreditation has had a large impact on the healthcare scene; it is essentially a framework that supports healthcare organisations in building objective systems focused on patient safety and quality care through the application of a holistic approach to Total Quality Management. Standards are typically dynamic, resulting in continuous quality improvement. A robust healthcare infrastructure is vital for a country's prosperity, and accreditation verifies that the hospital is capable of providing outstanding patient care.

Accreditation has had a profound effect on the healthcare landscape, and it is essentially a framework that assists healthcare organisations in developing objective systems focused on patient safety and quality care through the application of a holistic approach to Total Quality Management. Standards are frequently dynamic, which results in continuous quality improvement. A robust healthcare infrastructure is critical to a country's development, and certification verifies that the hospital is capable of providing superior patient care.

Hospitals are under constant pressure to maintain and improve their quality, and are pursuing certification in order to be recognised as reputable providers of high-quality care, which results in increased patient satisfaction.

Accreditation is defined as the public acknowledgement of a healthcare organization's conformity with accreditation requirements as established by an independent external evaluation of the organization's performance against the standard. Accreditation is based on the technical capabilities of an organisation to provide services that meet accreditation requirements.

It is about more than compliance. It requires sustained excellence. This aspect contributes to the system's market-driven nature, which involves all stakeholders, including customers, empaneling agencies, regulators, and other third parties. Accreditation is also a well-established procedure for promoting nationally and internationally accepted conformity assessment outcomes. In other words, accreditation is based on the existence or absence of such standards, as determined by qualitative indicators (proof of performance) observed by a body of experts. Accreditation is a completely voluntary undertaking.[117]

It places a premium on education, self-improvement, enhanced performance, and risk mitigation. Accreditation is based on high standards, professional accountability, and an organization's commitment to continuous excellence. Accreditation of hospitals is a concept that has existed for a long period of time. Accreditation in healthcare services refers to the process by which an accrediting authority inspects a healthcare institution to ensure compliance with a set of standards established by subject-matter experts. Accreditation is typically conducted by a diverse group of health professionals who evaluate the setting in which clinical care is provided against established standards.

National standards are frequently derived from a variety of sources, including national statutes, official directives, independent reports, international accreditation standards, and biomedical and health services research. The requirement to develop standards for all services provided by a general hospital, for example, in accordance with universally/nationally accepted quality standards, is a necessary component of the process of quality evaluation via

[117] Report - niti.gov.in. http://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp11/wg11_hclinic.doc (last visited on September 20, 2021)

accreditation. The optimal country-specific approach, on the other hand, is determined by the certification system's intended outcomes.

Fundamental requirements for an accreditation system include the following: provision of an independent, objective evaluation process; high credibility and objectivity; representation of the broadest possible consensus among users and stakeholders; promotion of healthcare delivery improvement; and trust by key users and stakeholders.

The regulation of clinical establishments involves a number of actors, including health care professionals, managers, and the ministry of health, commercial interests, non-governmental organisations (NGOs), and community and consumer groups. By taking a global view, we can see that regulatory frameworks in the health sector take on a variety of different forms. Numerous challenges confront countries in such situations, including achieving consensus on the definitions of various forms of regulation and evaluation. Tools such as licensure, certification, and accreditation of healthcare organisations have been used primarily to define the required characteristics of acceptable healthcare services. Their voluntary or obligatory status varies according to the system objectives.

The most critical of these mechanisms is legislation or the imposition of legal restrictions or controls on participants that compel them to comply with statutorily mandated requirements. There may be informal codes of conduct, standards, guidelines, or recommendations in addition to formal rules. Any regulatory process would entail the establishment of rules, their application to specific circumstances, the detection or monitoring of violations, and the imposition of penalties on violators.

Accreditation is a transparent system of oversight over accredited hospitals that ensures they consistently meet accreditation criteria. The experienced accreditation assessment team's on-site survey of the hospital and staff encourages them to establish educational and performance improvement goals. The best part is that it allows patients to provide feedback on the services they received during their hospital stay and also to lodge a complaint if they were dissatisfied. There is a substantial body of evidence demonstrating that general accreditation programmes improve clinical outcomes across a broad range of clinical conditions. Additionally, there is substantial evidence that subspecialty accreditation programmes improve clinical outcomes. Accreditation programmes should be bolstered as a means of enhancing the quality of healthcare. Finally, it ensures that hospitals, whether public or private, domestic or international, perform their assigned functions within the national health system.

CHAPTER 3

OVERVIEW OF CLINICAL ESTABLISHMENT (REGISTRATION AND REGULATION) ACT, 2010.

3.1 INTRODUCTION

The state shall prioritise improving the nutritional status and standard of living of its citizens, as well as public health, and in particular, the state shall work to eliminate the consumption of intoxicating beverages and drugs that are harmful to health, except for medicinal purposes. At a time when the fundamental right to life has been expanded to include the right to health and nutrition, the National Health Policy 2002[118] expresses concern that the "existing public health infrastructure is far from satisfactory," citing insufficient funding and trained personnel, gross inadequacy of consumables, obsolete equipment, dilapidated buildings, non-availability of essential drugs, and low quality of care. The policy then discusses the consequences of this neglect on poor and marginalised communities who are pushed into private facilities despite the fact that the majority of these patients lack the financial means to pay for private health services except at the expense of other essential expenditures such as basic nutrition. The Working Group on Clinical Establishments, Professional Services Regulation, and Accreditation of Health Care Infrastructure, established by the Planning Commission for the 11th Five-Year Plan, notes in its report that[119], while the for-profit private sector accounts for 50% of inpatient care and 60% to 70% of outpatient care, the system has remained largely fragmented and uncontrolled, with issues ranging from inadequate and inappropriate treatments, excessive In its statement of objects and reasons, the Clinical Establishments (Registration and Regulation) Act 2010[120] reiterates the Working Group's concerns. This is a proposed Act that would streamline the operation and provision of services

[118]National Health Policy 2002, available at https://www.nhp.gov.in/sites/default/files/pdf/NationaL_Health_Pollicy.pdf (last visited September 25, 2021)
[119] Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan, available at https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp11/wg11_hclinic.pdf (last visited September 25, 2021)
[120] Clinical Establishments (Registration and Regulation) Act 2010, available at, https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf (last visited September 25, 2021)

by clinical establishments. Notably, this is a matter that affects not only allopathic facilities, but also clinical establishments that provide services in a variety of Indian medical systems.

The significance of this enactment stems from growing concern about the gross inadequacy of public health facilities on the one hand and the absence of any standards governing existing facilities, both public and private, on the other. The virtual collapse of the public health system, particularly in rural and remote tribal areas, has exposed already marginalised communities to unregulated and unmonitored health care providers. In cities, corporate health care has taken over health services without establishing transparent accountability mechanisms. With the discovery of kidney theft from unsuspecting poor people and the offer of large sums of money in exchange for kidneys to people on the verge of death by a homoeopathic doctor who ran a hospital specialising in kidney transplants near Delhi, the issue of clinical establishment regulation has become critical.[121] This Act was enacted in response to a growing call for increased oversight in the wake of spiralling malpractice and gross negligence. Thus, it is a welcome move in terms of its objectives and justifications. However, there are too many gaps in its operational components, which may well mean that we have yet another legislative response to a public demand that is merely a action taken report that cannot be implemented. Finally, the issue of self-regulation, transparency, and its prospects in relation to clinical establishments is one that professional bodies and individual practitioners must revisit on a regular basis. Resistance to the commodification of health services and unethical, illegal practises must originate both internally and externally.

3.2 NEED FOR A NATIONAL LEGISLATION

The national legislation grew out of a 1980s patient rights movement. Health activists across the country have responded to mounting claims of unethical behaviours within a largely privatised healthcare system and the full inability of self-regulation, via medical councils, to act against doctors. They argued that medical care was fundamentally a consumer service and sought remedies under the Consumer Protection Act (CPA) from medical negligence and malpractice. The Indian Medical Association IMA filed a lawsuit opposing this move. The

[121] Singh, N. and Kumar, A. Kidney transplantation in India: Challenges and future recommendation. *MAMC Journal of Medical Sciences*, 2(1), p.12.

movement gained momentum in 1995, when the Supreme Court ruled in a landmark decision that the CPA applied to the medical profession as well (IMA v. VP Shantha and others[122]).

The medical profession's position has been that doctors must always put their patients' wellbeing first, above all other considerations, including their own. It maintains that medical care is not a commercial transaction between consumer and provider, and that viewing it as such would violate the doctor-patient relationship's fiduciary nature. This fiduciary aspect, however, is being questioned today, since doctors practise medicine within a massive healthcare industry, where their personal interests frequently conflict with those of their patients. For instance, when medical students are willing to "invest" Rs 1 crore in a postgraduate seat, their desire to return their investment would undoubtedly collide with their obligation to provide the finest care possible to their patients.[123]

Health campaigners have identified a number of inconsistencies in the law. For instance, the current human power requirements cannot be reached. Second, some pro visions, such as the obligation to provide emergency care, are imprecise. Third, no provision is made for the increased workload associated with regulating private clinical enterprises. Fourth, basic standards should not be restricted to structural requirements such as physical space, equipment, and personnel; they should also include some process requirements, such as adherence to patients' human rights. Perhaps most significantly, the national council is composed entirely of government institutions and medical associations, with no representation from civil society organisations or health movements that were instrumental in enacting the law. However, patients' distrust of medical practitioners has reached catastrophic levels, necessitating the passage of legislation such as the Clinical Establishment Act. Our priority must be to close gaps in the law and to ensure its proper execution.[124]

3.3 CLINICAL ESTABLISHMENT ACT

Concerns about how to improve the quality of health care have been expressed in India by the general public and a diverse range of stakeholders, including the government,

[122] IMA v. VP Shantha and others 1995 SCC (6) 651.
[123] Pandit MS, Pandit S. Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective. Indian J Urol. 2009;25(3):372-378.
[124] High-quality health systems in the Sustainable Development Goals era: time for a revolution, available at https://www.thelancet.com/action/showPdf?pii=S2214-109X%2818%2930386-3 (last visited September 25,2021)

professional organisations, private providers, and health-care finance organisations. Additionally, initiatives have been launched to establish systems and processes to ensure that health care providers deliver high-quality care.

According to a report titled "Clinical Establishments, Professional Services Regulation, and Accreditation of Health Care Infrastructure" published by the Government of India's Planning Commission for the 11th Five-Year Plan,[125] health regulation in India entails a plethora of elements and challenges. These include legislation governing health care facilities and services, disease control and medical care, human power (education, licencing, and professional responsibility), ethics and patient rights, radiation protection, pharmaceuticals and medical devices, poisons and hazardous substances, disabled and rehabilitation families, occupational health and accident prevention, mental health, smoking/tobacco control, and social security and health insurance. As a result, the report emphasised the importance of developing a centralised regulatory framework for the registration of clinical establishments in the country, as well as common criteria for the entire country.

The Central Government enacted the Clinical Establishments (Registration and Regulation) Act, 2010 ("Act") to regulate and register all clinical establishments in India with the objective of establishing minimum standards for their facilities and services.

The Central Government enacted it to provide for the registration and regulation of all clinical establishments in the country with the objective of prescribing minimum standards for the facilities and services they provide. This Act applies to all types of clinical establishments, both public and private, that practise any recognised system of medicine, including single physician clinics. The only exception will be military-run establishments. The Act applies to all types of Clinical Establishments (therapeutic and diagnostic) in the public and private sectors, and to all recognised systems of medicine, including single doctor clinics. The only exception is for Armed Forces Clinical Establishments.[126]

[125] *Supra.117*
[126] Singh, M., 2017. Clinical Establishments Registration and Regulation System (CERRS) in India. International Journal of Healthcare Education & Medical Informatics, 04(02), pp.15-19.

3.4 OBJECTIVE OF THE ACT

The Act requires registration of all clinical establishments, including diagnostic centres and single-doctor clinics, in the public and private sectors, except those run by the armed forces. The registering authority facilitates policy development, resource allocation, and establishes treatment standards. It has the authority to impose fines for violations of the Act's provisions. The Act establishes Standard Treatment Guidelines for common disease conditions and establishes a core committee of experts to oversee their implementation. Additionally, the Act requires all clinical establishments to provide the medical care and treatment necessary to stabilise any individual who comes or is brought to the clinical establishment in an emergency medical condition, particularly women delivering babies and individuals involved in accidents.

The Act came into force on 28 January 2010 in four Indian states, namely Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories. Later, pursuant to Article 252(1) of the Constitution[127], Uttar Pradesh, Rajasthan, and Jharkhand adopted the Act. Additionally, the Kerala Clinical Establishments (Registration and Regulation) Act, 2018[128] was enacted to provide for the registration and regulation of clinical establishments in the State of Kerala.

Article 47[129] of the Constitution establishes that the State is responsible for promoting public health and shall regard this responsibility as one of its primary responsibilities. As a result of this responsibility, the Government of India enacted the Act to regulate and licence clinical establishments in India, as well as to address related issues.

Whereas the Parliament lacks the authority to make laws for the States on any of the aforesaid subjects except as provided in Articles 249[130] and 250[131] of the Constitution, pursuant to Article 252(1)[132] of the Constitution, resolutions have been passed by all the Houses of the

[127] Article 252(1) Constitution of India Available at, https://legislative.gov.in/constitution-of-india (last visited September 25, 2021)
[128] Kerala Clinical Establishments (Registration and Regulation) Act, 2018, available at https://www.indiacode.nic.in/bitstream/123456789/15955/1/2_2018.pdf (last visited September 25, 2021)
[129] Article 47 Constitution of India Available at, https://legislative.gov.in/constitution-of-india (last visited September 25, 2021)
[130] Article 249 Constitution of India Available at, https://legislative.gov.in/constitution-of-india (last visited September 25, 2021)
[131] Article 250 Constitution of India Available at, https://legislative.gov.in/constitution-of-india (last visited September 25, 2021)
[132] Supra 7.

Legislatures of Arunachal Pradesh, Himachal Pradesh, Mizoram, and Sikkim to the effect that the aforesaid subjects should be regulated by Parliament through legislation in those States;

"Clinical establishment" means[133] a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered[134] or maintained by any person or body of persons, whether incorporated or not; or a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include a clinical establishment owned, controlled or managed by[135] the Government or a department of the Government;[136]a trust, whether public or private;[137]a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;[138] a local authority;[139] and a single doctor, but does not include the clinical establishments owned, controlled or managed by the Armed Forces.[140]

3.5 REGISTRATION OF CLINICAL ESTABLISHMENTS

According to Section 11 [141] of the Act, a clinical establishment may not be operated unless it has been legally registered in compliance with the Act's provisions. Additionally, Section 12 [142] of the Act states that in order for a Clinical Establishment to be registered and continue in operation, it must meet the following conditions, minimum standards of facilities

[133] Section 2(c) Clinical Establishments (Registration and Regulation) Act 2010, available at, https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf (last visited September 25, 2021)
[134] Section 2(c) (i) Clinical Establishments (Registration and Regulation) Act 2010
[135] Section 2(c) (ii) Clinical Establishments (Registration and Regulation) Act 2010
[136] Section 2(c) (ii) (a) Clinical Establishments (Registration and Regulation) Act 2010
[137] Section 2(c) (ii) (b) Clinical Establishments (Registration and Regulation) Act 2010
[138] Section 2(c) (ii) (c) Clinical Establishments (Registration and Regulation) Act 2010
[139] Section 2(c) (ii) (d) Clinical Establishments (Registration and Regulation) Act 2010
[140] Pingle, S., 2010. The Clinical Establishment Act, 2010: laws must be implemented in the right spirit. *Indian Journal of Medical Ethics*, (4).
[141] Section 11 Clinical Establishments (Registration and Regulation) Act 2010
[142] Section 12 (1) Clinical Establishments (Registration and Regulation) Act 2010

and services, minimum personnel requirements, provisions for record keeping and reporting and any other conditions prescribed.

Minimum standards for hospitals are established based on the level of care provided by such facilities. To obtain a provisional certificate for a clinical establishment as required by Section 11[143] of the Act, an application in the prescribed form shall be submitted to the authority specified in Section 10[144] along with the prescribed fee. It also provides for those clinical establishments that were in existence at the time of the Act's commencement to file an application for registration within one year of the Act's commencement, and for those clinical establishments that come into existence after the Act's commencement to file an application for permanent registration within six months of its establishment. Additionally, clinical establishments that are currently registered under any law requiring such registration shall register under the Act.

Within ten days of receipt of such application, the authority shall issue to the applicant a certificate of provisional registration in such form and containing such particulars and information, and each such provisional registration shall be valid until the last day of the twelfth month following the date of issue of the certificate of registration, and such registration shall be renewable.

The clinical establishment is responsible for publicly displaying the certificate in a manner that is apparent to all visitors. Renewal applications must be submitted within 30 days of the provisional certificate's expiration date; if submitted after the provisional certificate's expiration date, the authority will approve renewal of registration upon payment of the higher fees. Provisional registration shall not be granted or renewed in respect of clinical establishments for which standards have been notified by the Central Government beyond the period of two years from the date of notification of the standards in the case of clinical establishments that came into existence prior to the commencement of this Act; the period of two years from the date of notification of the standards in the case of clinical establishments that came into existence after the commencement of this Act; the period of two years from the date of notification of the standards in the case of clinical establishments that Permanent registration applications for clinical establishments shall be submitted to the authority in the manner and with the fees stipulated. The clinical establishment shall substantiate its compliance

[143] Supra 20
[144] Section 10 Clinical Establishments (Registration and Regulation) Act 2010

with the stipulated minimum requirements in this manner. Permanent registration shall be given only when a clinical establishment satisfies the registration standards established by the Central Government.

Following are the other conditions for registration and continuation of clinical establishments under the Clinical Establishments (Central Government) Rules, 2012[145] A prominent display of the rates charged for each type of service and facility available in both the local and English languages, Maintain and provide electronic medical records or electronic health records for all patients, as determined and issued by the Central or State Governments., Clinical Establishments shall charge fees for procedures and services in accordance with the range of fees established by the Central Government in consultation with the State Governments from time to time, Clinical Establishments are responsible for adhering to any Standard Treatment guidelines issued by the Central or State Governments and ensure that data and statistics are maintained in accordance with all applicable laws and regulations.[146]

3.6 INSTITUTIONAL ARRANGEMENTS UNDER CLINICAL ESTABLISHMENT ACT

The Act establishes a National Council for Clinical Establishment, which is primarily responsible for establishing standards to ensure that clinic founders provide appropriate health care and for developing sub-standards and conducting periodic reviews.[147].

The National Council's functions are as follows: Within two years of the Act's effective date, compiling and publishing the National Register of Clinical Institutions; Sort clinic locations into distinct categories; Improving lower standards and conducting periodic reviews; Establishing the first set of standards for ensuring proper health care by clinical facilities within two years of its establishment; Collecting statistics at treatment centres; and performing any other duties assigned by the Central Government. The Joint Secretary of the Ministry of Health

[145] Clinical Establishment (Central Government) Rules, 2012. Available at https://thc.nic.in/Central%20Governmental%20Rules/Clinical%20Establishment%20(Central%20Government)%20Rules,%202012.pdf (last visited September 25, 2021)
[146] Kannabiran, K., 2008. The Clinical Establishments (Registration and Regulation) Bill 2007: A brief review. Indian Journal of Medical Ethics,.
[147] https://dghs.gov.in/content/1361_3_NationalCouncilClinicalEstablishments.aspx

and Family Welfare, Government of India, shall serve as the National Council of Clinical Institutions' position secretary.[148]

The National Council Secretariat is comprised of one DDG-level officer and one CMO-level officer drawn from the existing pool of CMOs. One coordinator (clinical establishment), one coordinator (information technology), one stage officer / stage officer first, one mathematical assistant, two assistant secretaries, one data input, and one multiple staff. The National Council may establish subcommittees and propose their chairs, as well as appoint to such subcommittees those who are not National Council members to review items for a period of two years.

The composition of the National Council is as follows: Secretary, Health by appointment, to be Chairperson. Director of Health Services - senior member of the secretary. Directors of various streams of Indian Systems of Medicine - members of ex officio. The representative of each person to be elected by the executive committee of Indian State Medical Council, State Dental Council of India, State Council of Nurses Council, Indian State Pharmacy Council. Three representatives to be nominated by the Executive of the State Council or the Union Territory Council, as the case may be, for Indian Medicine representing the Ayurveda, Siddha and Unani medicine programs. One representative to be nominated by the Medical Association of India's State Council. One emergency services representative. Two representatives from state-level consumer organisations or renowned non-governmental health organisations.[149]All countries adopting this Act shall establish a State Council with a majority of its members to perform the following functions like Compiling and updating State Registers for the Establishment of Clinics; Bringing a monthly return on renewal of the National Register; Representing Government in the National Assembly; Complaints against high order breaches; Publish the annual report on the implementation of standards in their provinces.

The District Registering Authority will be chaired by the District Collector / District Magistrate (DM), the Compiler will be the Region CMO / CMHO, and three members will be appointed by the DM. Councillor Police Commissioner / SSP / SP or nominee, Chief executive officer of local government at the district level, and Professional medical association / body are the three members.

[148] Section 5 Clinical Establishments (Registration and Regulation) Act 2010
[149] Section 3 (2) Clinical Establishments (Registration and Regulation) Act 2010

The DRA's powers and responsibilities include the following: providing / renewing temporary (within ten days) / permanent registration, Publication of the List of Provisional Registrations (within 45 days after the grant), Clinical institutions that give evidence of perpetual registration and encourage any opposition (30 days), Registration that has lapsed, Enter and search for CE that is not registered (after due notice), Evaluating and asking about registered clinic facilities via a multi-member evaluation team - alerts Clinical Establishment to problems and corrective actions that need to be made. After revoking the registration, immediately prohibit the clinic from being established if the danger is imminent to the patient's health and safety. Refunds, Maintain a regional registry of clinic locations.[150]

3.7 PROCEDURE FOR REGISTRATION OF CLINICAL ESTABLISHMENTS

Chapter IV of the Act[151] deals with the procedure for registration. The application for provisional certificate of registration is[152]- An application in the prescribed form and payment of the prescribed fee shall be made to the authority for the purpose of registering the clinical establishment under section 10. The application may be submitted in person, by the mail, or electronically. [153] The application shall be made in the manner and with such particulars as may be prescribed by this Act or its rules[154]. If a clinical establishment is in existence at the time of the Act's commencement, an application for registration must be made within one year of the Act's commencement, and a clinical establishment that is established after the Act's commencement must apply for permanent registration within six months of its establishment[155]. If a clinical establishment is already registered under any existing law requiring registration of such establishments, it shall apply for registration in accordance with the provisions of sub-section (1)[156]. Additionally, the authority should issue to the applicant a

[150] Chamberlain, J., 2010. Regulating the Medical Profession: From Club Governance to Stakeholder Regulation. Sociology Compass, 4(12), pp.1035-1042.
[151] Clinical Establishments (Registration and Regulation) Act, 2010
[152] Section 14 Clinical Establishments (Registration and Regulation) Act, 2010
[153] Section 14(2) Clinical Establishments (Registration and Regulation) Act, 2010
[154] Section 14(3) Clinical Establishments (Registration and Regulation) Act, 2010
[155] Section 14(4) Clinical Establishments (Registration and Regulation) Act, 2010
[156] Section 14(5) Clinical Establishments (Registration and Regulation) Act, 2010

certificate of provisional registration in the form and with the particulars and information stipulated within ten days of receipt of such application.[157]

As far as an inquiry is concerned, there will be no inquiry prior to provisional registration[158]. Prior to granting provisional registration, the authority shall make no inquiry[159].Regardless of whether a provisional certificate of registration is granted, the authority shall cause to be published, in the manner required, all details of the clinical establishment thus registered provisionally within 45 days of the provisional certificate of registration being granted.[160]

Additionally, each provisional registration is valid until the last day of the twelfth month following the date of the certificate of registration's issuance, subject to the conditions of section 23, and such registration is renewed.[161]. Additionally, the Act requires that the certificate be clearly posted in the clinical establishment in a manner that is visible to all persons visiting the establishment. [162] If the certificate is misplaced, destroyed, mutilated, or damaged, the authority shall produce a duplicate upon request and payment of any necessary fees. [163]

The certificate issued is non-transferable[164]. No transferable registration certificate shall be issued[165]. In the event that the clinical establishment's ownership or management changes, the clinical establishment shall notify the authority in the manner prescribed[166]. If a clinical establishment's category or location changes, or if it ceases to operate as a clinical establishment, the authority shall relinquish the clinical establishment's registration certificate and the clinical establishment shall reapply for registration.[167].

The authorities shall cause the publication of the names of clinical establishments whose registration has expired within the time and manner specified. [168]. Applications for renewal of registration must be made thirty days prior to the expiration of the validity of the provisional registration certificate; if the application is made after the provisional registration

[157] Section 15 Clinical Establishments (Registration and Regulation) Act, 2010
[158] Section 16 Clinical Establishments (Registration and Regulation) Act, 2010
[159] Section 16(1) Clinical Establishments (Registration and Regulation) Act, 2010
[160] Section 16(2) Clinical Establishments (Registration and Regulation) Act, 2010
[161] Section 17 Clinical Establishments (Registration and Regulation) Act, 2010
[162] Section 18 Clinical Establishments (Registration and Regulation) Act, 2010
[163] Section 19 Clinical Establishments (Registration and Regulation) Act, 2010
[164] Section 20 Clinical Establishments (Registration and Regulation) Act, 2010
[165] Section 20(1) Clinical Establishments (Registration and Regulation) Act, 2010
[166] Section 20(2) Clinical Establishments (Registration and Regulation) Act, 2010
[167] Section 20(3) Clinical Establishments (Registration and Regulation) Act, 2010
[168] Section 21 Clinical Establishments (Registration and Regulation) Act, 2010

certificate has expired, the authority may allow renewal of registration upon payment of such increased fees as may be prescribed[169].

The time limit for provisional registration[170] are: Where the clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond (i) the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act; (ii) the period of two years from the date of notification of the standards for clinical establishments which come into existence after the commencement of this Act but before the notification of the standards; and (iii) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified.

Application for permanent registration[171] by a clinical establishment shall be made to the authority in such form and be accompanied by such fees, as may be prescribed. For verification of the application[172], the clinical facility shall submit evidence in such a manner as may be prescribed that it has met with the prescribed minimum criteria. Once the clinical establishment submits the required evidence of compliance with the prescribed minimum standards, the authority shall display all evidence submitted by the clinical establishment of compliance with the prescribed minimum standards for thirty days prior to processing for grant of permanent registration for the general public's information and for filing objections, if any, in such manner as may be prescribed[173].

If objections are received within the time frame provided in the preceding section, they must be communicated to the clinical establishment within 45 days for response. [174]. Permanent registration shall be awarded only when a clinical establishment satisfies the Central Government's registration standards. [175]

It is the authority's responsibility to issue an order immediately following the expiration of the stipulated term and within thirty days thereafter, either approving or rejecting the application for permanent registration, depending on the circumstances: Provided, however,

[169] Section 22 Clinical Establishments (Registration and Regulation) Act, 2010
[170] Section 23 Clinical Establishments (Registration and Regulation) Act, 2010
[171] Section 24 Clinical Establishments (Registration and Regulation) Act, 2010
[172] Section 25 Clinical Establishments (Registration and Regulation) Act, 2010
[173] Section 26 Clinical Establishments (Registration and Regulation) Act, 2010
[174] Section 27 Clinical Establishments (Registration and Regulation) Act, 2010
[175] Section 28 Clinical Establishments (Registration and Regulation) Act, 2010

that if an application for permanent registration is denied, the authority must document its reasons for doing so.[176].

If the authority approves the clinical establishment's application, it will issue a certificate of permanent registration in the form and with the information specified by the authority in the application. It is intended that the certificate be valid for a period of five years following the date of issuing. For the purpose of issuance of permanent registration, the provisions of sections 18, 19, 20 and 21 shall also apply. Applications for renewal of permanent registration must be submitted at least six months before the certificate of permanent registration's validity expires. If the renewal application is not filed within the prescribed time period, the authority may issue the renewal subject to the payment of any applicable additional fees and penalties. [177]

After an application for permanent registration has been denied, a clinical establishment may reapply under section 24 and provide any further documentation that may be required to demonstrate that the defects that led to the earlier application's denial have been corrected.[178]

Cancellation of registration is provided under the Act as follows: [179]If the authority becomes convinced that a clinical establishment is not complying with the registration conditions or that the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act, the authority may issue a notice to the clinical establishment requiring it to show cause within three months as to why its registration under this Act should not be cancelled.

If the authority determines, after giving a reasonable opportunity to the clinical establishment, that there has been a violation of any of the provisions of this Act or the rules made thereunder, it may cancel the clinical establishment's registration by order, without prejudice to any other action it may take against the clinical establishment. In the event that no appeal has been filed against such order, the order shall take effect immediately upon expiration of the time period prescribed for such appeal; and in the event that an appeal has been filed but has been dismissed, the order shall take effect from the date on which it was dismissed. However, if an imminent threat to patient health and safety exists, the authority may, upon the

[176] Section 29 Clinical Establishments (Registration and Regulation) Act, 2010
[177] Section 30 Clinical Establishments (Registration and Regulation) Act, 2010
[178]Section 31 Clinical Establishments (Registration and Regulation) Act, 2010
[179] Section 32 Clinical Establishments (Registration and Regulation) Act, 2010

cancellation of registration for specified reasons stated in writing, immediately restrict the clinical establishment from continuing operations until the situation is corrected.[180]

3.8 INSPECTION OF CLINICAL ESTABLISHMENTS [181]

The registering authority may authorize the examination or investigation of any clinic. Clinical facilities must endure the right to be represented for any examination or inquiry. The official will convey his or her opinion and may recommend steps to be taken. If the official believes that the clinic is not complying with the conditions of its registration or if the person in charge of the clinic has been convicted of a criminal violation under the Act, a notice of reason may be issued. If an official believes that an institution has violated the law, he or she has the authority to cancel the institution's registration. If the officer has reasonable grounds to believe that the clinic is operating without a valid licence, he or she may enter and search the facility in the manner prescribed after notifying the clinic of his or her purpose.[182]

Appeal [183]

Any person who is aggrieved by an order of the registering authority refusing to grant or renew a certificate of registration or revoking a certificate of registration may, in the manner and within the time period prescribed, file an appeal with the State Council: Provided, however, that the State Council may entertain an appeal filed after the expiration of the prescribed period if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the prescribed time period; and every appeal under sub-section (1) must be filed in the manner and with the fee prescribed.[184]

[180] Singh, M., 2017. Clinical Establishments Registration and Regulation System (CERRS) in India. International Journal of Healthcare Education & Medical Informatics, 04(02), pp.15-19.
[181] Section 33 Clinical Establishments (Registration and Regulation) Act, 2010
[182] Shrivastava, A., The Clinical Establishment Act, 2010: need for transparency. Indian Journal of Medical Ethics,2011
[183] Section 36 Clinical Establishments (Registration and Regulation) Act, 2010
[184] *Supra 181*

3.9 REGISTER OF CLINICAL ESTABLISHMENTS

Chapter V elaborates on the provisions relating to the Register of Clinical Establishments. According to the Act[185], A register of clinical establishments registered by the authority is required to be compiled, published, and maintained in digital format within two years of the authority's establishment, and the details of the certificate issued are to be entered in a register that must be maintained in the form and manner prescribed by the State Government. The State Council of clinical establishments shall receive in digital format from each authority, including any other authority established for the registration of clinical establishments under any other law currently in force, a copy of every entry made in the register of clinical establishments in such a manner as may be prescribed in order to ensure that the State Register is constantly up to date with the registers maintained by the registering authority in the State.[186]

Every State Government shall maintain in digital and in such form and containing such particulars, as may be prescribed by the Central Government a register to be known as the State Register of clinical establishments in respect of clinical establishments of that State. Every State Government shall supply in digital format to the Central Government, a copy of the State Register of clinical establishments and shall inform the Central Government all additions to and other amendments in such register made, for a particular month by the 15th day of the following month[187].

It is the responsibility of the Central Government to maintain in digital format an All India Register, to be known as the National Register of clinical establishments, which will be an amalgamation of the State Register of clinical establishments maintained by the State Governments, and it is the responsibility of the State Governments to cause the same to be published in digital format.[188]

[185] Section 37 Clinical Establishments (Registration and Regulation) Act, 2010
[186] *Supra 179*
[187] Section 38 Clinical Establishments (Registration and Regulation) Act, 2010
[188] Section 39 Clinical Establishments (Registration and Regulation) Act, 2010

3.10 PENALTIES [189]

Chapter VI deals with the provisions relating to the Penalties in case of default. If anyone works for a clinic without registration, he or she will first be found guilty of fines of up to Rs 50,000, in the second case he or she will be fined Rs 2 lakh and in any subsequent case he or she will be fined Rs 5 lakh. If a person works in an unregistered medical facility, he or she will be fined up to Rs 25,000. If anybody violates the Act and no other penalty is imposed, he or she may be fined up to Rs 10,000 for the first violation. The fine in the second case may be up to Rs 50,000, and in any instance, the fine in the subsequent case may be up to Rs 5 lakhs.

Whoever operates a clinical facility without registration is subject to a monetary penalty of up to fifty thousand rupees for the first offence, a monetary penalty of up to two lakh rupees for the second offence, and a monetary penalty of up to five lakh rupees for any successive offence. Whoever serves in a clinical establishment that is not properly registered under this Act faces a monetary penalty of up to twenty-five thousand rupees. The authority shall conduct an enquiry in the required way for the purpose of imposing any monetary penalty under sub-sections (1) and (2) after affording any individual affected a reasonable opportunity to be heard.

While conducting an inquiry, the authority has the authority to summon and compel the attendance of any person acquainted with the facts and circumstances of the case to give evidence or produce any document that, in the authority's opinion, may be useful for or relevant to the subject matter of the inquiry, and if the authority determines that the person has violated the provisions specified in sub-sections (1) and (2), it may impose the penalty specified in sub-section (2) by order. The authorities shall consider the category, size, and type of the clinical facility, as well as the local conditions of the area in which the establishment is located, while deciding the amount of the monetary penalty. Any person aggrieved by an authority decision may appeal to the State Council within three months of the date of the decision. The procedure in which an appeal pursuant to sub-section (6) shall be filed shall be as provided.[190]

Whoever wilfully disobeys any lawful directive given by any person or authority empowered under this Act, or who obstructs any person or authority in carrying out any functions necessary or empowered under this Act, shall be subject to a monetary penalty of up to five lakh rupees. Whoever refuses to provide information required by or under this Act

[189] Section 40 Clinical Establishments (Registration and Regulation) Act, 2010
[190] Section 41 Clinical Establishments (Registration and Regulation) Act, 2010

wilfully or provides information he knows to be false or does not believe to be truthful shall be subject to a monetary penalty of up to five lakh rupees. To determine whether any monetary punishment is appropriate under sub-sections (1) and (2), the authority shall conduct an inquiry in the required way after affording any individual interested a reasonable opportunity to be heard. While conducting an inquiry, the authority has the authority to summon and compel the attendance of any person acquainted with the facts and circumstances of the case to give evidence or produce any document that, in the authority's opinion, may be useful for or relevant to the subject matter of the inquiry, and if the authority determines that the person has violated the provisions specified in sub-sections (1) and (2), it may impose the penalty specified in sub-section (2) by order (8). The authorities shall consider the category, size, and type of the clinical facility, as well as the local conditions of the area in which the establishment is located, while deciding the amount of the monetary penalty. Any person aggrieved by an authority decision may appeal to the State Council within three months of the date of the decision. The mode in which an appeal pursuant to sub-section (6) may be filed should be prescribed. The monetary penalty imposed under sections 41 and 42 shall be credited to the account specified by the State Government in this regard by order.[191]

Whoever violates any provision of this Act or any rule issued thereunder, resulting in inadequacies that do not represent an imminent danger to any patient's health or safety and may be corrected within a reasonable period, shall be subject to a fine of up to ten thousand rupees.[192]

When a person violates any provision of this Act or any rule made thereunder, every person who was in charge of and accountable to the company for the conduct of the company's business at the time the violation occurred, as well as the company, shall be deemed guilty of the violation and liable to fine: Provided, however, that nothing in this sub-section shall subject any such person to punishment if he establishes that the contravention was committed without his knowledge or that he exercised all reasonable diligence to prevent its commission. Regardless of what is contained in sub-section (1), where a company violates any provision of this Act or any rule made thereunder and it is established that the violation occurred with the consent or connivance of, or is attributable to, any director, manager, secretary, or other officer

[191] Section 42 Clinical Establishments (Registration and Regulation) Act, 2010
[192] Section 43 Clinical Establishments (Registration and Regulation) Act, 2010

of the company, such director, manager, secretary, or other officer shall also be deemed to be guilty of the violation.[193]

If any Department of Government commits an offence under this Act within six months of the Act's commencement, the Head of the Department is held guilty of the crime and is entitled to be prosecuted and punished accordingly: Provided, however, that nothing in this section shall subject such Head of the Department to punishment if he establishes that the offence was committed without his knowledge or that he took all reasonable precautions to prevent its commission. Despite anything in sub-section (1), where an offence under this Act is committed by a Department of Government and it is established that the offence was committed with the consent or connivance of, or is attributable to, any officer other than the Head of the Department, such officer shall also be deemed guilty of the offence and shall be prosecuted and punished accordingly.[194]

Whoever fails to pay the fine, the State Council of clinical establishments may prepare a certificate signed by an officer authorised by it specifying the amount due from such person and sending it to the Collector of the District in which such person owns property, resides, or conducts business, and the Collector shall proceed to collect the amount specified in the certificate from such person as if it were an arrear of land revenue. [195]

3.11 CLASSIFICATION OF CLINICAL ESTABLISHMENTS UNDER THE CENTRAL ACT

Under the Act, the Central Government is empowered to classify clinical establishments of various systems into such categories. As a result, the Central Government classified it first by treatment system, namely allopathic and AYUSH. Different standards have been prescribed for various establishments that employ a variety of treatment modalities.

Under Clinical Establishment Act, 2010, Allopathic Hospitals have been broadly defined under following four levels:[196] Hospital Level 1 (A): General medical services, including indoor admission, are provided by recognised allopathic medical graduates and may

[193] Section 44 Clinical Establishments (Registration and Regulation) Act, 2010
[194] Section 45 Clinical Establishments (Registration and Regulation) Act, 2010
[195] Section 46 Clinical Establishments (Registration and Regulation) Act, 2010
[196] OPERATIONAL GUIDELINES FOR CLINICAL ESTABLISHMENTS ACT available at http://clinicalestablishments.gov.in/WriteReadData/2591.pdf (last visited October 12, 2021)

also include general dentistry services provided by recognised BDS graduates. For instance, PHCs, government and private hospitals, and nursing homes are all run by MBBS physicians.[197] Hospital Level 1 (B): This level of hospital shall include all general medical services provided at level 1(A) above, as well as specialist medical services provided by physicians practising in one or more basic specialties, including general medicine, general surgery, paediatrics, obstetrics & gynaecology, and dentistry, providing both inpatient and outpatient care. Level 1(A) and Level 1(B) hospitals shall also include support systems such as pharmacy, laboratory, and so on. For instance, a general hospital, a community health centre, a sub-district hospital, and a private hospital with comparable scope, a nursing home, and a civil/district hospital in a few locations, etc.[198]Hospital Level 2 (Non-Teaching): This level may include all services provided at levels 1(A) and 1(B), as well as services provided by other medical specialties listed below, in addition to the basic medical specialties listed at level 1(B) like Orthopaedics, ENT, Ophthalmology, Dental, Emergency with or without ICU, Anaesthesia, Psychiatry, Skin Pulmonary Medicine and Rehabilitation, etc. and support systems required for the above services like Pharmacy, Laboratory, Imaging facilities, Operation Theatre etc. Example: District Hospital, Corporate Hospitals, Referral Hospital, Regional/State Hospital, Nursing Home and Private Hospital of similar scope etc.[199] Hospital Level 3 (Non-Teaching) Super-specialty services: This level may include all services provided at levels 1(A), 1(B), and 2, as well as services from one or more super specialties with their own departments and/or Dentistry, if available. It will also include additional support systems for services such as pharmacy, laboratory, imaging facility, and operating theatre. For instance, corporate hospitals, referral hospitals, regional/state hospitals, nursing homes, and similar private hospitals.[200] Hospital Level 4 (Teaching): This level will include all level 2 services and may also include Level 3 facilities. It will, however, be distinguished by its status as a teaching/training institution and by the presence or absence of super specialties. Tertiary healthcare services are provided at this level by specialists, some of whom may be super specialists (if available). It will also have the necessary support systems in place to provide these services. It will also comply with MCI/other registering bodies' requirements for teaching hospitals and will be governed by their rules. However, registration of teaching hospitals under the Clinical Establishment Act will be required for purposes other than those covered by the

[197] *Ibid*
[198] *ibid*
[199] *ibid*
[200] *ibid*

MCI, such as maintaining records and reporting information and statistics, and adhering to a range of rates for medical and surgical procedures, among others.[201]

3.12 THE CLINICAL ESTABLISHMENTS (CENTRAL GOVERNMENT) RULES, 2012

Power of Central Government to make rules

By notification, the Central Government may enact rules to carry out all or any of the provisions of this Act. Without limiting the generality of the preceding authority, such rules may address all or any of the following: allowances for National Council members pursuant to section 3(5); The Central Government appoints such person as Secretary of the State Council pursuant to section 3(10); establishing norms and classifying clinical establishments pursuant to section 7; the qualifications , terms and conditions applicable to authority members pursuant to clause (c) of sub-section (1) of section 10; the mechanism by which the District Health Officer or Chief Medical Officer may exercise the authority's powers for the purpose of interim registration of clinical establishments pursuant to subsection (2) of section 10; the basic standards for facilities and services set forth under clause (i) of sub-section (1) of section 12; the minimum number of personnel under clause (ii) of sub-section (1) of section 12; the maintenance of records and reporting by the clinical establishment under clause (iii) of sub-section (1) of section 12; other conditions for registration and continuation of clinical establishment under clause (iv) of sub-section (1) of section 12; classification of clinical establishment under sub-section (1) of section 13; the different standards for classification of clinical establishments under sub-section (2) of section 13; the minimum standards for permanent registration required by section 28; the format and content of the register required by section 38.[202]

Each rule made by the Central Government under this Act shall be laid before each House of Parliament during its session for a period of thirty days, which may be divided into one session or two or more successive sessions, and if, before the expiration of the session

[201] *Ibid*
[202] Section 52 Clinical Establishments (Registration and Regulation) Act, 2010

immediately following the session or successive sessions aforesaid, both Houses agree to modify the rule or agree that the rule shall be repealed, the rule shall be amended.[203]

The Central Government, in exercise of the authority provided by section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010), sets the following rules, namely: - Ex-officio Secretary of the National Council for clinical establishments created under sub-section (1) of section 3 of the Act should be an officer of the level of Joint Secretary in the Ministry of Health and Family Welfare of the Government of India. The Secretary of the National Council is responsible for the control and management of the National Council's secretariat, as well as for the supervision of the National Council's other staff, and for performing such other duties as the National Council may require of him for the purposes of the Act. He will be a member of the National Council for Clinical Establishments meetings. The National Council's staff shall have such tasks and obligations as may be prescribed from time to time by the National Council's Secretary.[204]

The National Council shall identify and categorise recognised systems of medicine's clinical institutions and submit them to the Central Government for approval. For the purpose of appointing each subcommittee, the National Council shall describe the subcommittee's functions, the number and character of members to be appointed, and the deadline for task completion. When each subcommittee is formed, efforts should be made to ensure that each committee has adequate representation from across the country, including experts in relevant fields from the private sector, public sector and its organisations, non-governmental sector, professional organisations, academia, and research institutions, among others. The National Council shall appoint the chairperson of each such subcommittee at the moment the subcommittee is appointed. Minutes of the meetings of the subcommittees shall be kept. The National Council shall evaluate and act on any suggestions offered by the subcommittees. The National Council of clinical establishments may solicit feedback on specific issues from State Councils or Union territory Councils. If necessary, at the request of the National Councils or the Central Government, the State Councils or Union territory Councils shall convene a subcommittee comprised of members of the State and Union territory Councils and field

[203] Section 53 Clinical Establishments (Registration and Regulation) Act, 2010
[204] Rule 3 Clinical Establishment Rules, 2012, available at http://clinicalestablishments.gov.in/WriteReadData/386.pdf (last visited September 25, 2021)

experts for a period not exceeding one year for the purpose of deliberating and making recommendations on a particular matter or issue.[205]

Official members of the National Council for clinical establishments should be reimbursed for travel and daily expenses in accordance with Government of India regulations from the same source as their remuneration. Travel and daily allowances shall be paid to non-official members of the Council in accordance with applicable Government of India rules from time to time for Group 'A' officers of Junior Administrative Grade.[206]

The National Council may invite representatives from one or more State councils or union territory councils to attend its meetings, if deemed appropriate, and the National Council shall cover such representatives' travel expenses.[207]

To ensure consistency in the collection of information by State Governments or Union Territory administrations and data flow in connection with the compilation and maintenance of State Registers and the National Register in digital format for the purposes of sections 38 and 39 of the Act, the National Council shall also develop a standard application form for clinical establishment registration.[208]

Each clinical establishment shall meet the following conditions for registration and continuation, namely: each clinical establishment shall prominently display the rates charged for each type of service provided and facility available, for the benefit of patients, in both the local and English languages; clinical facilities shall charge rates for each type of procedure and service in accordance with the range of rates defined and issued by the Central Government in conjunction with the State Governments from time to time; clinical establishments shall guarantee compliance with the Standard Treatment Guidelines as defined and released from time to time by the Central Government or the State Government; clinical facilities shall retain and furnish Electronic Medical Records or Electronic Health Records for each patient, as determined and provided by the Central Government or the State Government from time to time; Each clinical establishment shall preserve records and data in compliance with all other applicable laws and rules in effect at the time.[209]

[205] Rule 4 Clinical Establishment Rules, 2012
[206] Rule 5 Clinical Establishment Rules, 2012
[207] Rule 6 Clinical Establishment Rules, 2012
[208] Rule 7 Clinical Establishment Rules, 2012
[209] Rule 9 Clinical Establishment Rules, 2012

Power of State Government to make rules.

The State Government may, by notification, create rules for the administration of matters not covered by section 52. Each regulation promulgated by the State Government pursuant to this section shall be brought before each House of the State Legislature, if such Legislature has two Houses, or before that House, if such Legislature has a single House, as soon as feasible after it is promulgated. [210]

However, this Act shall not apply to the States to which the enactments listed in the Schedule apply: Provided, however, that the States to which the enactments referred to in sub-section (1) apply, and such States adopt this Act pursuant to clause (1) of article 252 of the Constitution subsequent to the commencement of this Act, the provisions of this Act shall apply in that State. The Central Government may amend the Schedule by notification as and when it deems necessary. The Schedule consists of the following: The Private Medical Care Establishments (Registration and Regulation) Act, 2002, in Andhra Pradesh; The Registration of Nursing Homes in Bombay Act, 1949; The Registration of Nursing Homes in Delhi Act, 1953; Upcharya Griha Tatha Rujopchar Sanbabdu Sthapamaue (Ragistrikaran Tatha Anugyapan) Adhiniyam, Madhya Pradesh, 1973; The Manipur Registration of Homes and Clinics Act, 1992; The 1997 Nagaland Act on Health Care Establishments; The Clinical Establishments (Control and Regulation) Act, 1990, in the state of Orissa; In 1991, the Punjab State Nursing Home Registration Act was enacted; The Clinical Establishments Act, 1950, in West Bengal.

3.13 CONCLUSION

Clinical Establishment Act 2010 is not a complete process; it has numerous issues and issues that have not been addressed yet. However, one must bear in mind that when an action is taken, it is subject to a variety of pressures from a variety of stakeholders. Second, there is a comprehensive law that addresses the concerns of all interested stakeholders, and we will continue to debate and await the final version of the law. It is critical that clinics in the country respond and act transparently, as this can significantly improve the country's health care quality. While the above effort is commendable in every way, it is insufficient to address the medical profession's challenges. On this subject, the broadest and most comprehensive view

[210] Section 55 Clinical Establishments (Registration and Regulation) Act, 2010

must be taken. The strictest consumer protection laws aimed at safeguarding consumers' interests in goods and services are insufficient to address cases of medical malpractice and poor medical practise. The hour has come to establish a comprehensive action against medical negligence and medical abuse that will regulate all aspects of the behaviour of doctors and hospitals that provide health care to Indian citizens. India is already a market leader in the global pharmaceutical industry. It is clear that it is a blessing from above that India is expected to make significant strides in its public life as the government takes a proactive approach to achieving the Clinical Establishments (Registration and Regulation) Act, 2010's objectives. Clinic construction in India will be organised and strictly enforced to include all levels of medical care, which is why the Indian healthcare sector is expected to grow rapidly.

CHAPTER 4

IMPACT AND CONSEQUENCES OF THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010

4.1 INTRODUCTION

The Central Government enacted the Clinical Establishments (Registration and Regulation) Act, 2010 to allow for the registration and regulation of all clinical establishments in the country with the objective of prescribing the minimum standards of facilities and services supplied by them. The Act applies to all types of clinical establishments, both public and private, and to all recognised medical systems, including single-doctor clinics. The lone exception is that facilities operated by the Armed Forces will be exempt from regulation under this Act.[211]

If fully implemented, the Clinical Establishment Act would be a magnificent step in the history of independent India. For decades, an unorganised health sector has posed significant barriers to the availability, accessibility, and affordability of healthcare for the general public. This act would be beneficial since it would establish basic criteria for all establishments that provide healthcare services. Although 11 states and all Union Territories have enacted this Clinical Establishment Act, it is unclear if they will fully or partially execute it. The Indian healthcare system is held to a high standard, as it provides services to a diverse population. As a result, it is critical to establish some level of consistency among them. Additionally, this act would emphasise 'affordability,' which alleviates financial burdens and out-of-pocket expenses. Additionally, the 2019 change to the Clinical Establishment Rules clarified matters by eradicating previously held misconceptions among laboratory workers.[212]

The Act was enacted to establish a computerised registry of clinical establishments at the national, state, and district levels, to prevent quackery by unqualified practitioners by the implementation of an obligatory registration system, and to improve the quality of healthcare by establishing minimum standards for all categories of health care establishments (except teaching hospitals) and ensuring compliance with other registration requirements such as

[211]The Clinical Establishments (Registration and Regulation) ACT, 2010, available at http://www.clinicalestablishments.gov.in/cms/Home.aspx (last visited September 30, 2021)
[212] India: Health Ministry Proposes Clinical Establishment (3rd Amendment Rules), available at https://www.mondaq.com/india/healthcare/854112/health-ministry-proposes-clinical-establishment-3rd-amendment-rules-2019 (last visited September 30, 2021)

adhering to standard treatment guidelines, stabilising emergency medical conditions, displaying the range of rates to be charged, and maintaining records. Many argue that the measure will represent a watershed moment for India's healthcare system. In terms of the Clinical Establishment Act, the primary flaw is the one-size-fits-all approach, which fails to effectively account for the variability of private sector healthcare. In a country where the private sector includes independent physicians, doctor-couple-run family clinics, and small nursing homes, implementation is tough, as it is in any other sector. This variety between clinical settings and states is a worry, as customising for each state takes effort. The legislation is also greatly diluted during the 'customization' process.[213]

Another problem is the diverse rules that prevail across states. Regulation in healthcare is a much larger issue for which the contribution of clinical establishment is only little. Moreover, the act fail to address the processes in healthcare settings as it pertains to physical infrastructure and registration of establishments. An act at the national level need to be accordingly tweaked to make it relevant for each state as the diversity in general and healthcare practices is phenomenally different.[214]

This Act and its goals appear to be quite promising. Mandatory registration of all forms of healthcare will help combat quackery. Standardization of infrastructure, manpower, and operating systems will occur. However, the Act contains a few loopholes. There are a few provisions that are just impossible to implement; they are neither realistic nor viable. For example, the Act mandated that every clinical establishment provide emergency care to a person. While this provides comfort to citizens that emergency medical assistance would not be withheld. However, is this truly possible? Consider a woman in active labour who arrives at a dental facility. Will a single physician be able to manage her and transfer her to the proper facility? Who will bear the expense of the same? Thus, fearful of prosecution, the doctor may just complete the appropriate documentation but fail to treat the patient adequately, resulting in more harm than good. It is admirable that the Act is concerned with patients' rights. However, it should have included a section on patient obligations, such as nonviolence in hospitals. The Act may have both positive and negative implications for the healthcare system. On the one hand, this simplifies data collecting and regulation; on the other hand, such unworkable regulations and the resulting failure to comply will increase corruption. The Act will exacerbate

[213]SANDHYA SRINIVASAN Regulation and the Medical Profession: Clinical Establishments Act, 2010, Vol. 48, No. 3 (2013), pp. 14-16

[214]Joseph, S., 2021. Impact assessment of accreditation in primary and secondary public health-care institutions in Kerala, India. Indian Journal of Public Health, 65(2), p.110.

the already overcrowded system by adding another channel for prosecuting doctors and hospitals.[215]

4.2 INITIAL IMPRESSIONS OF THE CLINICAL ESTABLISHMENTS ACT

The Indian Medical Association (IMA), which represents allopathic physicians in India, has predictably opposed the Clinical Establishments Act. The IMA has not specified the reasons for opposition in any statement and must be cobbled together from statements made by leaders of the national association and its many branches. These statements demonstrate that the leadership is unaware of the issue. The then national President G Samaram stated, "The government's sincerity will be appreciated if it initiates and works to eradicate quacks and quackery from our country, which has been harming our society's health under the premise of providing first-aid care." Additionally, putting "corporate hospitals and rural area hospitals on the same accreditation track is indefensible since it promotes corporatization of health care and jeopardises access to health care for the ordinary man." Dr Samaram challenged the government, saying, "First, adopt these 'nice to hear regulations' at government and corporate hospitals to establish them as model health care delivery service centres."[216]

Declaring that there should be no regulation until the government establishes its capacity to abolish practise by unqualified practitioners is purely polemic. Additionally, it is simple to assert that only unqualified individuals engage in quackery and illogical practise. Irrational behaviour by qualified individuals at all levels, including many corporate hospitals and many so-called trust hospitals, is a serious issue today.[217]

This anti-regulation stance also ignores the fact that, in industrialised countries, some type of control of the quality and cost of services provided by private physicians has been a necessary component of the healthcare system. In the post-World War II era, governments and businesses in industrialised countries either provided healthcare themselves or contracted with

[215] Health Ministry proposes minimum standards for clinical establishments, available at https://health.economictimes.indiatimes.com/news/industry/health-ministry-proposes-minimum-standards-for-clinical-establishments/70316470 (last visited September 30, 2021)
[216] Why is private healthcare opposing the Clinical Establishments Act? Available at, https://www.downtoearth.org.in/news/health/why-is-private-healthcare-opposing-the-clinical-establishments-act-59766 (last visited September 30, 2021)
[217] *Ibid*

private providers to offer healthcare to specific segments of the population. India, too, must work toward such a system. Private healthcare should be used in conjunction with strengthening, expanding, and upgrading the public health system. There is a dire need for standardised, publicly-funded healthcare in India. Given the majority of people's low incomes, the poor and a sizable segment of the middle class are unable to access high-quality private treatment when they are in need. The only option to ensure universal access to private healthcare is for the private sector to decrease unnecessary medical expenses by standardisation of care and for the government to pay the bills of this standardised private sector through tax revenues.[218]

We should not have a split system consisting of a public system for the poor and a private system for the wealthy; any system designed exclusively for the poor will remain poor. We must integrate the private system into a unified national health system. To do this, private physician expenses must be paid with public funds. And this payment must adhere to particular standards and uniformity. This does not mean that all levels of care must adhere to the same standards. In this respect, a provision in the Act is welcome: it authorises the Central Government, through section 13, to enact rules classifying clinical institutions of various systems into categories and establishing different requirements for each category, taking into account local situations.[219]

This approach of standardisation and payment of private bills using public monies would benefit private practitioners who wish to perform science-based medicine. Today's physicians must be skilled not only in medicine, but also in business and marketing. Many physicians despise such commercial competition and would benefit from a regulated system. A regulated system would benefit both doctors and patients. Patients would not be denied healthcare owing to poverty, and doctors would see an increase in patient volume. Standardisation and regulation are difficult to achieve without establishing a "inspector raj." However, that obstacle must be confronted squarely.[220]

As is the case in other countries, the IMA will need to employ professional, compensated employees to advocate and negotiate on behalf of doctors' legitimate interests at

[218] *Ibid*
[219] Section 13 THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010, available at https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf (last visited September 30, 2021)
[220] Factors Affecting Medical Service Quality, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450689/ (last visited September 30, 2021)

multiple levels. The IMA leadership cannot continue to carry out these functions only on a volunteer, amateur basis.[221]

4.3 IRRATIONAL OPPOSITION TO THE CLINICAL ESTABLISHMENTS ACT

Other justifications for the IMA's resistance have been presented. N Diwan, the then president of the IMA in Ludhiana, told a public assembly against the Clinical Establishments Act that doctors were already regulated by laws such as the Pre-Natal Diagnostic Techniques Act, biological waste legislation, and the Consumer Protection Act. The Clinical Establishments Act would vest regulators with an excessive amount of authority and would preclude physicians from defending themselves against allegations. He was also cited as saying: "The proposed National Council, which will serve as the governing body, will be formed of quasi-literate individuals recruited from the Unani, Siddha, Nursing, and Paramedical branches of the profession." Only two of the National Council's 18 members will be medical graduates. If passed, the Clinical Establishments Act will allow any unqualified individual to register under the pretence of Yoga, Unani, Siddha, Nursing, or Pharmacy."[222]

To refer to allopathic graduates as medical graduates or to imply that paramedics are "quasi-literate" is arrogant. Shivkumar Utture, the then head of the IMA's Mumbai chapter, shared similar sentiments during a programme in Mumbai. He asserted that the Clinical Establishments Act will result in a licence raj and the abolition of the family physician as a source of cheap healthcare. Rajendra Trivedi, the then secretary of the Indian Medical Association, has stated that "regulations and licence raj" will worsen the trend among fresh medical graduates to eschew family practise in favour of specialised hospitals. Additionally, this is a polemical argument. There is no indication of the financial resources required to implement basic criteria. When we examine the Bengal Act's infrastructure criteria or the proposed rules in Maharashtra under the Bombay Nursing Home Registration Act, we see that they are relatively modest.[223]

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[221] Amitava Banerjee, The Health impact Fund: a potential solution to inequity in global drug access, *Indian journal of medical ethics, 2010*

[222] Phadke, A., 2010. The Indian Medical Association and the Clinical Establishment Act, 2010: irrational opposition to regulation. *Indian Journal of Medical Ethics*, (4).

[223] *Ibid*

IMA Punjab even held a half-day bandh in protest of the Clinical Establishments Act, the dissolution of the Medical Council of India, and the establishment of the Bachelor in Rural Medicine and Surgery programme. The then President RS Parmar claimed in a memorandum that the government is attempting to regulate an organisation that is already regulated by the state medical council, the medical council of India, and 41 other statutes, as well as by patients who visit doctors and are satisfied with the services offered. He conveniently skipped over the reality that individual physician certification does not and cannot prescribe basic hospital requirements. The statement reads, Governments and administrations have utterly failed to rein in unqualified individuals' misuse of allopathic and ayurvedic medicine. The strict conditions established in this act, such as having a sufficient number of qualified paramedical staff, will also be impossible to meet, due to the skilled manpower deficit that exists even in government institutions. Additionally, it will increase the expense of treatment, which may increase several fold. Inspection will have a detrimental influence on the thoughts of patients waiting in waiting areas, as if the doctor committed a crime, eroding their trust in the doctor. Imposing fines for small infractions is an undesirable practise.[224]

The Central Act contains no requirements for human power. This will be incorporated into the rules. However, based on the number of qualified nurses specified in the draft rules of Maharashtra's legislation, the Bombay Nursing Home Registration Act (BNHRA)[225], as amended in 2005, we can see that, while this criterion is sensible, it is now impracticable to achieve. With the nursing school system in shambles, the requisite number of educated nurses just isn't available. As a result, the doctor's concerns on this subject are entirely legitimate. However, the IMA Punjab memorandum's criticism of hospitals being required to submit to routine inspections is misplaced. How is it possible for the registering authority to issue a certificate without checking the facilities and infrastructure claimed in the registration application during a site visit? Inspection is performed during registration and may be repeated every five years. On what rationale might it be argued against? Minimum standards' proponents should provide evidence that they will increase expenses. Second, the concept of "small

[224] Vishal Sharma, Attitudes and practices of medical graduates in Delhi towards gifts from the pharmaceutical industry, *Indian Journal of Medical ethics*, 2010

[225] Bombay Nursing Home Registration Act, available at, https://lj.maharashtra.gov.in/Site/Upload/Acts/8-The%20Maharashtra%20Nursing%20Homes%20Reg.%20Act.pdf (last visited September 30, 2021)

offences" as used in this memorandum and for which a waiver of fines is requested must be explained.[226]

By and large, the IMA has not responded thoughtfully to the Act. Rather than that, some IMA leaders have advanced extremely broad and erroneous arguments. IMA Bengal has made recommendations to the West Bengal Clinical Establishments (Registration and Regulation) Act[227] on particular provisions. In the context of this Central Act, a similarly detailed response is required. In Maharashtra, civil society organisations, including the Jan Aarogya Abhiyan, made concrete recommendations for the BNHRA's policies[228]. CEHAT[229], a non-governmental organisation, was tasked with the responsibility of developing minimum criteria pursuant to this Act. CEHAT convened a series of discussions with representatives of physicians and civil society organisations and developed proposed rules in response to their views. The director of health services finalised these draught guidelines and submitted t2hem to the government for final approval in June 2006. Regrettably, three consecutive Maharashtra health ministers have failed to find time to grant the bill final approval. The BNHRA was enacted in 1950, but the rules were not prepared until 1955. Even after the rules were drafted, they have been awaiting final approval for the previous four years.[230]

Clearly, much work has to be done following the passage of the Central Act, 2010. The IMA still has time to advocate for doctors' legitimate interests. However, it must make specific, significant recommendations.[231]

[226] Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan, available at https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp11/wg11_hclinic.pdf (last visited September 30, 2021)
[227] West Bengal Clinical Establishments (Registration and Regulation) Act, available at http://www.bareactslive.com/WB/wb700.htm (last visited September 30, 2021)
[228] The Bombay Nursing Homes Registration (Amendment) Act, 2005, available at https://prsindia.org/files/bills_acts/acts_states/maharashtra/2006/2006MH2.pdf (last visited September 30, 2021)
[229] Centre for Enquiry in to health and allied themes, available at http://www.cehat.org/about (last visited September 30, 2021)
[230] Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779963/ (last visited September 30, 2021)
[231] The Strategy That Will Fix Health Care, available at https://hbr.org/2013/10/the-strategy-that-will-fix-health-care (last visited September 30, 2021)

4.4 ISSUES IN IMPLEMENTING THE ACT IN PRIVATE HEALTHCARE SECTOR

Clinical Establishments Act implementation is critical for accountability in the health industry. While private healthcare organisations promise to provide high-quality care, they are notorious for botching situations. A few recent examples demonstrate that the Union Government was correct in delivering a timely reminder to all states on the Clinical Establishments Act's implementation.[232]

The following examples demonstrate why regulation is necessary in private healthcare sector: Recently, a baby wrapped in a plastic bag was handed over to its parents for burial by Max Hospital in North Delhi. The said baby was later discovered to be alive.[233] Another incident in which Fortis Hospital in Gurugram charged the family of a seven-year-old dengue patient Rs 16 Lakhs for treatment. The patient ultimately died.[234] Another patient's relatives have written to Haryana Chief Minister Manohar Lal Khattar stating that Paras Hospital in Gurugram overcharged him by Rs 83 Lakhs for treatment of his spinal injury. Rather than improving, the patient's condition has deteriorated. It is however pertinent to note that no action has been taken against the hospitals in any of these instances. Though the Delhi government initially revoked Max's licence, Lieutenant Governor Anil Baijal later delayed the ruling.[235]

So naturally, a question that arises in all our minds is why the medical profession is so fearful of the Clinical Establishments (Registration and Regulation) Act? When Clinical Establishments Act was notified in 2010, it was lauded as a model. The law, which applies to all types of health establishments and all branches of medicine, intends to streamline healthcare services throughout the country while ensuring private hospitals adhere to ethical standards. However, until this day, little has changed on that ground. Doctors, particularly those linked with private clinics and hospitals, are exerting such influence over the wording of the Clinical

[232] Why is private healthcare opposing the Clinical Establishments Act? Available at, https://www.downtoearth.org.in/news/health/why-is-private-healthcare-opposing-the-clinical-establishments-act-59766 (last visited September 30, 2021)
[233] Newborn declared dead by hospital found alive before burial, available at https://www.greaterkashmir.com/india/newborn-declared-dead-by-hospital-found-alive-before-burial (last visited September 30, 2021)
[234] Dengue patient dies, parents billed Rs 16 lakh for 2 weeks in ICU, available at https://timesofindia.indiatimes.com/city/delhi/dengue-patient-dies-parents-billed-16-lakh-for-2-weeks-in-icu/articleshow/61732259.cms (last visited September 30, 2021)
[235] Family Alleges Negligence, Overcharging By Gurgaon Hospital, available at https://www.ndtv.com/gurgaon-news/family-alleges-negligence-overcharging-by-gurgaon-hospital-1795569 (last visited September 30, 2021)

Establishments Act that states are submitting to pressure and delaying implementation of the law, despite a recent reminder from the Central Government.[236]

In November 2017, when the Haryana government prepared to execute the Clinical Establishments Act, which it had adopted three years prior, the state chapter of the Indian Medical Association mounted a strong pushback (IMA). On December 15, all outpatient services at the state's private hospitals were suspended. The government has caved in to criticism and stated that hospitals with fewer than 50 beds will be spared from the Act's provisions.[237]

Doctors in Uttarakhand are also exercising their powers to thwart the state government's attempt to enforce the Clinical Establishments Act, and are demanding revisions similar to those proposed by the Haryana government.[238]

R N Tandon, the then IMA Secretary General, explains the objection by stating that it is impossible to comply with the law's provisions. It compels private hospitals and clinics to provide a basic level of care while charging a minimal fee. Additionally, the law mandates hospitals and clinics to stabilise patients in critical condition—those in imminent danger of death. Tandon notes that this is not achievable for everyone due to the degree of specialised required. For example, part-time practitioners can only provide preliminary treatment and first assistance. If the bill is enforced, it will harm such practitioners, who provide healthcare to almost 80% of the population, he argues. Additionally, Tandon questions why a government that has been unable to improve the public healthcare system wishes to oversee the private sector.[239]

However, health campaigners argue otherwise. "Private practitioners are opposed to the Clinical Establishments Act because it jeopardises their interests," says Abhay Shukla, a public health activist with Jan Swasthya Abhiyan.[240]

According to Arun Gadre, author of Dissenting Diagnosis, a book about medical corruption, the law establishes the very minimal requirements for establishing a clinic or

[236]Clinical Establishment Act Standard for HOSPITAL (LEVEL 1A &1B), available at http://clinicalestablishments.gov.in/WriteReadData/147.pdf (last visited September 30, 2021)
[237] Haryana govt notifies Clinical Establishment Act, available at https://www.tribuneindia.com/news/archive/haryana/news-detail-542265 (last visited September 30, 2021)
[238] *Ibid*
[239] Why is private healthcare opposing the Clinical Establishments Act? Available at https://www.downtoearth.org.in/news/health/why-is-private-healthcare-opposing-the-clinical-establishments-act-59766 (last visited September 30, 2021)
[240] *Ibid*

hospital. "For example, under the legislation, a health facility must have adequate seating, adequate waste management, and must conform to particular requirements if it has facilities such as an operation theatre or labour room," he adds. In the event of a discrepancy, the law authorises patients or their relatives to file complaints against the establishment, which will result in action being taken against the establishment. Additionally, the Clinical Establishments Act addresses the need to maintain patient data.[241]

The Clinical Establishments Act's enforcement is a concern because health is a state responsibility and states are submitting to the private healthcare sector's pressure. The key reason for this is because the bulk of the country's population receives healthcare from private facilities.[242]

Additionally, the 2015 National Sample Poll Office survey[243] indicates that due to the deplorable state of public healthcare, individuals rely on private institutions to treat more than 70% of ailments—72 percent in rural areas and 79 percent in urban areas. And the private health sector is not bashful about capitalising on this frenzy. According to Frost & Sullivan, the private healthcare industry's value is predicted to reach US $280 billion in 2020, up from the present $45 billion.[244]

The states of Assam, Jharkhand, Arunachal Pradesh, Rajasthan, Uttar Pradesh, Bihar, Uttarakhand, and Sikkim have all adopted the Clinical Establishments Act. However, no one has yet to enforce it. Even states like Karnataka and West Bengal, which regulated the private healthcare sector on their own, are feeling the heat. The former was the first state to enact such a law, the Karnataka Private Medical Establishments Act, 2007, prior to the introduction of the Clinical Establishments Act. However, not a single lawsuit has been filed under it in recent years. The administration modified the law in December 2017 to make it harsher. However, this sparked uproar, and the state administration subsequently amended it. The current law provides that no state-level authority has the jurisdiction to monitor the performance of private health establishments. Through the West Bengal Clinical Establishments (Registration,

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[241] *Ibid*

[242] High-quality health systems in the Sustainable Development Goals era: time for a revolution, available at https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30386-3/fulltext (last visited September 30, 2021)

[243] National Sample Survey Office (NSSO), available at http://mospi.nic.in/NSSO (last visited September 30, 2021)

[244] HEALTH CARE IN INDIA - VISION 2020 ISSUES AND PROSPECTS, available at https://niti.gov.in/planningcommission.gov.in/docs/reports/genrep/bkpap2020/26_bg2020.pdf (last visited September 30, 2021)

Regulation, and Transparency) Act, 2017, West Bengal is the only state that has successfully reined in private hospitals and clinics. Thus far, the commission established by the law has penalised two private establishments—Kothari Medical Centre and SVS Marwari Hospital—for service failures and unethical business practises. However, the law is only applicable to hospitals with more than 100 beds.[245]

Because states are dragging their feet on enacting legislation to regulate the health sector, the Centre should establish a body akin to the Telecom Regulatory Authority of India or the National Green Tribunal to ensure their proper implementation and take action against violators. If the Clinical Establishments Act is implemented in its entirety, it has the potential to significantly reduce corruption in the healthcare industry.[246]

4.5 UNRESOLVED ISSUES IN THE ACT

The Clinical Establishment Act contains a number of problematic provisions. Several of them arise as a result of certain broad provisions. For instance, Section 12 (2) states that "the clinical establishment shall undertake to provide, within the scope of its staff and facilities, such medical examination and treatment as may be necessary to stabilise any individual's emergency medical condition who comes or is brought to such clinical establishment."[247]

This means that before transferring a patient with an emergency medical condition – whether myocardial infarction or appendicitis – all clinical institutions will be obligated to intervene to "stabilise" the patient. This places an excessive burden on clinical institutions. Though there is a caveat – that such interventions must be done "within the scope of available staff and facilities" - its interpretation will become contentious. The Supreme Court's original directive was issued in the context of providing life-saving first aid to accident victims. To expect doctors to apply it to all types of emergency circumstances is unreasonable, unrealistic, and unjust. The inclusion of such restrictions provides a strong argument for physicians to

[245] Regulation for better governance, available at https://www.india-seminar.com/2019/714/714_sunil_nandraj.htm (last visited September 30, 2021)
[246] The Governmental Public Health infrastructure, available at https://www.nap.edu/read/10548/chapter/5 (last visited September 30, 2021)
[247] Section 12 (2) The Clinical Establishments (Registration and Regulation) Act, 2010, available at https://www.indiacode.nic.in/bitstream/123456789/7798/1/201023_clinical_establishments_%28registration_and_regulation%29_act%2C_2010.pdf (last visited September 30, 2021)

reject regulation in general. Indeed, doctor organisations may dispute the constitutionality of this clause, delaying the Act's implementation.[248]

Second, no provision is made for additional machinery to deal with the increased burden associated with regulating private clinical enterprises. Thus, either the Act is not implemented or it is administered in an inefficient manner - in either case, both honest physicians and patients lose. For example, while the National Council established pursuant to this Act will have a special secretary, it will also have an ex-officio member and chairperson in the director-general (DG) of health services from the Ministry of Health and Family Welfare. One consequence is that critical meetings and decisions may be delayed due to the DG's inability to perform this new task. There will be no new appointments at the state level to oversee the work — the secretary of health and the director of health services will serve as ex-officio chairman and secretary, respectively. At the district level, the situation will be even worse, as the district collector and district health officer will serve as the chairperson and secretary of the district registering authority, which would serve as the primary functional unit for implementing this Act. For all of these officials, the Act will significantly increase their workload, and the task will not be executed on time or with proper diligence.[249]

Thirdly, hospital owners who seek to appeal a district health authority order must do so through the state council. Each state has thousands of medical institutions, and there are certain to be numerous disagreements with the district registering authority, at least initially. These physicians will be required to report to the state capital for all work related to these issues. When the Bombay Nursing Home Registration Act's draught rules were being drafted in 2005, the Jan Aarogya Abhiyan proposed the formation of a "multi stakeholder district advisory committee" to advise the district authority, providing a forum for dialogue with the district registering authority and thus some accountability at the district level. This proposal was not approved. Such recommendations can still be advanced if all parties exert pressure on the government. However, this will need engaging authority using logic and evidence.[250]

[248] LAW COMMISSION OF INDIA 201 ST REPORT ON EMERGENCY MEDICAL CARE TO VICTIMS OF ACCIDENTS AND DURING EMERGENCY MEDICAL CONDITION AND WOMEN UNDER LABOUR available at https://lawcommissionofindia.nic.in/reports/rep201.pdf (last visited September 30, 2021)
[249] Dr. Ashwani Goyal vs Union Of India & Anr. on 31 July, 2012 available at https://indiankanoon.org/doc/27605138/ (last visited September 30, 2021)
[250] Why does the Clinical Establishment Act remain mostly on paper? Available at https://www.moneycontrol.com/news/business/why-does-the-clinical-establishment-act-remain-mostly-on-paper-2530741.html (last visited September 30, 2021)

While formulating minimum requirements under this Central Act, a much more robust and concrete debate will need to take place. In Maharashtra, the Jan Aarogya Abhiyan claimed that basic standards should not be confined to structural requirements like as physical space, equipment, and staff; they should also include some process requirements, such as adherence to patients' human rights. This was approved, and some patient rights were incorporated into the BNHRA's proposed rules, however this is currently in limbo. The notion is that the government must be compelled to engage in communication with stakeholders; all stakeholders must be involved in developing and enforcing new Act regulations and processes. But for this to happen, doctor's organisations must change their attitude and come up with more credible arguments and concrete suggestions.[251]

There are many other issues, all of which require proactive, vigorous engagement with the concerned authorities. Then the central government announced that it would chart out a "National Standard Treatment Policy"[252]. This policy is meant to ensure that doctors use optimum medical procedures and prescribe limited drugs so that patients are neither overcharged nor over-drugged during treatment. Ranjit Roy Chowdhary, a leading clinical pharmacologist, who is part of the policy making team, has stated: "The policy will also safeguard doctors." He has added: "If a patient dies due to a drug which is not as per the schedule that we give, [the doctor] can be in trouble. But for those who follow the policy, there will be a ring of protection since the medicines and treatments were as per standard policy prepared by experts from across the country,"[253]

4.6 CONSEQUENCES OF THE ACT

The Clinical Establishments (Registration and Regulation) Act, on the other hand, may have similarly significant consequences for healthcare throughout the country. The legislation argues in its introduction that healthcare in India is inconsistent and unclear in quality, that supervision is inadequate, and that the current healthcare delivery system does not provide

[251] Jan Arogya Abhiyan to intensify campaign on rate regulation and patients' rights in pvt hospitals, available at https://indianexpress.com/article/india/jan-arogya-abhiyan-to-intensify-campaign-on-rate-regulation-and-patients-rights-in-pvt-hospitals-testimonies-by-patients-at-public-hearing-7176350/ (last visited September 30, 2021)

[252] Standards and Protocols, available at https://www.nhp.gov.in/standards-and-protocols_pg (last visited September 30, 2021)

[253] REPORT OF THE PROF. RANJIT ROY CHAUDHURY EXPERT COMMITTEE on POLICY AND GUIDELINES FOR APPROVAL OF NEW DRUGS, CLINICAL TRIALS AND BANNING OF DRUGS available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4073545/ (last visited September 30, 2021)

sufficient incentives for efficiency development. Additionally, it notes that central legislation is intended to address concerns raised by the general public and a variety of stakeholders, as well as the widespread perception of an insufficient regulatory framework, by establishing a common standard of facilities and services across the states.[254]

As the name implies, it is charged with the responsibility of registering, regulating, and setting standards for clinical establishments. It shall apply to all federally recognised territories and four states. Other states may enact legislation similar to the Clinical Establishments Act. A clinical establishment is described as a hospital, maternity home, nursing home, or other comparable bed-based facility. Additionally, a laboratory that provides pathological, bacteriological, and other diagnostic services is included in the term. A National Council shall be established by the central government. Its primary responsibilities include the creation of standards for clinical establishments and the maintenance of a registry of clinical establishments. Each therapeutic facility will be required to register. The Act allows for both provisional and permanent registration upon fulfilment of specified conditions. The district registering authority is responsible for registering clinical establishments, examining them, and cancelling registrations that do not adhere to required requirements. Several of these have come under fire. Additionally, the website has a concise examination of the controversial provisions and topics. These have been detailed here, with a few additions. Clinical establishments are defined in section 2(c)(i) as facilities with beds.[255]

Thus, out-patient clinics are automatically excluded, despite the fact that they account for 60 to 70% of private healthcare (Report of the Working Group on Clinical Establishments, Professional Services Regulation, and Accreditation of Healthcare Infrastructure (RWG)). Section 2(c)[256] applies to independent laboratories and radiology institutions that provide diagnostic and/or investigative services. Outpatient surgery, which is becoming more prevalent in the United States, is catching on in India as well – several scientific reports involving specific surgical procedures have been published – though no exact figures on their prevalence in freestanding clinics are available. (A good guess is that less capital-intensive procedures (e.g., traditional forms of cataract surgery) are more prevalent.) These facilities are typically affiliated to outpatient clinics, requiring patients' attendance only for the duration of the surgery

[254] An Overview Of The Clinical Establishments (Registration And Regulation) Act, 2010, available at https://www.mondaq.com/india/healthcare/446404/an-overview-of-the-clinical-establishments-registration-and-regulation-act-2010 (last visited September 30, 2021)
[255] Section 2(c)(i) The Clinical Establishments (Registration and Regulation) Act, 2010
[256] Section 2 (c) The Clinical Establishments (Registration and Regulation) Act, 2010

and a brief period of post-operative observation that typically lasts less than a full day, and do not require beds or admission. Such institutions, regardless of the nature of the care provided, would also be excluded from the scope of this legislation.[257]

Section 5 authorises the government to develop both 'appropriate' and 'minimum' healthcare standards.[258] The latter is should be used exclusively in assessing the state of any institution. Creating such standards will be extremely challenging in a country with insufficient knowledge about the nature and quality of healthcare, no national programme for the development of practise guidelines or medical review criteria (World Bank Report, 2003)[259], and significant regional and social differences.

The RWG recognises this[260] and, given the lengthy nature of the procedure, advises decoupling it from registration[261], a position reflected in the draught bill. Section 10[262] establishes the District Health Officer (DHO) or Chief Medical Officer (CMO) as the district registering authority for clinical establishment registration in each district. Additionally, the DHO/CMO is responsible for the district's management of government buildings. As a result, a conflict of interest arises. Section 39 has a constraint requiring that the register be maintained in digital format. There is concern that newer non-digital technologies will be excluded as a result.[263]

To foster cooperation and alleviate the private healthcare establishment's cynicism, however, the National Council charged with creating standards[264] is required to use a participatory approach[265].

A 2003 World Bank (WB) report titled 'Health Policy Research in South Asia:[266] Strengthening Capacity for Reform', a goldmine of information on the private sector (from which the RWG appears to have drew at several points), summarises the various malpractices

[257] Report on the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure For the 11th Five-Year Plan, available at https://niti.gov.in/planningcommission.gov.in/docs/aboutus/committee/wrkgrp11/wg11_hclinic.pdf (last visited September 30, 2021)
[258] Section 5 The Clinical Establishments (Registration and Regulation) Act, 2010
[259] Health Policy Research in South Asia : Building Capacity for Reform, available at https://openknowledge.worldbank.org/handle/10986/15071 (last visited September 30, 2021)
[260] Supra 47 Para 37
[261] *Ibid para 40*
[262] Section 10 The Clinical Establishments (Registration and Regulation) Act, 2010
[263] Section 39 The Clinical Establishments (Registration and Regulation) Act, 2010
[264] Section 5 The Clinical Establishments (Registration and Regulation) Act, 2010
[265] Section 7 The Clinical Establishments (Registration and Regulation) Act, 2010
[266] Health Policy Research in South Asia : Building Capacity for Reform, available at https://openknowledge.worldbank.org/handle/10986/15071 (last visited September 30, 2021)

identified in the private sector by previous studies: "There are numerous reports of problems with diagnostic and treatment practises; with insufficient facilities and equipment; and with doctors overprescribing, subjecting patients to unnecessary investigations and interventions, charging patients exorbitantly, engaging in unethical and irrational behaviour, and failing to provide patients with information."[267] The report, like several previous studies, advocates for regulation in general, albeit its authors (all of whom are famous in their fields) are not totally in agreement on how to proceed. One of them advocates for decentralisation and a stronger regulatory regime[268] another, writing more extensively on this subject, strongly advocates for a 'minimum set of basic regulations covering practitioner and institution licencing, measures to ensure minimum quality standards, pricing guidelines, and actions to prevent service (including technology) oversupply.'[269]; a third, while confident of the necessity of state intervention, maintains that comprehensive review is a necessary precondition, as little is known about the regulatory mechanisms already in place[270]. It should be noted, however, that many of the studies documenting misconduct did not confine themselves to private hospitals and nursing homes. They frequently concentrated on individual healthcare professionals and even included individuals who worked only in ambulatory clinics, without assessing the proportional contributions of each type of setting separately. Given the prevalence of such clinics, the legislation's wording will restrict regulatory investigation of a sizable portion of such ethical infractions.

Additionally, the RWG asserts that, while 'state-specific variances are unavoidable, the imperative of the hour is [to have] universal standards.'[271]. The act's statement of purposes and justifications reiterates this theme[272]. Which gets us to the following question: Is it a good idea to have a uniform standard? The exact solution will have to await the formal enunciation of these criteria. One can speculate about the ministry's intentions based on the bill's language and the RWG.

Section 12 of the act[273] establishes minimum standards for facilities and services, whereas clause (ii)[274] establishes minimum standards for employees, in order for clinical

[267] *Ibid*
[268] *Supra 47* p59
[269] *Supra 47* p249
[270] *Supra 47* p250
[271] *Supra 47* para 34
[272] *Supra 47* para 3
[273] Section 12 (i) The Clinical Establishments (Registration and Regulation) Act, 2010
[274] Section 12 (ii) The Clinical Establishments (Registration and Regulation) Act, 2010

institutions to comply with the Act's requirements. In terms of facilities, the Act is likely to benefit private institutions in metropolitan regions. Significant findings previously reported in restricted investigations include a lack of sanitary conditions and space constraints. Both are readily identifiable, albeit the latter may be more challenging to address in a congested metropolitan context (that study was conducted in Bombay). The extent to which the governing authority will grant freedom for such places remains to be seen.[275]

Services can be divided into two broad categories: those that are immediately related to patient care and those that are either peripheral to patient care but include interaction with the public or are more directly related to the institution's upkeep. The former category encompasses medical, surgical, nursing, and other services directly related to patient care that are governed by professional guidelines and whose professionals' conduct is monitored to a significant extent by professional bodies and also falls under the purview of other laws (such as the Consumer Protection Act, 2019)[276]. Any legislation may wind up interfering not just with the jurisdiction of these authorities, but also with professional autonomy, eliciting strong opposition. However, the most egregious medical errors that are documented frequently entail poor professional judgement or practise. Numerous past initiatives have resulted in little discernible change in practises, with their failure attributed to 'weakness,' a lack of clarity or relevance, strong practitioner resistance, and state apathy. Certain clauses requiring medical records to be examined for abnormalities already exist in some states' statutes but have not been applied. It remains to be seen whether a similar destiny awaits this renewed attempt in the absence of a mechanism to ensure that defined standards are consistently followed (Prominent instances attracting media attention may still lead to exacting regulatory scrutiny in the absence of a routinely enforced system of auditing records of private health centers). The second category of services is more regulateable; governments and certification agencies frequently target them in their efforts to improve healthcare quality. The same is likely to be true in India as well. Indeed, the RWG makes reference to the criteria set by the National Accreditation Board for Hospitals and Healthcare Providers (NABH)[277], a subsidiary of the Quality Council of India

[275] Maharashtra govt all set to adopt Clinical Establishment Act after 5 years, available at, http://pharmabiz.com/ArticleDetails.aspx?aid=93610&sid=1 (last visited September 30, 2021)
[276] Consumer Protection Act, 2019 , available at https://consumeraffairs.nic.in/acts-and-rules/consumer-protection (last visited September 30, 2021)
[277] National Accreditation Board for Hospitals and Healthcare Providers, available at https://www.nabh.co/ (last visited September 30, 2021)

(QCI). Additionally, additional accrediting agencies have formed. It is also likely that the standards ultimately set under this Act will draw heavily on some of these existing models.[278]

Personnel issues are prevalent in the healthcare business. Apart from the widely documented rural doctor scarcity, there have been reports of nursing shortages. Due to the vast disparities in the number of medical colleges between states (Supe and Burdick, 2006), the number of graduating physicians will continue to be uneven, with geography, lifestyle preferences, and linguistic barriers preventing large-scale redistribution from overserved to underserved areas. These issues, which are embedded in the existing system of incentives and constraints, are bound to persist for the foreseeable future. The pertinent question here is how new restrictions will affect them. If the medical education system is any indication, the answer is in the negative. Professional medical colleges must adhere to the MCI's faculty recruitment guidelines or risk losing their accreditation. Simultaneously, they have been experiencing a severe faculty shortage in a number of (mainly non-clinical) specialties, which has been partially blamed on the MCI, with calls to lessen these criteria to address the issue. Similar staffing shortages also exist in the broader healthcare sector. Allopathic hospitals occasionally employ homoeopathic house surgeons and recruit unskilled nurses.[279] If qualification criteria are aggressively enforced, private institutions may either mutiny or turn to a variety of unscrupulous techniques to avoid inspection (see this news item's 'Hoodwinking the medical council'). This issue has been somewhat addressed in remote areas by current workers delivering additional services outside the scope of their training. I knew a surgeon at a well-known rural clinic in North Karnataka who doubled as a gynaecologist and was reported to be capable of performing orthopaedic surgery when the normal orthopaedic surgeon was unavailable. The WB Report admits this practise in Uttar Pradesh[280], but understanding that the alternative is no service, suggests allowing it to continue 'for the time being' on the condition that practitioners make full disclosure to community leaders and the general public. Section 13(2)[281] requires the Central Government to consider 'local conditions' when prescribing standards for clinical establishments. This struck me as somewhat strange — aren't concepts of uniformity and central involvement diametrically opposed to the notion of a local solution?

[278] Annual Report 2019-2020, available at https://main.mohfw.gov.in/sites/default/files/Annual%20Report%202019-2020%20English.pdf (last visited September 30, 2021)
[279]The West Bengal Clinical Establishment Rules, 2003 available at, https://www.wbhealth.gov.in/other_files/ce_act.pdf (last visited September 30, 2021)
[280] *Ibid*
[281] Section 13(2) The Clinical Establishments (Registration and Regulation) Act, 2010

Is it true that Central experts are more aware of and sympathetic to local concerns than local health officials? In any case, failing to include some wiggle room in the regulations enacted under the section[282]will undoubtedly damage rural providers. It remains to be seen how these disparate criteria will be addressed.

Additionally, there have been several reports of various shortcomings in the behaviour of individual providers - rampant absenteeism, open positions that remain unfilled, incompetence, and a poor work ethic. Numerous instances of these have been documented in the public sector, with the absence of rigorous accountability practises being blamed. What effect will improved regulatory standards have on this Sections 42 to 44[283] empower the government to impose fines for non-compliance, and a proviso to Section 32(3(b))[284] permits the institution to be restrained from 'going on' if an imminent threat to the health and safety of patients exists. As previously stated, because the DHO/CMO is responsible for all government facilities in the district, the resulting conflict of interest makes it highly improbable that he/she will take severe action against erring individuals or facilities. Apart from that, the coercive effect is diminished because any fine imposed is simply one arm of the government compensating another. If a facility is forced to close due to non-compliance, the consequences may be more severe. That is, however, a rare occurrence; if it is bad enough to scandalise the government or otherwise galvanise it into action, the finger will once again point directly at the DHO/CMO who ordered it. Thus, even if more rigorous accountability standards are devised and implemented, these limits will very certainly impede their successful implementation.[285]

Along with governmental consistency, the RWG discusses parity between public and private healthcare institutions: Commercial sector companies are quick to accuse the government of applying double standards by setting minimum criteria for private establishments while doing nothing to enhance public health institution conditions. The administration would need to approach this issue with the appropriate spirit. There are no exclusions for government organisations in legislation governing the management of biomedical waste, the establishment of blood banks, and prenatal diagnostic testing, among other things. All of these laws have had a beneficial effect on their respective fields. That is all the more reason for government establishments to be forced to register and adhere to defined requirements as well. On the surface, the initiative appears to be commendable. However, Ajay

[282] Section 12 (ii) The Clinical Establishments (Registration and Regulation) Act, 2010
[283] Sections 42 to 44 The Clinical Establishments (Registration and Regulation) Act, 2010
[284] Section 32(3(b)) The Clinical Establishments (Registration and Regulation) Act, 2010
[285] *Supra 47*

Mahal writes in the 2003 World Bank Report, quoting classical economic theory, as follows the suggestion to improve the quality of public sector care, in particular, runs up against the problematic observation made by Besley and Coate (1991) that greater equity and improved insurance for the poor can be achieved if the quality of available public services is not 'too high.' They claim that the public sector can serve the poor's interests if the wealthy begin to use private care or unsubsidized public facilities such as paid inpatient wards. To accomplish this, however, the nonpoor must view the quality of care provided by private, unsubsidized facilities to be superior to that provided by subsidised public services.[286] Additionally, discovered that the BIMARU states and Orissa had the least equitable allocation of public health subsidies, implying that the wealthiest segments of society utilise public health facilities more than the poorer segments. If the minimum criteria are set high enough to require both public and private businesses to upgrade their facilities, thereby increasing parity, it is possible that the targeting of subsidies to impoverished groups may deteriorate and healthcare disparities will increase. The same consequence would occur if private establishments, unable to meet the requirements, simply closed their doors or relocated. The Indian Medical Association (IMA) which has consistently resisted state regulation, not surprisingly, came out against this particular effort also. As it alleges, this is, in a sense, a return to the license-permit raj with registration and inspection becoming potential focal points of corruption.[287]

4.7 CONCLUSION

To summarise, in a country as diverse as India, it is reasonable to be sceptical of a broad endeavour to achieve consistency by state-mandated regulation. The Clinical Establishments Act is likely to have some beneficial consequences, as seen by noticeable improvements in urban private sector facilities. However, a comprehensive assessment must consider the complete range of costs and benefits incurred by the healthcare system's constituent sections as well as its participants. Thus yet, just a few states have endorsed this proposal. Assuming this continues to be the case, it may eventually provide an opportunity, after it is implemented (if it is adopted at all), to analyse its effectiveness through comparison analysis.

[286] Para 59 Health Policy Research in South Asia : Building Capacity for Reform, available at https://openknowledge.worldbank.org/handle/10986/15071 (last visited September 30, 2021)
[287] The Clinical Establishments Bill, 2007: Boon or Bane? Available at https://lawandotherthings.com/2007/12/clinical-establishments-bill-boon-or/ (last visited September 30, 2021)

It is remarkable that, until the Clinical Establishments (Registration and Regulation) Act (CEA), 2010, was enacted, health facilities, unlike most other business establishments such as shops, beauty parlours, and dance bars, were not required to register or obtain a licence to operate in a majority of Indian states. States' laws in this area were antiquated, lacking in content and coverage, and lacking in the formation of regulations and byelaws, as well as in the presence of mandated standards. CEA, 2010 is applicable in 11 states and six UTs as of March 2021. Though it is a major piece of legislation, the 2010 CEA establishes only minimal criteria for infrastructure, human resources, supported services, and medical equipment, among other things. It makes no provision for process or outcome standards. Additionally, there are no legislative procedures in place to regulate service costs, perform clinical and social audits, or protect patients' rights.

Among outreach services, home-based care is the least regulated, while medical camps are regulated to a limited level by government recommendations and court decisions but are not governed by particular legislation. The CEA, 2010 covers mobile medical health services, albeit the minimum standards have not yet been declared. A thorough examination of the regulations governing diagnostic and treatment services, such as laboratories and diagnostics, pharmacies, blood banks, and ambulances, is also a critical component of the study. The Clinical Establishments (Registration and Regulation) Act, 2010 was the first to make laboratory and diagnostic centre registration mandatory. There are no restrictions governing how practitioners and health care facilities charge for health care services/procedures. Similarly, there are no restrictions requiring health facilities, laboratories, or diagnostic centres to reduce costs. In States that have enacted the Clinical Establishments (Registration and Regulation) Act (CEA), 2010, the Clinical Establishments (Central Government) Rules (CER), 2012, require clinical establishments registered under the CEA, 2010 to display the rates charged for various services/facilities available, and the rates must be within a range determined by the Union/State government. The National Council for Clinical Establishment (NCCE) has authorised a set of standard procedures and a template for their costing in accordance with CER 2012 Rule 9 (ii) and (iii). These are distributed to States/UTs that have accepted the Central Act, with the recommendation that they use them to determine the standard cost of each process, taking into account all relevant local conditions. This, however, has not been implemented. In some states, like as West Bengal and Kerala, the legislation requires that information about prices/fees be given to persons seeking to use services.

According to the Clinical Establishments (Central Government) Rules, 2012, health facilities registered under the CEA, 2010, are required to publish the prices charged for the various services/facilities available, and the rates must be within a range specified by the Union or State governments. The National Council for Clinical Establishment has authorised a list of standard procedures and a template for pricing these processes in accordance with Rules 9 (ii) and (iii) of the Clinical Establishments (Central Government) Rules, 2012. These are distributed to States/UTs that have accepted the Union government Act, with the recommendation that they use them to determine the standard cost of each procedure, taking into account all relevant local conditions.

The Clinical Establishments (Central Government) Rules, 2012, require clinical establishments registered under the CEA, 2010, to indicate the rates charged for the various services/facilities available, with the rates to be set within a range defined by the Union/State governments. The National Council for Clinical Establishment has authorised a list of standard procedures and a template for pricing these processes in accordance with Rules 9 (ii) and (iii) of the Clinical Establishments (Central Government) Rules, 2012. These are distributed to States/UTs that have accepted the Union government Act, with the recommendation that they use them to determine the standard cost of each procedure, taking into account all relevant local conditions.

CHAPTER 5

CONCLUSION AND SUGGESTIONS

5.1 CONCLUSION

The global network has long seen health as a fundamental and major human right protected by international human rights legislation. In contrast to other human rights, the right to health obligates nations to ensure that the right to health is recognised, protected, and fulfilled for each of its people.

The term 'right to the greatest attainable standard of health' refers to a precise set of legislative standards that states must adhere to in order to ensure that all individuals, without regard for prejudice, have adequate opportunity to enjoy health. In Indian society, access to health care is a vital concern. Not only the medical profession is responsible for protecting, upholding, and honouring the right to health, but also public officials such as administrators and judges. Historically, public health care has been linked to statistical determinants such as life expectancy, mortality rates, and access to new pharmacological goods and procedures.

Health care, more than any other issue, is a key priority for governments and individuals alike. That is because we all require the services of the health care system to differing degrees and at varying intervals in our lives. It is self-evident that the right to health is inextricably linked to the right to life. The Supreme Court of India viewed the right to health as a subset of the right to life, bringing it within Article 21 of the Indian Constitution. As a result, the state bears the burden of enforcing the law and providing proper medical care. India, as a big country, has all the infrastructure necessary for good execution, and it is up to the public and private sectors of health care to organise and work to improve the existing state of health care. This article discusses some modern challenges in India's healthcare sector, highlighting several weak links that require strengthening.

The majority of countries have placed a premium on the quality of care delivered by their health care delivery systems. Because quality is critical in health care, measures to improve health care quality have become a global phenomenon. Numerous countries are examining various ways and methods for enhancing the quality of health care. In India, the quality of governmental and private sector services to the populace remains largely ignored. The health care delivery system's current structure provides insufficient incentives for

efficiency development. In India, the mechanisms used in other countries to increase hospital efficiency, accountability, and governance have not yet been applied.

Accreditation in healthcare services refers to the process by which an accrediting body confirms that a healthcare organisation adheres to a set of criteria developed by subject-matter experts. Typically, accreditation is undertaken by a diverse team of health professionals and involves comparing the setting in which clinical care is delivered to stated criteria. Frequently, national standards are the product of a synthesis of national statutes, government advice, independent reports, international accrediting requirements, and biological and health services research. Accreditation entails the setting of standards for all of a general hospital's services, for example, in accordance with universally/nationally recognised quality standards. However, the most appropriate country-specific approach is determined by the certification system's intended goals. Fundamentally, an accreditation system should provide an objective, independent assessment process, be extremely reputable and unbiased, represent the broadest possible consensus among users and stakeholders, advance healthcare service advancement, and be trusted by significant users and stakeholders.

In the current environment, it is necessary to establish bodies and methods for monitoring the clinical and non-clinical efficacy of services provided in public and private facilities. Concerns regarding how to enhance the quality of health care in India have been often addressed by the general public and a diverse range of stakeholders, including the government, professional groups, commercial providers, and organisations that finance health care. Additionally, initiatives have been made to build systems and processes that would ensure the health providers' delivery of high-quality care.

The Central Government adopted the Clinical Institutions (Registration and Regulation) Act, 2010 to facilitate the registration and regulation of all clinical establishments in the country in order to establish minimum standards for their facilities and services. The Act requires registration of all clinical enterprises, including diagnostic centres and single-doctor clinics, in the public and private sectors, save those managed by the armed forces. The registering authority aids policy development, resource distribution, and establishes treatment standards. It has the authority to impose fines for violations of the Act's provisions. The Act establishes Standard Treatment Guidelines for prevalent medical problems and establishes a core group of specialists to oversee their implementation.

Additionally, the Act requires all clinical establishments to provide the medical care and treatment necessary to stabilise any individual who comes or is brought to the clinical establishment in an emergency medical condition, particularly women delivering babies and individuals involved in accidents. Article 47 of the Constitution imposes a responsibility on the State to promote public health and to regard this responsibility as one of its primary responsibilities. In particular, the State shall work to eliminate the usage of intoxicating beverages and hazardous substances, except for medicinal grounds. Thus, the Government of India approved the Act, which provides for the registration and regulation of clinical establishments in India, as well as matters associated with or incidental to such registration and control.

The Act defines "Clinical Establishment" and includes all hospitals, maternity homes, nursing homes, dispensaries, and clinics, as well as any other institution by whatever name that provides services, facilities, or care for illness, injury, or any other condition, as well as any place established as an independent entity or part of an establishment for the diagnosis or treatment of certain diseases. Additionally, it includes a clinical facility that is owned, controlled, and managed by the government or a government department, a trust, a corporation registered under a federal, provincial, or state statute, a municipal government, and a single physician.

It appears to be a boon in addition to that, as India's public health is predicted to improve dramatically as a result of the Government's enthusiastic attitude to achieving the Clinical Establishments (Registration and Regulation) Act, 2010. With the diligently drafted standards being implemented through this Act, it is expected that in the coming years, every clinical establishment in India will be systematised and stringently compelled to provide all the basic minimum standards of medical care, resulting in a tremendously appreciable revolution in the healthcare sector in India.

It's natural to be sceptical of a broad effort to achieve consistency through state-mandated regulation in such a diverse country as India. As seen by considerable improvements in urban private sector institutions, the Clinical Establishments Act is likely to have some favourable effects. A thorough assessment, on the other hand, must take into account the whole spectrum of costs and benefits borne by the healthcare system's constituent parts as well as its participants. Only a few states have approved this proposition thus far. Assuming this continues to be the case, it may eventually provide an opportunity to evaluate its effectiveness using

comparative analysis after it is implemented (assuming it is done at all). It is remarkable that, prior to the passage of the Clinical Establishments (Registration and Regulation) Act (CEA), 2010, health facilities, unlike the majority of other business establishments such as shops, beauty parlours, and dance bars, were not required to register or obtain a licence to operate in the majority of Indian states. State legislation in this field were archaic, deficient in content and coverage, and deficient in the development of rules and byelaws, as well as the presence of legislated standards. As of March 2021, the CEA, 2010, is applicable in 11 states and six UTs. While the 2010 CEA is a significant piece of legislation, it specifies only bare-bones standards for infrastructure, human resources, supported services, and medical equipment, among other things. It contains no references to process or outcome standards. Additionally, there are no legislative provisions governing service charges, clinical and social audits, or patient rights protection.

5.2 SUGGESTIONS

- **Lack of uniform legislation and it's implementation**

Lack of standard law and enforcement results in ineffective regulation and a related breach of Article 21's right to health. Recent advances in the spread of the Covid-19 virus highlighted vulnerabilities in the Indian healthcare system and emphasised the critical nature of fully implementing the CEA 2010 and Rules 2012, as well as the presence of a uniformly regulated and effective healthcare system in the country.

For the entire country, uniform standards must be set. These standardised practises should not be limited to infrastructure alone, but should also include service delivery. Under the proposed modifications to the Clinical Establishment (Central Government) Rules, 2019, health institutions that do not meet required standards in terms of infrastructure, manpower, equipment, medications, support services, and record registration will be denied registration.

The Clinical Establishment (Registration and Regulation) Act, 2010, requires that all clinical establishments be registered. However, the Act is now only applicable to 11 states: Arunachal Pradesh, Himachal Pradesh, Rajasthan, Jharkhand, Mizoram, Uttar Pradesh, and Uttarakhand.

Minimum standards are now available only to medical diagnostic laboratories that were notified on May 21, 2018. The suggested revisions are intended to ensure consistency in the quality of healthcare services supplied by various facilities. The physical facility must be designed and maintained to provide a safe and secure environment for patients, their families, staff, and visitors, according to the proposed criteria. It should also be located in an area with clean surroundings and must adhere to any applicable local by-laws. A sufficient quantity of space must be provided to perform the facility's basic functions, as defined in the rules. The clinic facility must be well-lit, ventilated, and clean, with an adequate supply of water. It shall have a prominent sign or board stating the clinic's name in the local language at the clinic's entrance or on the clinic's building. Additionally, the doctor's name and registration number, the cost structure for various doctors or specialists, the hours of clinics, and the services offered within the facility should be prominently displayed in signage in a language known by the area's residents.

- **Shift from public healthcare sector to private healthcare sector**

Due to the shift in emphasis from public to private healthcare, a need for regulation and standardisation of clinical establishments, active promotion and adoption of standard treatment guidelines in these sectors, as well as protection of patients' rights in clinical establishments, has been identified. These rights include information access, access to medical records and reports, informed consent, confidentiality, and privacy. CEA enforcement is a challenge because health is a state responsibility and states are bowing to the private healthcare sector's demand. Given that states are dragging their feet on enacting legislation to regulate the health sector, the Centre should establish a body like to the Telecom Regulatory Authority of India or the National Green Tribunal to ensure their correct implementation and take action against violators. CEA, if implemented in its entirety, has the potential to significantly reduce corruption in the healthcare industry.

- **Patient rights' centric laws are required**

The Act and the Rules regulate clinical establishments and all matters related with or incidental to them, including prescribing minimum requirements of facilities and services in

order to ensure cheap and high-quality healthcare. The Patient Rights' Charter (adopted by the NHRC) affirms and implements a patient-centered health care system.

- **Affordability of healthcare services**

The Indian government has already enacted the Clinical Establishments (Registration and Regulation) Act, 2010. According to the Clinical Establishments (Central Government) Rules, 2012, one of the conditions for registration and continuation of clinical establishments (in the States / Union Territories to which the said Act applies) is that the clinical establishments charge rates for each type of procedure and service within the range of rates determined by the Central Government in consultation with the State Governments from time to time. Additionally, healthcare enterprises must prominently advertise the fees charged for each type of treatment performed and facility available in both the local language and English. The National Council for Clinical Establishments approved a standard list of medical operations and a standard costing template for medical procedures and distributed them to the States and Union Territories. Additional action is the responsibility of the state/UT governments.

- **Revamping the public healthcare sector**

Regulating the private sector alone will not suffice; the public healthcare system must be redesigned to act as an alternative. Pricing ceilings and punitive measures may act as a deterrent to providers, impeding service. This will simply exacerbate the situation, as neither the public sector nor the private sector is incentivised to achieve what it is capable of doing.

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APPENDIX

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CERTIFICATE ON PLAGIARISM CHECK

1.	Name of the Candidate	JOSE TOM
2.	Title of Thesis/Dissertation	REGULATION OF CLINICAL ESTABLISHMENTS IN INDIA
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