
A CRITICAL ANALYSIS OF THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010

Dr. Nitish Kumar Sharma, Bahra University, Wagnaghat, District Solan, Himachal Pradesh

ABSTRACT

The Clinical Establishments (Registration and Regulation) Act, 2010 is India's first central statute aimed at creating a uniform regime for the registration and minimum standards of clinical establishments across all recognised systems of medicine. This paper examines the constitutional basis, legislative history, scope, institutional design, registration framework, enforcement machinery and judicial context of the Act. It argues that while the Act marks a significant move from fragmented state nursing-home laws towards a national standard-setting framework, its promise has been constrained by its limited territorial adoption, weak enforcement, the unresolved controversy over regulation of rates, the absence of a patient grievance mechanism and low penalties. The paper concludes with suggestions for reform.

Keywords: clinical establishments; registration; minimum standards; right to health; Article 252; health regulation; India.

I. INTRODUCTION

Health care in India is delivered through a mixed system in which public facilities coexist with a large and rapidly growing private sector. For decades, the regulation of private hospitals, nursing homes and laboratories depended on a patchwork of state laws, many of which were confined to "nursing homes" in modern medicine, set no meaningful clinical standards and were weakly enforced.¹ The consequence was a sector in which a patient had little assurance about the facilities, personnel or quality of care behind the signboard.

The Clinical Establishments (Registration and Regulation) Act, 2010 ("the Act") was enacted to address this gap. It received Presidential assent on 18 August 2010² and provides for the registration and regulation of clinical establishments in the country with a view to prescribing minimum standards of facilities and services.³ This paper analyses the Act under the following heads: its constitutional and legislative background, scope and applicability, institutional framework, registration regime, rules and standards, enforcement, judicial context, and a critical assessment with suggestions for reform.

II. CONSTITUTIONAL AND LEGISLATIVE BACKGROUND

A. *The Right to Health and Directive Principles*

The Supreme Court has read the right to health and medical care into the right to life under Article 21 of the Constitution.⁴ In *Consumer Education and Research Centre v. Union of India*, the Court held that the right to health and medical care is a fundamental right of workers.⁵ In *Parmanand Katara v. Union of India*, it held that preservation of human life is of paramount importance and that every doctor, whether in a government hospital or otherwise, has a professional obligation to extend medical aid to preserve life.⁶ In *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, the Court held that failure of government hospitals to provide timely medical treatment to a person in need violates Article 21.⁷ The Directive Principles reinforce this position: Article 47 imposes on the State a duty to raise the level of

¹The Bombay Nursing Homes Registration Act, 1949.

²The Clinical Establishments (Registration and Regulation) Act, 2010 (Act 23 of 2010).

³Statement of Objects and Reasons, the Clinical Establishments (Registration and Regulation) Bill, 2010.

⁴The Constitution of India, art. 21.

⁵*Consumer Education and Research Centre v. Union of India*, (1995) 3 SCC 42.

⁶*Parmanand Katara v. Union of India*, (1989) 4 SCC 286.

⁷*Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, (1996) 4 SCC 37.

nutrition and the standard of living and to improve public health.⁸

B. Federal Distribution of Legislative Power

"Public health and sanitation; hospitals and dispensaries" is Entry 6 of the State List, while "legal, medical and other professions" is Entry 26 of the Concurrent List.⁹ Since the regulation of hospitals and dispensaries falls within the State List, Parliament could not ordinarily legislate on the subject. The Act therefore relies on Article 252, under which Parliament may legislate on a State subject for two or more States where the legislatures of those States pass resolutions to that effect, and other States may later adopt the law by resolution.¹⁰ This route explains both the Act's structure and its principal weakness: its operation depends on adoption by individual States.

C. Pre-existing Regulatory Landscape

Before 2010, regulation was largely state-driven. The Bombay Nursing Homes Registration Act, 1949 and its counterparts in several States required registration of nursing homes but were primarily registration statutes with limited standard-setting.¹¹ Karnataka's Private Medical Establishments Act, 2007 was a comparatively more recent and broader enactment.¹² A national framework was seen as necessary to prescribe uniform minimum standards across States and systems of medicine.

III. GENESIS OF THE ACT

The Act originates in a Bill introduced in Parliament in 2007, which was examined by the Department-Related Parliamentary Standing Committee on Health and Family Welfare. The Bill of 2010 incorporated several recommendations of the Committee.¹³ Among the stated features of the legislation were the creation of a National Council and State Councils, provisional registration of existing clinical establishments without prior inquiry, a requirement that provisionally registered establishments fulfil notified standards, and the creation of registers of clinical establishments at the State and national levels.¹⁴ The Act was passed under

⁸The Constitution of India, *supra* note 4, art. 47.

⁹*Ibid.*, sch. VII, List II, entry 6 and List III, entry 26.

¹⁰*Ibid.*, art. 252.

¹¹The Bombay Nursing Homes Registration Act, *supra* note 1.

¹²The Karnataka Private Medical Establishments Act, 2007.

¹³Statement of Objects and Reasons, *supra* note 3.

¹⁴*Ibid.*

Article 252 on the basis of resolutions of the legislatures of the first States that consented, and was brought into force on 1 March 2012 in Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and in all Union Territories except Delhi.¹⁵ Other States, including Uttar Pradesh, Rajasthan, Uttarakhand, Jharkhand, Bihar and Assam, adopted the Act subsequently.

IV. SCOPE AND APPLICABILITY

A. Definition of "Clinical Establishment"

The definition in the Act is broad. A clinical establishment includes a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or any institution by whatever name called that offers services or facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine. It also includes a place, whether independent or part of another establishment, where pathological, bacteriological, genetic, radiological, chemical, biological or other diagnostic or investigative services are carried out with the aid of laboratory or other medical equipment. The definition covers establishments run by any person or body of persons, whether incorporated or not, and applies irrespective of whether the establishment is run for gain.¹⁶

B. Recognised Systems of Medicine

The Act applies to all recognised systems of medicine, namely allopathy, yoga, naturopathy, Ayurveda, homoeopathy, Siddha and Unani, together with any other system the Central Government may recognise by notification.¹⁷ This is a notable feature, as many earlier state laws were confined to allopathic institutions.

C. Exclusions

Establishments owned, controlled or managed by the Armed Forces are excluded from the Act.¹⁸ Government and private establishments are otherwise covered, which distinguishes the Act from regimes that regulate only private institutions.

¹⁵The Clinical Establishments Act, *supra* note 2, s. 1.

¹⁶*Ibid.*, s. 2(c).

¹⁷*Ibid.*, s. 2.

¹⁸*Ibid.*, s. 2(c).

V. INSTITUTIONAL FRAMEWORK

A. National Council for Clinical Establishments

Section 3 establishes the National Council for Clinical Establishments, chaired by the Director General of Health Services and composed of representatives of statutory professional councils such as the Medical Council of India (now replaced by the National Medical Commission), the Nursing Council, the Pharmacy Council and the Central Councils for Indian Medicine and Homoeopathy, as well as representatives of Zonal Councils and the North-Eastern Council.¹⁹ The National Council's functions include developing the standards and the classification of clinical establishments, and it is required to follow a consultative process in doing so.²⁰ The Council therefore operates as an expert, standard-setting body rather than as an enforcement agency.

The replacement of the Medical Council of India by the National Medical Commission under the National Medical Commission Act, 2019 has not been accompanied by a corresponding amendment to the composition of the National Council, a drafting gap that illustrates the difficulty of keeping a central statute adapted to changes in allied regulatory frameworks.²¹

B. State Councils and the District Registering Authority

The Act provides for State Councils whose function is to compile, maintain and update the State registers of clinical establishments and to send monthly returns for updating the National Register.²² Registration is administered at the district level by a District Registering Authority.²³ This decentralised arrangement places responsibility for day-to-day implementation on the district administration, which has other competing responsibilities and often limited technical capacity in health regulation.

VI. THE REGISTRATION REGIME

A. Mandatory Registration

Section 11 provides that no person shall run a clinical establishment unless it has been

¹⁹Ibid., s. 3.

²⁰Ibid., ss. 4–5.

²¹The National Medical Commission Act, 2019 (Act 30 of 2019).

²²Statement of Objects and Reasons, *supra* note 3.

²³The Clinical Establishments Act, *supra* note 2, s. 10.

duly registered in accordance with the Act.²⁴ Registration is thus compulsory for all establishments covered by the Act, and the registration certificate must be displayed.

B. Conditions and Minimum Standards

Section 12 sets out the conditions for registration. These include compliance with minimum standards of facilities and services, minimum requirements of personnel, and provision for maintenance of records and reporting as may be prescribed.²⁵ The Act further provides for classification of clinical establishments into categories, and the standards are to be prescribed by the Central Government on the recommendation of the National Council.²⁶ Standards are intended to be revised from time to time, and the Act contemplates differentiated standards for different categories of establishments, a feature intended to avoid imposing the same burden on a small clinic and a tertiary hospital.

C. Provisional and Permanent Registration

The Act adopts a two-stage model. Existing establishments may obtain provisional registration without prior inquiry, and such registration is valid for a limited period, after which the establishment must apply for permanent registration upon fulfilling the prescribed standards.²⁷ The Statement of Objects and Reasons records that existing establishments were to be allowed provisional registration so that they could carry on business, with no prior inquiry, but must then fulfil the notified standards.²⁸ The design reflects a pragmatic transition strategy: it avoids closing existing facilities overnight while creating a pathway towards compliance. The corresponding risk is that provisional registration becomes a de facto permanent licence if the follow-up inspection and verification machinery is not active.

D. Cancellation, Inspection and Registers

The Act empowers the authority to cancel registration for failure to comply with its provisions,²⁹ and provides for inspection of registered clinical establishments.³⁰ It also requires State and National Registers of clinical establishments to be maintained, which can in principle

²⁴Ibid., s. 11.

²⁵Ibid., s. 12.

²⁶Ibid., ss. 4, 12.

²⁷Ibid., Chapter III.

²⁸Statement of Objects and Reasons, *supra* note 3.

²⁹The Clinical Establishments Act, *supra* note 2, s. 32.

³⁰Ibid., Chapter III.

give policymakers a reliable database of health facilities.³¹

VII. THE RULES OF 2012: STANDARDS, EMERGENCY CARE AND RATES

The Central Government notified the Clinical Establishments (Central Government) Rules, 2012, which elaborate the registration procedure, fees and conditions for registration.³² Three features of the Rules deserve emphasis.

First, the Rules require every clinical establishment to provide within its staff and facilities such medical examination and treatment as may be required to stabilise an emergency medical condition of any individual who comes or is brought to the establishment. This translates the principle in *Parmanand Katara* into a statutory condition of registration.³³ Failure to comply may put the registration at risk.³⁴

Second, the Rules require clinical establishments to display rates for each type of service and to charge within the range of rates determined by the Central Government in consultation with State Governments.³⁵ This transparency and rate-range provision has been the most controversial feature of the regime, discussed in Part IX.

Third, the Rules require establishments to maintain medical records and to meet the reporting requirements prescribed, which contributes to health information systems and supports accountability in the event of a dispute.³⁶

VIII. ENFORCEMENT AND PENALTIES

The Act contains a graded penalty structure. Running an unregistered establishment attracts monetary penalties that escalate for repeat contraventions, and there is a separate and lower penalty for minor deficiencies in standards.³⁷ The penalties are imposed by an adjudicating authority and are subject to appeal and to recovery as an arrear of land revenue.³⁸ The Act thus favours a regulatory, compliance-oriented enforcement model over a criminal

³¹*Ibid.*, Chapter IV.

³²The Clinical Establishments (Central Government) Rules, 2012.

³³*Ibid.*, r. 9.

³⁴*Parmanand Katara*, *supra* note 6.

³⁵The Clinical Establishments Rules, *supra* note 32, r. 9.

³⁶*Ibid.*, r. 9.

³⁷The Clinical Establishments Act, *supra* note 2, ss. 40–43.

³⁸*Ibid.*, Chapter VII.

one, though it retains offences for specified contraventions.

Two observations follow. First, the monetary penalties fixed in 2010 have not been revised and may be too modest to deter large corporate hospitals from non-compliance, while being sizeable for small clinics. Second, enforcement depends on district authorities and State Councils that, in many States, have limited staff and no dedicated inspectorate.

IX. JUDICIAL PERSPECTIVES

The Supreme Court's jurisprudence on medical care supplies the normative context for the Act. In *Indian Medical Association v. V.P. Shantha*, the Court held that medical services rendered for a consideration fall within the ambit of "service" under consumer protection law, which opened private health care to consumer remedies.³⁹ In *Jacob Mathew v. State of Punjab*, the Court laid down the standard for criminal liability of medical professionals for negligence, requiring gross negligence or recklessness.⁴⁰ In *Samira Kohli v. Dr. Prabha Manchanda*, the Court dealt with informed consent as a component of patient autonomy.⁴¹ These decisions address liability after harm has occurred; the Act, by contrast, is a preventive instrument that seeks to ensure standards before harm occurs.

The most significant recent engagement with the Act concerns the rate-regulation provisions. In proceedings before the Supreme Court, the Union of India was called upon to explain its failure to determine the standard range of rates envisaged by the Rules, and the Court indicated that it was prepared to direct the use of existing government-scheme rates as a default if the Central Government did not act.⁴² The proceedings highlight a recurring theme: the Act's regulatory architecture exists, but key operational decisions depend on executive follow-through.

X. CRITICAL ANALYSIS

A. Strengths

The Act's principal strength is conceptual. It establishes a uniform definition of clinical

³⁹*Indian Medical Association v. V.P. Shantha*, (1995) 6 SCC 651.

⁴⁰*Jacob Mathew v. State of Punjab*, (2005) 6 SCC 1.

⁴¹*Samira Kohli v. Dr. Prabha Manchanda*, (2008) 2 SCC 1.

⁴²*Veterans Forum for Transparency in Public Life v. Union of India*, Writ Petition (Civil), Supreme Court of India (orders of 2024).

establishments across systems of medicine, requires registration, links registration to minimum standards, and contemplates differentiated standards by category. It also moves regulation from a purely licensing function towards quality, transparency and record-keeping, and the establishment of registers creates the possibility of a national health facility database, an objective endorsed in subsequent health policy.⁴³

B. Limitations

Limited territorial reach. Because the Act operates only in States that adopt it under Article 252, most large States continue to be governed by their own legislation. The result is a fragmented regulatory landscape which defeats the stated aim of a uniform national framework. Several large States have instead enacted their own comprehensive laws, such as West Bengal's statute of 2017, which creates an independent Regulatory Commission with grievance-redress powers.⁴⁴

Rate regulation. The requirement to charge within a determined range of rates has been resisted by sections of the medical profession, which argue that costs differ across locations and categories of establishment. The protracted delay in determining rate ranges has left patients without effective protection against excessive charges, even though the transparency requirement under the Rules is in force.⁴⁵ The litigation before the Supreme Court is evidence of this implementation gap.⁴⁶

No patient grievance mechanism. The Act focuses on registration and standards and does not itself create a dedicated forum for patient complaints. Patients must resort to consumer fora, civil or criminal courts, or professional disciplinary bodies.⁴⁷ The non-statutory Charter of Patients' Rights and Responsibilities, prepared by the National Human Rights Commission, remains advisory and is not enforceable as such.⁴⁸ By contrast, the criminal law addresses death caused by negligent acts, but only after the fact.⁴⁹

Compliance burden on small providers. Smaller clinics and AYUSH practitioners have

⁴³Ministry of Health and Family Welfare, Government of India, *National Health Policy, 2017* (2017).

⁴⁴The West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017.

⁴⁵The Clinical Establishments Rules, *supra* note 32, r. 9.

⁴⁶*Veterans Forum for Transparency in Public Life*, *supra* note 42.

⁴⁷The Consumer Protection Act, 2019 (Act 35 of 2019).

⁴⁸National Human Rights Commission, *Charter of Patients' Rights and Responsibilities* (2018).

⁴⁹The Bharatiya Nyaya Sanhita, 2023 (Act 45 of 2023), s. 106.

argued that infrastructure and documentation requirements are disproportionate to their scale. While the Act contemplates classification by category, the effective calibration of standards remains an unresolved task that affects access to care in underserved areas.

Weak enforcement capacity. The reliance on district authorities, the absence of dedicated inspection cadres, and low penalties mean that the threat of enforcement is often not credible. Provisional registration has in practice often become a long-term status.

Statutory currency. The Act continues to refer to bodies that have since been reconstituted, such as the Medical Council of India, and has not been comprehensively updated since 2010 to reflect developments such as the National Medical Commission and digital health records.⁵⁰

XI. COMPARATIVE OBSERVATIONS WITH STATE LEGISLATION

A comparison with state statutes is instructive. The Bombay Nursing Homes Registration Act, 1949 is essentially a registration law for nursing homes.⁵¹ The Karnataka Private Medical Establishments Act, 2007 extended regulation to a wider range of private establishments and incorporated provisions on rates and grievance redress.⁵² West Bengal's Act of 2017 went further by establishing an independent Regulatory Commission, mandating transparency of charges and creating a complaint mechanism.⁵³ These laws indicate that States have pursued stronger regulation of private health care than the central Act provides, and suggest that the central framework is best viewed as a floor of minimum standards rather than a complete regulatory code.

XII. SUGGESTIONS

First, the Union and the States should consider moving towards a framework of cooperative federalism in which the minimum standards of the Act are adopted or mirrored by all States, whether through adoption under Article 252 or through harmonised state legislation. Second, the Central Government should determine and periodically revise the standard range of rates in consultation with States, with a transparent methodology that reflects regional cost

⁵⁰The National Medical Commission Act, *supra* note 21.

⁵¹The Bombay Nursing Homes Registration Act, *supra* note 1.

⁵²The Karnataka Private Medical Establishments Act, *supra* note 12.

⁵³The West Bengal Clinical Establishments Act, 2017, *supra* note 44.

differences. Third, the Act should be amended to create a statutory patient grievance mechanism and to give legal force to a patients' charter.⁵⁴

Fourth, penalties should be indexed and revised to ensure deterrence, with graded consequences for repeated non-compliance. Fifth, State Councils and District Registering Authorities should be equipped with trained personnel and a digital registration and inspection system, and provisional registrations should be time-bound in practice. Sixth, the Act should be updated to reflect the National Medical Commission Act, 2019 and to integrate standards for electronic health records and data protection.⁵⁵

XIII. CONCLUSION

The Clinical Establishments (Registration and Regulation) Act, 2010 represents a significant legislative attempt to bring uniform minimum standards to a diverse and largely private health sector. Its design – broad coverage across systems of medicine, mandatory registration, a two-stage registration model, differentiated standards and national registers – is sound. However, its impact has been limited by the constitutional route of adoption, the absence of enforcement capacity, delays in determining rates and the lack of a patient grievance mechanism. If the Act is to fulfil the constitutional promise of the right to health under Article 21, the Union and the States must strengthen adoption, enforcement and accountability.⁵⁶

⁵⁴Charter of Patients' Rights and Responsibilities, *supra* note 48.

⁵⁵The National Medical Commission Act, *supra* note 21.

⁵⁶The Constitution of India, *supra* note 4, art. 21.

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