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Holding Healthcare Providers Accountable: Regulation of Healthcare Facilities

December 2023

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VIDHI Centre for Legal Policy

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The errors, if any, rest with the authors.

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Introduction

Introduction

Under the Constitution, health facilities regulation (**"HFR"**) is within the exclusive legislative competence of the states.[1] Bombay in 1949 and Delhi in 1953 were the first to legislate a system of licensing and minimum standards for private hospitals and dispensaries, popularly known as "nursing homes."[2] Various states continued to enact legislation between the 1970s and the 2000s, partly as a regulatory response to the burgeoning private healthcare sector.[3] As the public sector's role in producing health services was shrinking, policymakers in the public sector expected a corresponding expansion of their oversight role.[4]

In reality, healthcare facilities in India are governed by a mosaic of regulatory systems administered by governments, professional bodies, insurance companies, and other actors.[5] But speaking strictly in terms of legislation, eighteen laws in India use a system of licensing and registration to regulate the quality of facilities. They do this by making licensing conditional on meeting certain minimum standards established by law. These laws take substantially different approaches. They have different scopes - some of them govern only private facilities, while others apply to government facilities too. Their regulatory structures are also different. They create different kinds of authorities and vest the power to grant or refuse registration to facilities in different people and bodies. They establish different standards, exact different penalties, and prescribe different mechanisms of appeal.

In the 2000s, the Planning Commission was not optimistic about the ability of the state to effectively perform regulatory functions in relation to healthcare facilities. Diverse distribution, low capital investment, and poor public records and registration made the regulatory role both difficult and expensive. The implementation of existing laws governing facilities was regarded as ineffective, partly because of a lack of objective criteria for defining "quality of care" and partly because of the fear that enforcing regulations would increase the cost of care.[6] The Commission later proposed a "sensible mix of external regulation and internal self-regulation in consultation with the profession".[7]

Implementation issues with healthcare facilities regulation in India persist to this day. In Maharashtra, for instance, state regulation has been deeply inadequate. In the 1990s, questions asked in the legislative assembly revealed that the state had no idea how many registered hospitals were within its territory.[8] Many of these data gaps still exist today, with Hunter et al. (2022) noting that their "attempts to collect healthcare facility registration data were severely restricted as data were outdated and had not been categorised systematically".[9] This inability to effectively count healthcare facilities is emblematic of both poor state capacity and major gaps in the legislative framework. Those gaps have been partially filled by various other actors such as insurers, marketplace platforms, accrediting bodies, and judicial authorities.[10]

The Clinical Establishments (Registration and Regulation) Act, 2010 (**"CEA 2010"**) provided a common regulatory structure by allowing states to accede to a framework defined by Parliament. While hospitals are within the exclusive legislative jurisdiction of states,[11] Article 252 of the Constitution allows Parliament to enact laws on state subjects if states pass resolutions consenting to them. The CEA 2010 is an example of such legislation - it applies automatically in seven union territories (UTs) and has been adopted by consent in twelve states. It applies to a wide variety of establishments, from single-doctor clinics, private hospitals, and diagnostic centres to government-run hospitals and psychiatric institutions. The CEA 2010 was the result of dissatisfaction with the efforts of state governments in enacting adequate healthcare facilities regulation. The Planning Commission, in a mid-term appraisal of the tenth five year plan, identified the necessity of a Public Health Development Authority to streamline oversight and regulation in provisioning healthcare, as well as to "prescribe standards in both private and public provisioning of healthcare and to ensure the observance of minimal standards by all providers."[12] By the eleventh five year plan, government approval had been given for the introduction of the CEA Bill, with the Planning Commission stating that "efforts will be made to enforce standards for government hospitals at all levels."[13]

In the twelfth five year plan, the Planning Commission wrote that since many states have no laws on the registration of clinical establishments, and the laws in the remaining states have major gaps, all states will be persuaded to adopt the Central Act.[14] Further, it stated that

"the service and quality standards shall be defined, made consistent with requirements under the Clinical Establishments Act, and performance of each registered facility made public, and periodically ranked. The work of quality monitoring will be suitably institutionalised."[15]

[1] Constitution of India 1950, sch VII, list II, entry 6.
[2] Ramesh Bhat, 'Regulation of the Private Health Sector in India' (1996) 11 The International Journal of Health Planning and Management 253.
[3] Planning Commission, Tenth Five Year Plan 2002-2007: Volume II (Planning Commission, Government of India 2002) [2.8.60].
[4] ibid [2.2.105].
[5] Benjamin M Hunter and others, 'Decentred Regulation: The Case of Private Healthcare in India' (2022) 155 World Development 105889, 3. We use the term "healthcare facilities" as a generic term instead of "clinical establishments" because different HFR laws use different terms to refer to their healthcare establishments and we wished to avoid confusion.
[6] Planning Commission, Tenth Five Year Plan 2002-2007: Volume II (Planning Commission, Government of India 2002) [2.8.61].
[7] Planning Commission, Mid-Term Appraisal of the Tenth Five Year Plan (2002-2007) (Planning Commission, Government of India 2005) [2.2.105].
[8] Indira Chakravarthi and Benjamin M Hunter (eds), *Regulation of Formal Private Healthcare Providers in Maharashtra: Journey of Bombay Nursing Homes Registration Act and the Clinical Establishments Act* (SATHI 2019) 23.
[9] Hunter and others (n 5) 5.
[10] Hunter and others (n 5).
[11] Constitution of India 1950, sch VII, list II.
[12] Planning Commission, *Mid-Term Appraisal of the Tenth Five Year Plan (2002-2007)* (Planning Commission, Government of India 2005) [2.2.80].
[13] Planning Commission, *Eleventh Five Year Plan 2007-12: Volume II* (Oxford University Press 2008) [3.1.107].
[14] Planning Commission, *Twelfth Five Year Plan 2012-17: Volume III* (SAGE Publications 2013) [20.84].
[15] Planning Commission, *Twelfth Five Year Plan 2012-17: Volume III* (SAGE Publications 2013) [20.109].

Public records on the implementation of these laws inspire little trust. For instance, the National Register of Clinical Establishments records that Uttar Pradesh has 1010 registered clinical establishments.[16] However, as per the 2022 National Health Profile, the state has 4903 government hospitals alone.[17] Maintaining an accurate and up-to-date record of existing clinical establishments is the most basic objective of the CEA 2010, and yet, the National Register is currently plagued by accuracy and clarity concerns. At the same time, the National Digital Health Mission's Strategy Overview in July 2020 stated that one of its objectives was to "establish registries at appropriate level to create a single source of truth in respect of clinical establishments, healthcare professionals, health workers, drugs and pharmacies."[18]

The tone of government papers regarding the implementation of the CEA has been decidedly pessimistic. In 2019, the NITI Aayog found only a loosely regulated private healthcare system in existence. In particular, they noted that CEA 2010 implementation was "uneven across states" and that enforcement was lax partly due to insufficient capacity at the state level. They noted gaps in the legislative scheme such as an absence of quality processes or a grievance redressal mechanism, and identified the need to review states' capacity to implement and enforce these laws. They also stated that it was an open question whether the CEA 2010 would be more effective in practice than its predecessors at the state level.

However, according to the NITI Aayog, not all states may be implementing the CEA 2010 poorly. While some states have been unable to conduct even an effective census of healthcare facilities, the NITI Aayog claims that "a number of states have been able to create directories of clinical establishments and use this information to build upon and enhance notification for disease, death and births, especially within the private sector."[19]

Some states even extend the scope of health facilities regulation by seeking to advance the interests of healthcare users. Historically, HFR in India has been a neglected instrument of healthcare provider accountability because their language and theory do not generally regard them as a tool for accountability. For most of their history, they were regarded as narrow tools for legibility – the desire of the state to order and subject facilities to state control. They provided only a process for registering and cancelling the registrations of facilities, and usually did not apply to government-run facilities.

While HFR laws in India primarily focus on licensing and registration as their principal mechanism, there is a need for wider discussion about their scope to hold healthcare providers accountable for providing quality and responsive healthcare to users. Some states have attempted to advance the interests of patients by adopting a rights-based approach that combats prevalent concerns about the practices of hospitals and clinics, like overcharging or refusal to discharge patients or hand over dead bodies until hospital bills are paid. Some seek to ensure that government doctors do not run parallel private practices and further create grievance redressal mechanisms for aggrieved patients.

The CEA 2010 is not the gold standard in India in terms of providing a regulatory structure for health facilities regulation. However, it has had a significant effect in increasing the scope of minimum standards regulation to include government facilities. Given the public concern about standards in hospitals as well as the persistent weaknesses in our healthcare delivery systems exposed by the Covid-19 pandemic, it is important to ensure that these laws are rights-based, that they ensure accountability, and that they are implemented and enforced.

This report examines these laws (CEA 2010 and beyond) and attempts to collect data on their implementation. In our analysis of the laws, our focus is on the different types of authorities, their administrative and regulatory functions, and the accountability mechanisms incorporated in these laws. We examine the prescribed consequences of non-compliance, the ability of patients and the public to raise grievances, and the mechanisms and processes for their redressal. In our analysis of the implementation of these laws, our focus is on determining whether these laws are enforced at all, and if so, to get a sense of the extent to which they are enforced.

[16] Ministry of Health and Family Welfare, Government of India, 'National Register of Clinical Establishments' <http://clinicalestablishments.gov.in/cms/national_register_of_clinical_establishments.aspx> accessed 6 June 2023.
[17] Central Bureau of Health Intelligence, Government of India, *National Health Profile 2022: 17th issue* (2022) 406 <http://www.indiaenvironmentportal.org.in/files/file/national%20health%20profile%202022.pdf> accessed 21 August 2023.
[18] National Health Authority, *National Digital Health Mission: Strategy Overview (2020)* 5 <https://www.niti.gov.in/sites/default/files/2023-02/ndhm_strategy_overview.pdf> accessed 10 September 2023.
[19] James Blanchard and others, *Vision 2035 Public Health Surveillance in India - A White Paper* (NITI Aayog 2020) <https://www.niti.gov.in/sites/default/files/2023-03/Vision-2035-Public-Health-Surveillance-in-India.pdf> accessed 10 September 2023.

Methodology

Methodology

This Report is about the statutory framework of health facilities regulation (i.e. what laws exist; and what regulatory structures and mechanisms those laws create) as well as the implementation of those frameworks.

We began by trying to find out how the CEA 2010 and its state equivalents worked as accountability mechanisms for healthcare establishments--essentially, were these laws performing the functions they were intended to? Particularly, the data points we set out to collect were as follows:

- Number of notices issued to clinical establishments for violating conditions of registration or other standards required to be maintained under the Act or its equivalent
- In states that require the establishment of internal grievance redressal systems by clinical establishments, details of complaints lodged
- Nature of violations/grievances (where applicable)
- Disposal Rates — This will include information on the time taken since the case was instituted or the complaint filed, as the case may be, until it is finally disposed of, allowing us to collect information on the proportion of cases in which appeals are filed, by whom, and in which forums.
- Nature of litigants/complainants and respondents — This will primarily focus on whether the respondents are in the public or private sector
- Nature of action taken (suspension, cancellation of registration of clinical establishment) and the quantum of penalties awarded
- Whether the regulatory forums under these laws are functioning, with the appropriate composition of members, as required under applicable legislation.

Legislative Overview

We also separately analysed, using a table of indicators and coding, the text of the CEA and the separate state laws. We revised the set of data points we planned to collect based on this overview.

Data Collection (RTIs)

Framing of Questions

We had initially planned to use a combination of methods to obtain data. Having determined that most of the data points we required were not publicly available, and most laws (including the CEA 2010) did not require publication or transparency, we had to use applications under the Right to Information Act to collect information. We amended our questions to make them suitable for applications under the Right to Information Act, 2005 (**"RTI Act"**).

We decided to collect information separately from the states as well as two districts in every state. For the first district, we chose the capital district. We assumed that capitals of states were likely to be urbanised and have greater regulatory capacity than other districts. For the second district, we chose the least populated district in every state. We assumed that the least populated districts were likely to be rural and have low allocations of funding and regulatory oversight. We expected the variance between the two, analysed against the responses from state authorities, to provide us at least with an indication of the extent to which the statute was being enforced.

CEA

We filed one set of applications under the Right to Information Act, 2005 on 29 September 2022 in order to gather information related to the data points mentioned above. These were filed with the Directorate of Health Services of each of the 12 states and seven UTs which have adopted the CEA 2010[20] to seek the following information:

- Current composition and vacancies in the State Council of Clinical Establishment
- List of District Registering Authorities established till date, as well as their current composition and vacancies
- Number of clinical establishments registered provisionally and permanently in the state
- Copies of annual reports published since the notification of the Act
- Details of the appeals received by the State Councils against the decision of the District Registering Authorities
- Minutes of meetings of the State Council of Clinical Establishments for the last five years

In order to track the effectiveness of the Act at the local level, we also filed applications with the District Registering Authorities of the capital and the least populated district of each of these states. We sought the following information from these authorities:

- Current composition and vacancies in the District Registering Authority
- Number of clinical establishments registered provisionally and permanently in the district
- Number of instances where objections were received from the public in response to a clinical establishment's application for permanent registration
- Number of instances where an application for permanent registration was disallowed, and notices were issued to the clinical establishment
- Number of instances where the registration of a clinical establishment was cancelled
- Number of instances in which the Authority immediately restrained the clinical establishment from carrying on due to imminent danger to the health and safety of patients.
- Number of inspections or inquiries undertaken
- Details of instances where a penalty was imposed on a clinical establishment under the Act.

[20] *See* infra 22-23 for an overview of the CEA 2010

Separate state laws

Similar to the first set of applications filed with states that have adopted the CEA 2010, we filed RTI applications with entities in sixteen out of seventeen states/UTs with separate state laws on 30 September 2022 in order to similarly gather information about the extent of implementation of laws regulating clinical establishments in states that have separate laws for this purpose. Accordingly, we sent applications to the state-level authorities as well as authorities of the capital and the least populated district of each of these states. Further, for 7 states, we filed additional applications with the appellate authorities which have been created under their respective laws.

Since the provisions and the structures of the laws of these 16 states differ vastly, we did not deem it prudent to request information using a template set of questions. Instead, we sought information based on questions tailored to the provisions of each specific law and the publicly available notifications which have been issued under each respective Act.

We omitted West Bengal, as we were at the time engaged in the process of other research relating to West Bengal's legislation, which we believed would help us obtain the relevant data without RTIs. We do not presently have data from West Bengal.

On 23 December 2022, we filed appeals to some entities which had not responded within the prescribed time (indicating a deemed rejection under the RTI Act) and made payments to entities which had demanded payment under the RTI Act for the sending of printed material.

Due to time and capacity constraints, the scope of our data collection was narrow. We did not file appeals or follow-up with entities following 23 December 2022. Neither did we file appeals with *all* non-responding entities on 23 December 2022. This was because our main objective was to arrive at a snapshot indication of the implementation of the Act. At certain points, we made subjective determinations to prioritise appealing the decisions of entities which we felt would yield positive outcomes within our timeframe.

It is important to emphasise that this data collection was not undertaken for the purpose of any substantive quantitative analysis.

Analysis

We collated the data from different entities into one spreadsheet that captured both the questions asked to individual states as well as their responses. We sought not to analyse or provide broad takeaways from the data, but to present them as snapshots of the level of implementation.

Major Limitations

Data Availability, underreporting, and non-response:
Hunter and King et al. (2022) point out in their study of Maharashtra's regulatory system for healthcare that obtaining data was difficult. This concern is not unique to Maharashtra. Authorities refused our RTI applications, informed us that data was not available on record, or simply returned the application unopened.

Lack of Uniformity across collected data points:
For laws other than the CEA 2010, RTI questions were framed on the basis of the language of relevant state legislation. State legislation generally did not use similar language or perform identical functions. For example, the legislation for one state might establish an obligation to maintain a register of licensed healthcare facilities, whereas another might not. This does not mean that the latter did not maintain such a register, but only that such a register was not mandated by the statute. However, our questions were directly purely at assessing compliance with the relevant statute. As a result, we do not have uniform data on the records management and enforcement practices of different states, but instead only indicators as to whether particular statutory obligations are being implemented.

Clinical Establishments (Registration and Regulation) Act 2010

Clinical Establishments (Registration and Regulation) Act 2010

Overview of the Act

Enactment:

The CEA 2010 was enacted to govern the registration and regulation of 'clinical establishments'. Brought into force on 1st March 2012, the Act has been adopted by 12 states and seven Union Territories (**"UTs"**). However, not all states and UTs were proactive in notifying their respective Rules for implementing the Act. While several states such as Sikkim, Uttarakhand and Rajasthan notified their Rules under the CEA 2010 within two-three years of its enactment, other states like Assam, Ladakh and Haryana notified their state Rules more than four years after the Act was enacted.

Table 3.1: Comparison between the year when the CEA 2010 was adopted by the states and the year when they notified their respective Rules

State	Year of Adoption	Date of Notification of State Rules
Andaman and Nicobar Islands	2012	6 March 2013
Arunachal Pradesh	2012	31 May 2012
Assam	2015	14 October 2016
Bihar	2011	28 November 2013
Chandigarh	2012	8 November 2013
Dadra & Nagar Haveli[22]	2012	10 November 2013
Daman & Diu	2012	4 September 2014
Haryana	2018	13 July 2018
Himachal Pradesh	2012	20 December 2012
Jammu & Kashmir	2012	19 May 2020
Jharkhand	2012	30 May 2013
Ladakh	2012	27 May 2022
Lakshadweep	2012	6 February 2017
Mizoram	2012	27 May 2014
Puducherry	2012	05 March 2014
Rajasthan	2011	05 June 2013
Sikkim	2012	19 April 2012
Telangana	2022	14 June 2022
Uttar Pradesh	2011	11 July 2016
Uttarakhand	2011	22 March 2013

[22] Even though Dadra & Nagar Haveli and Daman & Diu have been merged under the Dadra and Nagar Haveli and Daman and Diu (Merger of Union territories) Act, 2019, section 17 of that Act requires that laws that were in force in their respective territories will continue to apply to those territories.

Applicability:

The term 'clinical establishment' has been defined broadly to include both public and private establishments, including single-doctor establishments. These include hospitals, maternity homes, nursing homes, clinics and generally institutions that offer services and facilities for diagnosis, treatment or care for medical issues under all systems of medicine recognised by the Central Government, including allopathy and Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy (**"AYUSH"**). The Act applies to all 'clinical establishments' except those owned, controlled or managed by the Armed Forces.

Key Provisions:

The CEA 2010 primarily performs the following functions:

1. Establishes the National Council for clinical establishments,
2. Mandates the registration of clinical establishments,
3. Lays down the conditions for registration of clinical establishments,
4. Prescribes the procedure for registration of clinical establishments, and
5. Empowers authorities under the Act to take action against the clinical establishments which violate the provisions of the Act.

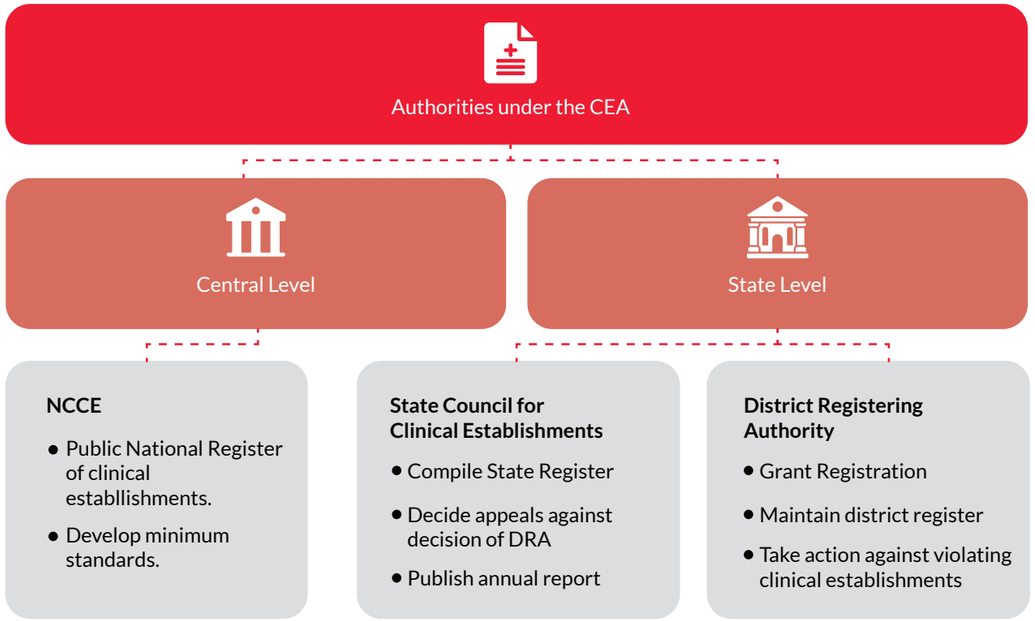
The Act also incorporates the principle of transparency, and by extension public accountability, by providing for the following:

1. Publication of the National and State registers of clinical establishments;
2. Publication of annual report on the state of implementation of standards within each state which has adopted the Act;
3. Publication of the names of clinical establishments whose registration has expired; and
4. Inviting objections from the public before permanently registering a clinical establishment.

Power to prescribe minimum standards and set rules:

The Central Government has the mandate under CEA 2010 to set rules for matters such as appointments to the National Council, the general standards with which clinical establishments must comply, and the minimum standards for facilities, services and personnel necessary for registration.[23] Accordingly, the Clinical Establishments (Central Government) Rules, 2012 came into force on 23rd May 2012 and have been amended in 2018[24] and 2020[25]. Additionally, the State governments are empowered to make rules over matters that are beyond the rule-making power of the Central Government such as the applications and fees for registration, the compliance and reporting requirements for clinical establishments and the appeal mechanism to be adopted by the State Council.[26]

Authorities under the CEA 2010



[23] Clinical Establishments (Registration and Regulation) Act 2010 (CEA 2010) s 52.
[24] Clinical Establishments (Central Government) Amendment Rules 2018.
[25] Clinical Establishments (Central Government) Amendment Rules 2020.
[26] CEA 2010, s 54.

The Act prescribes a diverse membership for the National Council for Clinical Establishments (**"NCCE"**).[27] The Council comprises 20 members, including:

- **Expert representation** from A) medical and paramedical councils such as the National Medical Commission and B) alternate systems of medicine such as Ayurveda;
- **Interest groups representation** from A) members from medical and paramedical professional associations such as Indian Medical Association ("IMA") and B) a national level consumer group;
- **Geographically diverse representation** through zonal and north-eastern councils; and
- **Technical representation** from A) Bureau of Indian Standards and B) Quality Council of India.
- Three *ex-officio* members from the Ministry of Health and Family Welfare and the Quality Council of India.

The State Councils have 14 members,[28] and they largely comprise state-level counterparts of the members of the NCCE.[29] There must be five *ex-officio* members in each State Council.

We sought information through RTI applications from state health departments / directorates of health services regarding the constitution and composition of State and UT Councils. For the states that did not reply to our application, we have attempted to fill the gap by supplementing the information from state government websites or publicly available notifications constituting these Councils, wherever possible.

- Daman and Diu and Lakshadweep Councils are the only two that do not include the Director of different streams of Indian systems of medicine.
- Several UTs lack representation from professional councils and interest groups.[30]
- Only Arunachal Pradesh and Ladakh Councils do not have a representative from any consumer group or non-governmental organisation.
- Only Arunachal Pradesh and Ladakh Councils do not have a representative from the State Council of IMA.

Since state councils are large bodies with representatives from such different fields, it is understandable that all states and UTs do not have such representatives. For instance, not all states and UTs have representatives from Siddha and Unani systems of medicines. Chandigarh, in its response specifically mentioned that "since no Siddha doctor is available in the UT of Chandigarh, the Council has been sent for partial modification to be notified without the said Member."

[27] CEA 2010, s 3.
[28] CEA 2010, s 8.
[29] Representatives from zonal and northeastern councils, the Bureau of Indian Standards and Quality Council of India are not included in these Councils.
[30] Andaman and Nicobar Islands, Chandigarh, Ladakh, Lakshadweep.

Registration

Registration of clinical establishments ensures that patients access only those service providers who are able to maintain certain standards of infrastructure and services.[31] The CEA 2010 makes it mandatory for a clinical establishment to be registered by the district registering authority[32] in the manner as prescribed in the Act.[33]

In this section of the chapter, we provide an overview of the relevant provisions of the CEA 2010 and examine the RTI replies of states, union territories and districts to determine the extent to which they have complied with the registration requirements set by the Act. In particular, we examine the following questions:

1. Have districts appointed their registering authorities as per the composition prescribed under CEA 2010?
2. How many certificates of provisional and permanent registration have states granted to clinical establishments?
3. Do registering authorities receive objections to applications for permanent registration as contemplated by the Act?
4. How often do registering authorities allow or disallow applications for permanent registration?

Registration authorities have varied composition across districts

The CEA 2010 provides that the State Government must set up district registering authorities (**"DRAs"**) consisting of[34]:

1. The District Collector as the Chairperson,
2. The District Health Officer as Convener and
3. 3 members with the prescribed qualifications for registration of clinical establishments in each district. These members must be[35]:
   a. A City Police Commissioner/Senior Superintendent of Police/Superintendent of Police/Nominee;
   b. Senior official of Local Self government at district level; and
   c. One representative of a professional medical association.

We sought information through RTI applications from state-level authorities regarding the constitution of their respective DRAs. We also sought the same information separately from authorities of the capital district and the least populated districts of each state.

- 7 states/UTs did not provide any information at all about the composition of DRAs in their state/UT, or suggested that such DRAs had not been constituted.
- All representatives of professional medical associations were from the district chapter of the IMA, with the exceptions of Anantnag and Bandipora districts, where the Joint Secretary, Doctor Association and Representative, Private Diagnostic Centres Association were appointed as members respectively.
- 12 districts did not have any representation from the local self government in their DRA at all, whereas, in two out of nine districts, specific details (name, designation etc) about the representative of local self government were not provided.
- Andaman and Nicobar appointed representation from non-governmental organisations (**"NGOs"**) instead of from local self-government in DRAs.
- Puducherry provided only the name of one person as the DRA.

Registration of clinical establishments is sporadic and uneven across states

Under the CEA 2010, a clinical establishment may be granted two kinds of registration - provisional[36] and permanent[37]. The establishment is first granted provisional registration by the relevant DRA[38] within ten days of its application for a period of twelve months and it may be renewed up to

a. Two years from the date of notification of the notified standards for establishments set up either before the CEA 2010 commenced or before the standards are notified, and
b. Up to six months from the date of notified standards for establishments set up after the Act commenced.

This suggests that while clinical establishments may be provisionally registered for a substantial period of time, provisional registration would no longer be available to clinical establishments set up after the prescribed period from the notification of the standards. However, the Operational Guidelines for the CEA 2010 note that provisional registration can be opted even beyond the above mentioned timelines, and new clinical establishments may also apply directly for permanent registration once the minimum standards have been notified.[39]

Permanent registration is to be granted only after clinical establishments submit proof of compliance with the prescribed standards of registration.[40]
A certificate of permanent registration would be valid for five years. The following table provides an overview of the salient features of provisional and permanent registration:

Table 3.2: Comparison between provisional and permanent registration under the CEA 2010

	Provisional Registration	Permanent Registration
How long is the certificate of registration valid for?	12 months	5 years
When should the application for renewal be filed?[41]	Within thirty days before the expiry of the validity of the certificate of provisional registration	Within six months before the expiry of the validity of the certificate of permanent registration
Are there any compliance requirements before granting registration?	No	Yes
Can the authority conduct any Inquiry before granting registration?	Prohibited	Permitted

[31] Ellie Scrivens and Lindsay Skelton, 'The role of organizational licensing in healthcare' (2008) 128(6) Journal of the Royal Society for the Promotion of Health 299 <https://pubmed.ncbi.nlm.nih.gov/19058470> accessed 18 August 2023.
[32] The district registering authorities are constituted by the State Government as per section 11 of CEA 2010.
[33] CEA 2010, s 11.
[34] CEA 2010, s 10.
[35] Clinical Establishments (Central Government) Rules 2012, r 8(1).
[36] CEA 2010, ss 14-23.
[37] CEA 2010, ss 24-31.
[38] CEA 2010, s 10.
[39] *Government of India, Operational Guidelines for Clinical Establishments Act* (2017) 29 <http://clinicalestablishments.gov.in/WriteReadData/2591.pdf> accessed 7 October 2023.
[40] CEA 2010, ss 12, 25, 28.
[41] For both provisional and permanent registration, applications for renewal may be submitted beyond the stipulated time period upon payment of the prescribed enhanced fees. *See* CEA 2010, ss 22 and 30(4).

States record a large range in the number of registrations granted

There is no exhaustive and updated source for the number of clinical establishments in the country. Consequently, it is onerous to confirm if all the operational clinical establishments in the country have been registered. The website of the CEA 2010 provides a dashboard listing the number of registrations in the digital National Register of Clinical Establishments.[42] This National Register is maintained by the Central Government and it is a compilation of the State Registers of clinical establishments maintained by the state governments.[43] The dashboard provides the number of registered clinical establishments for 15 states across the categories of allopathy, ayurveda, unani, siddha, homoeopathy, yoga, naturopathy and sowa-rigpa.[44]

The National Register makes no distinction in this official dashboard between provisional and permanent registrations in these numbers, and there is no distinction between the number of private and public establishments either. The NCCE did note this year that a new website for CEA 2010 is under development and would have several features for registration and grievance redressal.[45]

In our RTI applications, we asked authorities for the number of provisional and permanent registrations of clinical establishments they have granted since the enactment of CEA 2010. The following two tables list the number of registered clinical establishments across states and districts as per the replies.

> The National Register of Clinical Establishments makes no distinction between provisional and permanent registrations, and there is no distinction between the number of private and public establishments either.

[42] Ministry of Health and Family Welfare, 'National Register of Clinical Establishments' <http://www.clinicalestablishments.gov.in/cms/national_register_of_clinical_establishments.aspx> accessed 20 August 2023.
[43] CEA 2010, s 39.
[44] Ministry of Health and Family Welfare, 'National Register of Clinical Establishments', <http://clinicalestablishments.gov.in/cms/national_register_of_clinical_establishments.aspx> accessed 18 August 2023.
[45] These features reportedly include provisions for both online provisional and permanent registration, payment gateways, an online grievance redressal mechanism and an appeal mechanism. See National Council for Clinical Establishments, *Minutes of 13th Meeting of National Council for Clinical Establishments* (16 March 2023) <http://clinicalestablishments.gov.in/WriteReadData/9631.pdf> accessed 18 August 2023.

Figure 3.1: State-wise registration of clinical establishments since the enactment of the CEA 2010 as per the RTI replies

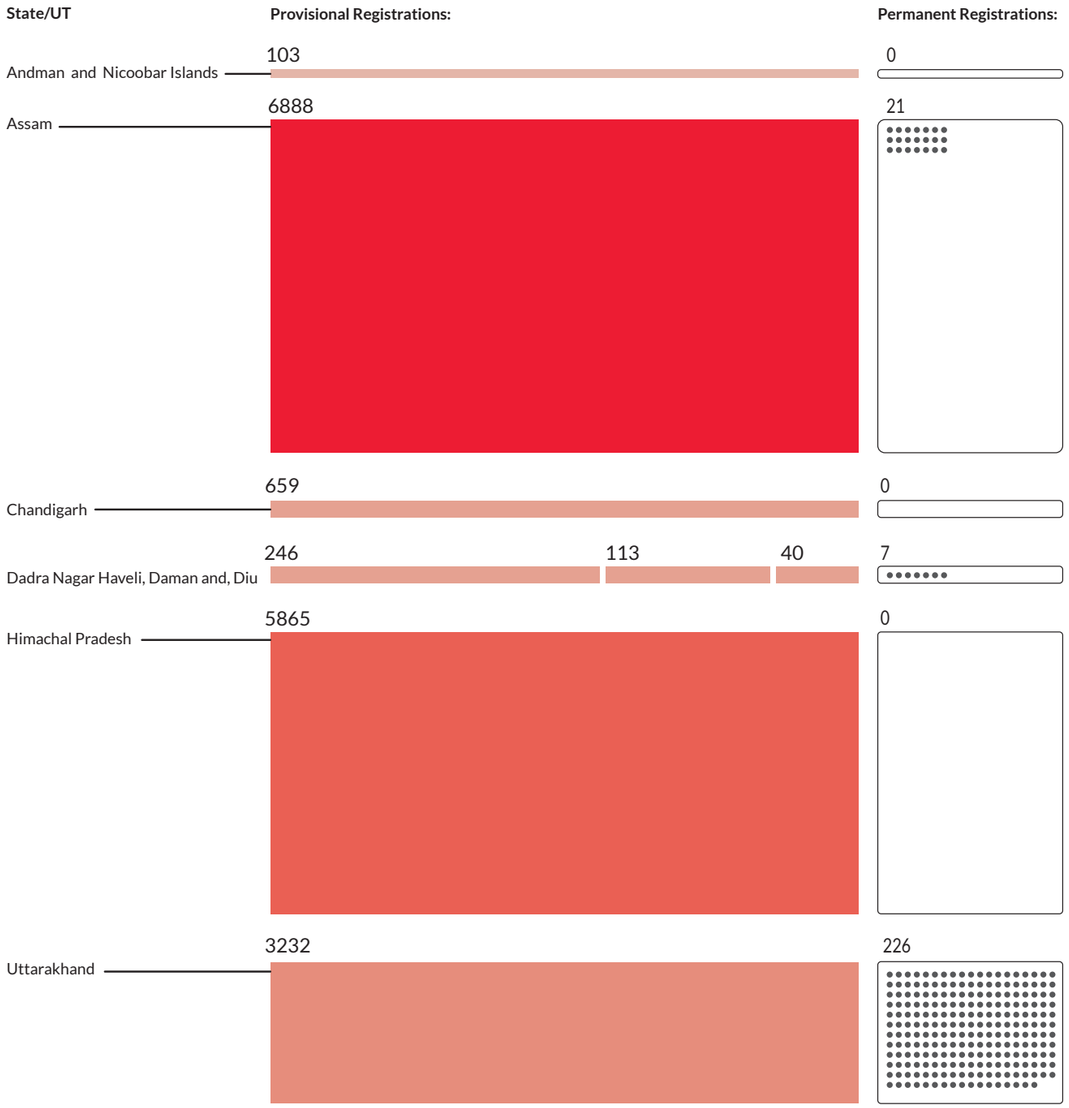
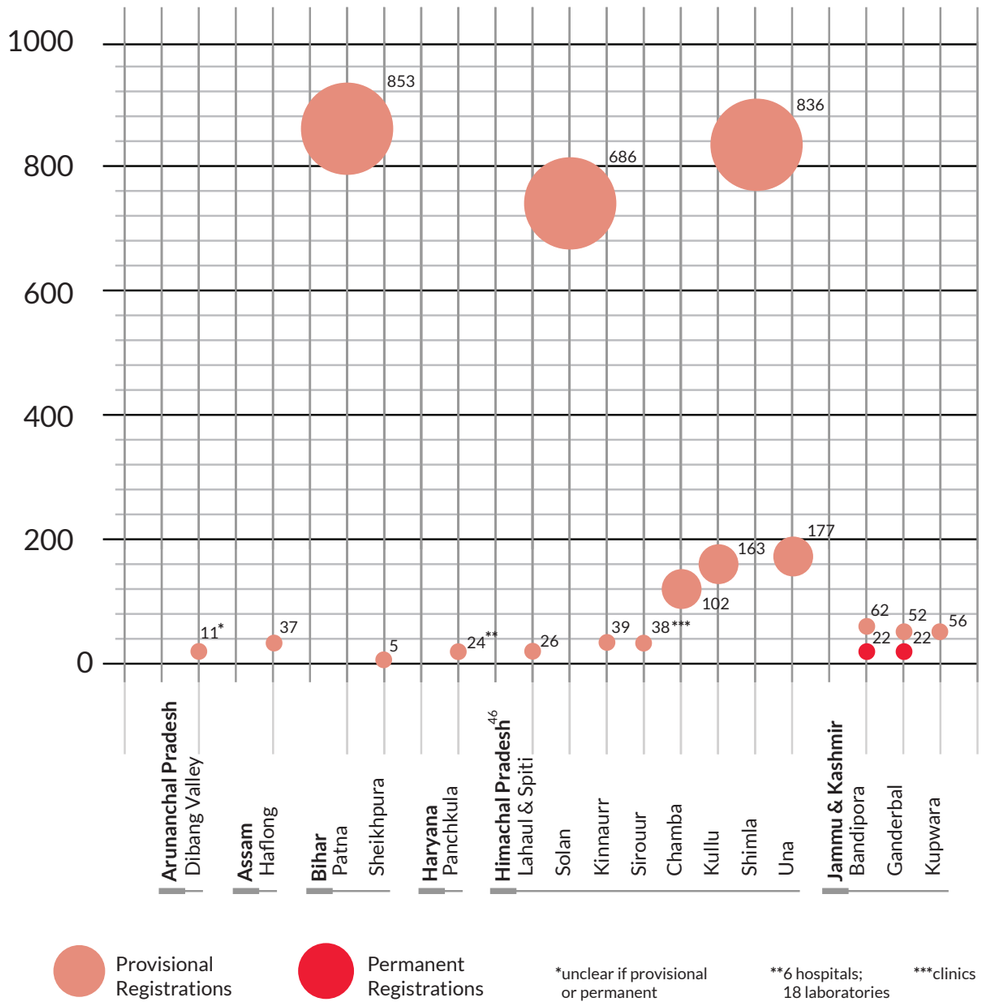
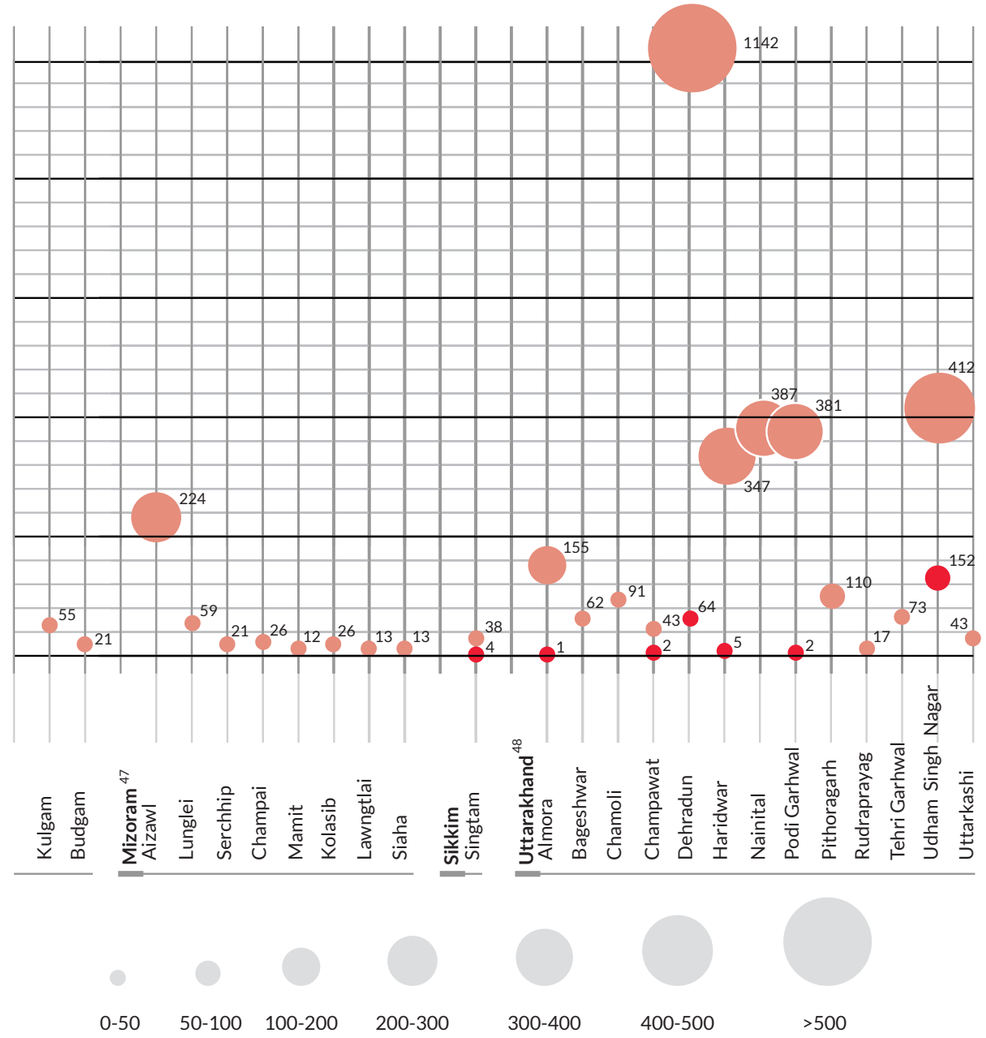


Figure 3.2: District-wise registration of clinical establishments





[46] The sum of these district-wise replies does not equal the state reply in the above table, as not all districts from each state have sent their respective numbers of registrations.

[47] Since we did not receive a reply from Mizoram CEA Council regarding these details, we sourced these district-wise details from their official website. *See* 'Performance and Achievement Report 2022- 2023' (Health and Family Welfare Department, Government of Mizoram) <https://health.mizoram.gov.in/page/mizoram-clinical-establishments-registration-regulsation-act-2014> accessed 18 August 2023.

[48] Information about the state-wise and district-wise numbers for Uttarakhand were provided in the same response.

As we observe from the above tables,

- Permanent registrations have been issued in only three states and two UTs - Assam, Uttarakhand, Sikkim, Dadra Nagar Haveli and Daman and Diu, and Jammu and Kashmir. However, it is unclear which categories of clinical establishments have been granted permanent registration.
- Only one state, one union territory and 11 districts have indicated whether the registered clinical establishments are government or private-owned.

Some states and districts have attempted to monitor registrations

Several authorities have reportedly been facing the issue of ensuring registration and have undertaken numerous measures to either monitor the registration rates or incentivise clinical establishments to register:

- The Assam State Council had resolved in 2016 that awareness campaigns about the CEA 2010 should be taken up at the earliest.[49]
- In Haryana, the State Council resolved that all Civil Surgeons would be tasked with ensuring the registration of all eligible public and private health facilities along with issuance of notices.[50]
- The Srinagar District Registering Authority decided that the approvals of registration for clinical establishments who were yet to complete the formalities would be deemed cancelled after providing them with one opportunity for compliance.[51]
- Uttarakhand State Council permitted urban Community Health Centres to register free of cost.[52] While the CEA 2010 prohibits inquiries before issuing provisional registration,[53] the Council Chairperson directed that all clinical establishments must submit "necessary records" while applying for provisional registration and the Chief Medical Officer or the District Registering Authority must verify these records before issuing provisional registration.

Some authorities have proactively undertaken to survey and identify unregistered establishments. The CEA also seems to have been used as a tool to crack down on unlicensed medical professionals, although these are regulated primarily through state medical council laws:

- The Chandigarh Council for Clinical Establishments resolved that a field survey report may be done for tracking unqualified individuals operating in temporary structures and providing medical services.[54] However, there is no available update regarding this.
- The Jharkhand State Council for Clinical Establishments directed Deputy Commissioners in 2018 to take action against unqualified/bogus medical professionals who were treating patients.

Registration of AYUSH establishments are yet to begin

In addition to clinical establishments within the allopathic system of medicine, AYUSH establishments have also sought registration under CEA 2010. The minutes of meetings held by two State Councils provide the following details:

- The Chandigarh Council for Clinical Establishments discussed the pending registration of 110 Ayurvedic practitioners[55] who had applied to provide allopathic services in addition to Ayurvedic medical services. The Chairperson noted that permission may be taken from the Union Government[56] in writing before rejecting online applications, although the reason for needing such permission is unclear.[57]
- The Haryana State Council noted that no AYUSH facility was registered as of February 2022, possibly due to the criterion of facilities having more than 50 beds to be eligible for registration.[58]

Analysing the slow progress in granting permanent registration

According to the CEA 2010, permanent registrations would effectively commence after the minimum standards for different categories of clinical establishments have been notified. Worryingly, several states are yet to commence permanent registration for any category of clinical establishments, even after over a decade since CEA 2010 was enacted. This is primarily due to the delay on the part of the Central Government in notifying the minimum standards.

A clinical establishment applying for registration (either provisional or permanent) must fulfil the following conditions[59]:

1. the minimum standards of facilities and services;
2. the minimum requirement of personnel;
3. provisions for maintenance of records and reporting;
4. other conditions that may be set by the Central or State Government.

In fact, permanent registration would be granted only when the applicant establishment fulfils the standards for registration as prescribed by the Central Government.[60]

The Central Government has not notified minimum standards for most clinical establishments

The Central Government is responsible for framing the minimum standards for various categories of clinical establishments.[61] In practice, the government would likely be notifying these standards by amending the rules prescribed under CEA 2010.[62]

It is only this year that several subcommittees have been set up by the NCCE to finally draft minimum standards for different categories of clinical establishments.[63] Since the NCCE has recently noted that it is yet to finalise the minimum standards for most categories of establishments,[64] we presume that the standards linked in the official website of the

[49] Assam State Council for Clinical Establishments, *Minutes of the First Meeting of the Assam State Council for Clinical Establishments* (6 December 2016).
[50] Haryana State Council for Clinical Establishments, *Minutes of Meeting* (18 February 2022).
[51] Srinagar District Registering Authority, *Minutes of the Meeting* (8 July 2022).
[52] Uttarakhand State Council for Clinical Establishments, *Minutes of the Meeting* (29 July 2020).
[53] CEA 2010, s 16(1).
[54] Chandigarh State Council for Clinical Establishments, *Minutes of the Meeting* (30 November 2022)
[55] Since this is sourced verbatim from the minutes of the meeting, it is inferred that these refer to single-practitioner establishments.
[56] Neither CEA 2010 nor the Union Territory of Chandigarh Clinical Establishments (Registration and Regulation) Rules, 2013 prescribe any such requirement.
[57] Chandigarh State Council for Clinical Establishments, *Minutes of the Meeting* (30 November 2022).
[58] Haryana State Council for Clinical Establishments, *Minutes of Meeting* (18 February 2022).
[59] CEA 2010, s 12.
[60] CEA 2010, ss 25 and 28.
[61] CEA 2010, s 52(l).
[62] The Clinical Establishments (Central Government) Amendment Rules 2018 and the Clinical Establishments (Central Government) Amendment Rules 2020 added minimum standards for medical diagnostic laboratories or pathological laboratories as Schedules. The draft Clinical Establishments (Central Government) Third Amendment Rules 2019 aimed to add minimum standards for different categories of clinical establishments of Allopathy and AYUSH, though they have not been notified yet.
[63] National Council for Clinical Establishments, *Minutes of 13th Meeting of National Council for Clinical Establishments* (16 March 2023) <http://clinicalestablishments.gov.in/WriteReadData/9631.pdf> accessed 18 August 2023.
[64] ibid.

CEA 2010[65] are simply draft minimum standards.[66] Significantly, the formulation of minimum standards had begun from 2013, when the IMA and the Quality Council of India Report conducted a survey to determine the minimum standards for different categories of clinical establishments.[67]

State replies record further reasons for delays in granting permanent registration

In 2016, the NCCE noted that permanent registrations were yet to start due to "state-level issues", even after all states were issued letters to begin permanent registration.[68] Multiple State Councils confirmed the status quo:

- In Himachal Pradesh, it was noted by two district authorities that permanent registration is not allowed in the online portal and manual registration is "not issued by the authority".
- In Puducherry, only provisional registration was being granted because the guidelines for permanent registration are yet to be published by the Government.
- In Chandigarh, although it was planned that a new website for permanent registration would be made functional by March 2023,[69] no such website appears to have been created till date.
- In Mizoram, although several steps were taken for commencing permanent registration, such as approving the proposal of fees for permanent registration and proposing brief training sessions for clinical establishments, chief medical officers and district representatives in this regard, the process for permanent registration was postponed on 30 January 2020 for unclear reasons.
- States and districts that have begun issuing permanent registrations did not specify in their RTI replies the categories of clinical establishments that are being permanently registered. However, we infer that only medical diagnostic/pathological laboratories have been issued permanent registration because they are the only category of establishments for which minimum standards have been notified.[70]

Additionally, the NCCE reportedly noted in 2014 that states and UTs may modify the minimum standards keeping in view the "ground realities" and that the central minimum standards may be considered as model standards.[71] However, the CEA 2010 does not empower state governments to prescribe the minimum standards necessary for permanent registration. In practice, Mizoram State Council recently sought to modify the minimum standards for certain categories of clinical establishments.[72]

No objections have been filed against applications of permanent registration across states

Under CEA 2010, the public is allowed to object to any of the evidence submitted by the clinical establishment for seeking permanent registration. This is presumably permitted to promote transparency and ensure that clinical establishments are held publicly accountable even before being issued permanent registration. The authority must display all the evidence submitted by the applicant establishment showing compliance with the prescribed minimum standards before their application is processed for the grant of permanent registration.[73] This must be done "as soon as" the clinical establishment submits such evidence, and these details would be displayed[74] for "information of the public at large" and for filing objections as per the prescribed procedure.[75] In case there are any objections filed within thirty days from the display of such evidence, they must be communicated to the clinical establishment for response within 45 days.[76]

In our RTI applications to districts, we requested district registering authorities to provide the number of objections they have received with respect to applications for permanent registration since the enactment of CEA 2010.

- None of the district authorities reported receiving any objections to permanent registrations.
- This situation does not even arise in states/UTs like Himachal Pradesh, Chandigarh and Puducherry where permanent registrations are yet to begin. In fact, as previously noted, only three states and two UTs have commenced permanent registration as per the RTI replies.

Almost no application for permanent registration is being disallowed by registering authorities

Within 30 days of passing an order regarding the application for permanent registration, the authority must either allow or disallow the application.[77] In our RTI applications, we asked districts for the number of applications for permanent registration they have disallowed since the enactment of the Act.

- Only Dehradun, Uttarakhand has disallowed applications for registration - The district registering authority has disallowed 51 applications as of November 2022.
- The other 24 districts have responded 'nil' for this question and did not confirm whether they have even received applications for permanent registration in the first place. As previously noted, only three states and two UTs have commenced permanent registration as per the RTI replies.

[65] Ministry of Health and Family Welfare, 'Minimum Standards' <http://clinicalestablishments.gov.in/En/1070-draft-minimum-standards.aspx> accessed 18 August 2023; Ministry of Health and Family Welfare 'AYUSH' <http://clinicalestablishments.gov.in/En/1075-ayush.aspx> accessed 18 August 2023.
Notably, the cover pages of the documents for all AYUSH systems clearly mention that these are drafts, but there is no such clarification in the documents for allopathic establishments.
[66] Worryingly, the NCCE in its meeting in March 2023 noted that the public comments on the draft 2019 Amendment Rules had been compiled and finalised only this year - *see* National Council for Clinical Establishments, *Minutes of 13th Meeting of National Council for Clinical Establishments* (16 March 2023) <http://clinicalestablishments.gov.in/WriteReadData/9631.pdf> accessed 18 August 2023. The public comments had been invited on 17 July 2019. As previously noted, these 2019 Amendment Rules aimed to notify minimum standards for allopathic and AYUSH establishments.
[67] Government of India-Quality Council of India and Indian Medical Association, *Survey Report & Recommendations of Clinical Establishments* (12 July 2013) <http://clinicalestablishments.gov.in/WriteReadData/788.pdf> accessed 10 September 2023.
[68] National Council for Clinical Establishments, *Minutes of the 9th Meeting of National Council for Clinical Establishments* (19 December 2016) <http://clinicalestablishments.gov.in/WriteReadData/8511.pdf> accessed 18 August 2023.
[69] Chandigarh State Council for Clinical Establishments, *Minutes of the Meeting* (30 November 2022).
[70] Clinical Establishments (Central Government) Amendment Rules 2018; Clinical Establishments (Central Government) Amendment Rules 2020.
[71] National Council for Clinical Establishments, *Minutes of the 6th Meeting of National Council for Clinical Establishments* (8 December 2014) <http://clinicalestablishments.gov.in/WriteReadData/933.pdf> accessed 18 August 2023.

[72] Mizoram State Council decided in 2020 that the minimum standards for hospital levels 1-3 as drafted by the Central Government would be unsuitable for the establishments in the state due to differences in human resources and infrastructure, it proposed to recategorise hospitals for the purpose of prescribing minimum standards. However, the RTI reply notes that deliberations have been postponed, and no further updates were provided. *See* Mizoram State Council for Clinical Establishments, *Meeting Minutes of the 11th Meeting of the State Council for the Clinical Establishment Act, 2010* (26 October 2021).
[73] CEA 2010, s 26.
[74] It is unclear where such details would be displayed. We found no such publicly available information online.
[75] CEA 2010, s 26.
[76] CEA 2010, s 27.
[77] CEA 2010, s 29.

Key Takeaways

Since permanent registration under CEA 2010 necessarily requires compliance with certain minimum standards of infrastructure, services and personnel, it is the primary accountability mechanism for clinical establishments. However, it is gravely concerning that the Central Government has not notified these minimum standards for any category of clinical establishments (except for medical diagnostic laboratories), even after more than a decade since the enactment of the Act.

As we observed, clinical establishments in most states are being issued provisional registration only. However, since there are no compliance requirements for provisional registration and the registering authorities are prohibited from making inquiries at this stage, it is apprehended that currently, registration by itself plays a limited role in holding such establishments accountable.

Amongst those that have replied to our RTI applications, no authority has reported receiving objections to any application for permanent registration. It is also uncertain if the authorities are displaying the details of the applicant establishment for public information and for filing objections.

We also note from the RTI replies that only one district authority has disallowed any application for permanent registration. This could either mean that most clinical establishments applying for permanent registration are either fully compliant with the minimum standards, or that they rectify any deficiencies before being granted permanent registration.

Inspections and Inquiries

External inspections for compliance with the law are undertaken in healthcare to ensure that improvements in the quality of care are prioritised.[78] Sections 33 and 34 of CEA 2010 empower the district registering authority or an officer authorised by it to either direct a multi-member team to conduct inspections in respect of any (provisionally or permanently) registered clinical establishment or cause an inquiry to be made into the establishment. In essence, they enable the authority to exercise oversight over registered clinical establishments.

In this section of the chapter, we provide an overview of the relevant provisions of the CEA 2010 and examine the RTI replies of states, union territories and districts to determine the extent to which they exercise their powers of inspection under the Act. In particular, we examined the number of inspections conducted by authorities across districts.

Inspections and inquiries made by District Registering Authorities are infrequent

In our RTI applications, we requested districts for the number of inspections and inquiries conducted by their respective registering authority since the enactment of the Act.

Table 3.3: District-wise number of inspections and inquiries under Section 33 of CEA 2010 since the enactment of the Act

State	District	Number of inspections and inquiries* (as per RTI replies)
Assam	Dima Hasao	2 inspections/inquiries
	Haflong	2 inspections/inquiries
Bihar	Patna	62 inspections and inquiries
Himachal Pradesh	Lahaul & Spiti	26 inspections
	Kullu	300 inspections
	Sirmour	38 inspections/inquiries
	Shimla	11 inspections/inquiries
	Solan	11 inspections
Mizoram	Siaha	15 inspections/inquiries
	Aizawl	Inspection is done once a year since the introduction of the Mizoram Clinical Establishments (Registration & Regulation) Rules, 2014
Uttarakhand	Dehradun	35 inspections/inquiries
	Rudraprayag	2 inspections/inquiries

* - Some districts clarified whether the numbers provided by them related to inspections and/or inquiries, and others simply responded to our question with a number.

[78] Gerd Flodgren, Daniela C Goncalves-Bradley and Marie-Pascale Pomey, 'External inspection of compliance with standards for improved healthcare outcomes' [2016] CDSR 12 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6464009/> accessed 20 August 2023.

Eleven districts replied 'nil' or 'NA', and we interpret them to mean that on record, no inspections have been conducted.

In focus: Proactive monitoring and inspection of clinical establishments by Srinagar

The minutes of meetings of Srinagar's district registering authority extensively record the inspection procedure that the authority follows:

- It was resolved to prioritise the inspection of all the clinical establishments by a team constituted by the Chief Medical Officer.[79] The team was instructed to follow the prescribed checklist, which would include the functioning of the machines, its quality output, the expertise available and the general facilities earmarked for the patients and attendants at the utility centres. It appears that the inspection team in Srinagar follows a standard procedure for inspection, though it is unclear who prescribed the checklist in question.
- The Chief Medical Officer was directed to periodically check the operation of establishments and action must be taken against any erring clinical establishment for their non-performance or any dereliction of their services.
- The DRA also constituted a committee to conduct a city-wide survey in order to examine the mushrooming of ill-equipped clinical establishments and suggest fixed ceilings on the number of clinical establishments required to be considered for specific locations in the district. The committee was instructed to keep the welfare of patients in mind and submit its report within a month.

Key Takeaways

It is difficult to draw inferences between the numbers of inspections and inquiries within districts as it is unclear if these registering authorities conduct inspections and inquiries periodically or on a case-to-case basis.

Amongst the responding districts, only Aizawl district of Mizoram appears to have a fixed periodicity of inspections. However, it is also to be noted that our RTI applications did not ask for details about how often or on what grounds these inspections and inquiries are conducted.

[78] Srinagar District Registering Authority, Minutes of the Meeting (27 January 2023).

Action against non-compliant clinical establishments

Under CEA 2010, monetary penalties can be imposed on any person for non-registration, disobedience of directions by an authority or for obstructing or refusing to supply information.[80] The Act permits the authority to impose monetary penalties on the defaulting person after taking into account the category, size and type of the clinical establishment and the local conditions of the concerned area.[81] The following table sets out the provisions of the Act regarding the monetary penalties that can be imposed:

Table 3.4: Monetary penalties prescribed under CEA 2010

Provision	Contravention	Fine/ Penalty	Amount		
			First contravention	Second contravention	Subsequent contraventions
Section 41(1)	Operating an unregistered clinical establishment	Monetary penalty	Up to 50000 INR	Up to 2 lakhs INR	Up to 5 lakhs INR
Section 41(2)	Serving in an unregistered clinical establishment	Monetary penalty	Up to 25000 INR		
Section 42(1)	Wilful disobedience of directions or obstructing any person or authority in the discharge of their functions	Monetary penalty	Up to 5 lakhs INR		
Section 42(2)	Wilful withholding of information or knowingly providing false information	Monetary penalty	Up to 5 lakhs INR		
Section 43	Minor deficiencies that do not pose any imminent danger to the health and safety of any patient and can be rectified within a reasonable time	Fine	Up to 10000 INR		
Section 40	Contraventions for which penalty not separately prescribed	Fine	Up to 10000 INR	Up to 50000 INR	Up to 500000 INR

[80] CEA 2010, ss 40-42.
[81] CEA 2010, ss 41(5) and 42(5).

The aggrieved person may then appeal to the State Council within three months of the decision of the authority.[82] The CEA 2010 does not prescribe imprisonment for any contravention. It had been suggested in a 2017 NCCE meeting that punitive actions against unregistered clinical establishments should be put on pause as the dissemination of information to stakeholders regarding CEA 2010 is incomplete.[83]

We notice two major measures that authorities take against clinical establishments that contravene CEA 2010 - (1) fines; and (2) cancellation of registration.

Fines are rarely imposed by the district authorities

In our RTI applications, we asked the district authorities for details regarding the number and dates of cases adjudicated under sections 40-45 of the Act, as well as the number of cases where fines had been imposed since the enactment of the CEA 2010.

- Three districts have responded with some details about cases that have been adjudicated and fines that have been imposed.
  a. In Una, Himachal Pradesh, three cases have been adjudicated, and they each took 11 days, one day and five days respectively. However, we have no information about the grounds on which the cases were initiated, so we cannot determine whether these cases were adjudicated within a reasonable period.
  b. In Patna, Bihar, the authorities imposed fines in one case. However, no further details were provided.
  c. In Dehradun, Uttarakhand, there have been nine cases against clinical establishments, and all of them have been directed to pay fines. However, no details were provided about how long it took to decide these cases.
- Interestingly, the District Registration/Chief Medical Officer of Rudraprayag, Uttarakhand directed 17 establishments to pay late fees as a penalty because they failed to apply for the renewal of their provisional registration on time. These late fees ranged from INR 46900 to 80500. One centre was ordered to pay double the amount of the registration fee along with late fees of Rs 100 per day, but the registration fee amount was not provided.
- The Chandigarh Council for Clinical Establishments imposed a penalty on one single-doctor clinical establishment in 2018 for non-registration under Section 11 of the 2010 Act.
- Twenty districts have replied 'nil' or 'NA', and we interpret them to mean that on record, the authorities from these districts have not imposed any fines.

Registrations of clinical establishments are rarely cancelled

In order to hold non-compliant clinical establishments accountable, the district registering authority may issue a show cause notice and cancel the registration of the establishment if the conditions of registration are being violated or if the person managing the clinical establishment has been convicted under the CEA 2010 itself.[84]

We had requested district registering authorities through RTI applications to provide the number of instances where they cancelled the registration of a clinical establishment since the enactment of CEA 2010.

- Dehradun, Uttarakhand reported that no clinical establishment has had its registration cancelled.
- Only Patna, Bihar has reported that registrations have been cancelled. In Patna, one registration was cancelled under Section 32(1)(a) for non-compliance with registration requirements, and another was due to the carelessness of the person responsible for the management of the establishment as per Section 32(i)(b) of CEA 2010.
- 23 districts have replied 'nil' or 'NA', and we interpret them to mean that these districts have not cancelled the registration of any clinical establishment.

Notices issued

As mentioned above, the authority may issue a notice to a registered clinical establishment to show cause why its registration should not be cancelled in the event of the two above mentioned circumstances.[85] The clinical establishment has to show cause within three months of the notice, and the notice must mention the reasons for which registration may be cancelled.

We requested district registering authorities for the number of notices they have issued to clinical establishments under Section 32 of CEA 2010 since the enactment of the Act.

- Only two districts have issued such notices to establishments. Patna district of Bihar issued one notice, and Siaha district of Mizoram has issued five notices.
- 22 districts have replied 'nil' or 'NA', and we interpret them to mean that these districts have not issued show-cause notices to any clinical establishment.

It had also been proposed that clinical establishments should be given notice of a few months if they have failed to apply for renewal of their registration on time.[86]

Restraining the clinical establishment

After cancelling the registration and recording the reasons, the authority may restrain the clinical establishment immediately from carrying on if there is imminent danger to the health and safety of patients.[87]

In our RTI applications to district registering authorities, we asked for the number of instances where they have restrained a clinical establishment from operating under Section 32(2).

- The district registering authority of Dehradun district of Uttarakhand has restrained 18 clinical establishments under this provision, but it did not specify why it was necessary to restrain the establishments. It is the only district within the RTI replies which has reported restraining establishments.
- 24 districts have replied 'nil' or 'NA', and we interpret them to mean that these districts have not restrained any clinical establishment from operating.

[82] CEA 2010, ss 41(6) and 42(6).
[83] National Council for Clinical Establishments, *Minutes of 10th Meeting of National Council for Clinical Establishments* (8 September 2017) <http://clinicalestablishments.gov.in/WriteReadData/5061.pdf> accessed 18 August 2023.
[84] CEA 2010, s 32.
[85] CEA 2010, s 32(1).
[86] *National Council for Clinical Establishments, Minutes of 10th Meeting of National Council for Clinical Establishments* (8 September 2017) <http://clinicalestablishments.gov.in/WriteReadData/5061.pdf> accessed 18 August 2023.
[87] CEA 2010, s 32(2).

Interestingly, however, even though the CEA 2010 empowers the registering authorities to restrain the clinical establishments after cancelling the licenses, it has been recently reported that the government itself is cancelling licenses of establishments and ordering their immediate shutdown as well.[88] The source of their legal authority to cancel hospital licenses and order immediate shutdown of the establishment is unclear.

Key Takeaway

Only 5 out of 24 districts appear to have adjudicated cases against clinical establishments for contravening provisions of the CEA 2010. Though this does not include all the district registering authorities across the country, it is a snapshot of how few clinical establishments are being held accountable by the authorities. While the more generous interpretation of this would be that clinical establishments are largely compliant, it is also likely that they are not being monitored properly to identify non-compliance.

[88] See 'Licence of private hospital in UP suspended after 2.5-year-old 'circumcised'' (*The New Indian Express* 27 June 2023) <https://indianexpress.com/article/cities/lucknow/licence-of-private-hospital-in-up-suspended-after-2-5-year-old-circumcised-8688002/> accessed 20 August 2023.

Appeals against orders of authorities

The CEA 2010 affords every clinical establishment an opportunity to appeal the decision of the registering authority refusing to grant or renew a certificate of registration or revoking a certificate of registration.[89] This appeal lies before the State Council. An appeal before the State Council also lies against the decision of the authority to impose monetary penalty in cases of:

- non-registration,[90]
- disobedience of directions, obstruction in performance of functions of the authority or refusing to share information with authorities,[91] or
- withholding of information which is required to be shared under the Act.[92]

The Act does not prescribe the time period, format or fees for filing the appeals, but delegates these to the rules.[93] However, no rules to this effect have been introduced yet.

We requested the State Councils through RTI applications to share the number of appeals that (i) have been filed; (ii) are pending, and; (iii) have been disposed of by them since the enactment of CEA 2010.

- Assam, Chandigarh and Uttarakhand Councils have reported zero appeals having been filed.
- Himachal Pradesh and Puducherry Councils have reported receiving one and two appeals respectively, and they have all been disposed of. We have no further information about the substance and timeline of the appeals adjudicated.
- Rajasthan noted that no complaints have been been filed at the district level.
- Six states and UTs replied 'nil', and we interpret them to mean that no appeals have been filed with these authorities.

Key takeaway

The appellate mechanism under the CEA 2010 is underdeveloped and underutilised. Given that the Act came into force in 2012, it is a matter of concern that even after more than a decade, the rules relating to the appellate procedure have not been prescribed.

[89] CEA 2010, s 36.
[90] CEA 2010, s 41.
[91] CEA 2010, s 42.
[92] ibid.
[93] CEA 2010, s 54.

Grievance redressal under the CEA 2010

The CEA 2010 does not provide for a grievance redressal mechanism for patients or members of the public to file a complaint or raise a grievance against a registered clinical establishment. Thus, the states which have adopted the CEA 2010 do not have any institutional mechanisms to receive complaints against clinical establishments.

The Charter of Patient Rights approved by the NCCE does provide patients the right to be heard and seek redressal. It states that every hospital shall establish a time bound grievance redressal mechanism to address the grievances of patients. The hospital shall identify a grievance redressal officer, whose name and contact details will be displayed in an accessible manner. The hospital also has to maintain records of grievances received and remedial action taken. Additionally, the name and contact details of the district registering authority, who may be contacted in case of non-redressal of the grievance of patients to their satisfaction, should be displayed.

However, as the Charter of Patient Rights has not been made enforceable at the state/UT level, these grievance mechanisms are not necessarily available in all clinical establishments and in all states. It also appears that the NCCE's direction to incorporate the Charter of Patient Rights is viewed as a recommendation, as only some states/UTs are taking steps to operationalise the NCCE's direction. For instance, in a 2022 meeting of the Chandigarh Council for Clinical Establishments, it was decided that each private hospital/nursing home would be directed to provide for a grievance redressal nodal officer as per the additional charter of patient rights. In July 2018, the Jharkhand Council for Clinical Establishments discussed that in order to strengthen the implementation of the CEA 2010, a grievance redressal system should be in place, where complaints must be received through a centre and forwarded to appropriate authorities for follow up action.

In some instances, the general public reaches out to the State Medical Councils (**"SMC"**) to raise complaints against clinical establishments. Since the SMCs do not have the jurisdiction to take actions against clinical establishments, they either forward the complaint to the Directorate of Health Services, or the State Council of Clinical Establishments or sometimes discard the complaint altogether. At the same time, we have noted that SMCs adjudicate such cases against healthcare facilities themselves. For instance, between 2002 and 2022, the Uttarakhand SMC issued warnings to the proprietors of clinical establishments in two instances and directed the Chief Medical Officer to cancel the registration of one hospital, and the Karnataka SMC issued warnings and directions for compliance to healthcare facilities in seven instances between 2015 and 2023. These are all, however, makeshift approaches towards grievance redressal.

Key Takeaway

At present, the CEA 2010 has no provision for grievance redressal, and notwithstanding the measures taken by Chandigarh and Jharkhand, no state or UT has proactively established an institutional grievance redressal system for the benefit of the patients. It is essential that legislation and authorities actively provide for grievance redressal mechanisms for those aggrieved.

[94] Chandigarh State Council for Clinical Establishments, *Minutes of the Meeting* (26 May 2022).
[95] Jharkhand State Council for Clinical Establishments, *Minutes of the Meeting* (25 July 2018).
[96] Reference to our SMC report.

Separate State Legislation

Separate State Legislation

There are seventeen states/UTs that have not adopted the CEA 2010, but have enacted separate laws to govern the functioning of healthcare facilities within their territories.[97] Though these state laws have common functions, such as licensing facilities and ensuring minimum standards, they are structured in different ways. Gaps in these laws, as well as poor implementation, were the impetus for the enactment of the CEA 2010.

In this chapter, we adopt similar themes from the previous chapter on the CEA 2010 and map the diverse provisions of these separate state laws to understand their key features. We also filed applications under the RTI Act with tailored questions to examine the implementation of each Act. The replies are presented accordingly.

Which kinds of facilities are regulated?

The CEA 2010 regulates most healthcare facilities from government establishments to single-doctor clinics.[98] In doing so, it creates a regulatory scheme focused on maintaining certain "minimum" standards at all establishments, instead of merely subjecting private hospitals to state control. This is not true of most separate state laws. Eleven out of the seventeen state laws we examined do not regulate establishments run by the government,[99] whereas six laws do.

The six laws which do regulate government establishments are those of Punjab, Kerala, Tripura, Tamil Nadu, Goa, and Gujarat.[100] These laws are generally modelled on the CEA 2010, with the exception of Tamil Nadu, which amended its Act in 2018 to adopt a definition of "clinical establishment" that included government establishments.[101]

We may speculate that states are more amenable to stricter regulation, and patient-centric mechanisms (charter of patient rights, grievance redressal etc) when the state's own establishments are not subject to them.[102] This certainly appears to be the case with West Bengal, which has one of the most extensive and progressive statutes, but does not include government establishments within its ambit. This is also true of Andhra Pradesh and Karnataka, which indicate that they regulate "private establishments" but are some of the most patient-focused and rights-focused HFR laws in the country.

The separate state laws differ in terms of the definitions adopted and their resulting scope. For instance, Delhi, Maharashtra and Meghalaya, all govern only 'nursing homes'. However, only Meghalaya expressly covers general hospitals and dispensaries within its definition of the term. Similarly, even though both Madhya Pradesh and Chhattisgarh use the similar nomenclature of 'clinical establishment', only the latter expressly includes 'hospitals' within its ambit. Variations like these are unlikely to be practically significant, as long as the principal intent to regulate facilities which provide patient care is present. The principal differences in scope are in whether they govern government facilities, diagnostic laboratories, and other types of facilities that are not private hospitals but which provide inpatient care.

What authorities exist at the state level?

The regulatory structure across the separate state laws can broadly fall into three categories based on the design of the state level regulatory body.

States having a State Council for Clinical Establishments

Followed by: **Kerala, Gujarat, Tripura, Punjab, Goa**

Five of the most recent state laws establish State Councils for Clinical Establishments in a manner similar to the one prescribed by the CEA 2010. The chairperson is usually a senior official in the Department of Health, with Gujarat being the sole exception. In Gujarat, the Minister for Health and Family Welfare is the chairperson. Each of these state Acts have members who are not ex-officio, as well as representation from bodies like the state medical council. No State Council has representation from the Quality Council of India or the National Accreditation Board for Hospitals & Healthcare Providers, even though these councils set minimum standards and the expertise provided by these bodies could be useful.

[97] Due to the unique status of the National Capital Territory of Delhi in India's constitutional structure, it has a legislative assembly despite being a union territory. Solely for the purposes of the report, we refer to Delhi as having a "state law".
[98] CEA 2010, s 2(c).
[99] Maharashtra Nursing Homes Registration Act 1949, s 18(i); Delhi Nursing Homes Registration Act 1953, s 17(i); Madhya Pradesh Upcharyagriha Tatha Ragopchar Sambandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973, s 2(e)(i); Orissa Clinical Establishment (Control and Regulation) Act 1990, s 1(4)(a); Manipur Homes and Clinics Registration Act 1992, s 17(1); Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 1(4); Nagaland Health Care Establishments Act 1997, s 1(iv); Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 2(k); Karnataka Private Medical Establishments Act 2007, s 2(n); Chhattisgarh State Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Adhiniyam 2010, s 19(a) [Uses the language "is deemed to be licensed" as opposed to "shall not apply to"]; West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, s 1(4)(a).
[100] Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 2(a); Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 2(c); Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 2(a)(ii); Goa Clinical Establishments (Registration and Regulation) Act 2019, s 2(c); Gujarat Clinical Establishments (Registration and Regulation) Act 2021, s 2(c); Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 2(a). In general here, Tamil Nadu is a special case, as it enacted its legislation in 1997 but did not bring it into force until well after the CEA was enacted. *See* 'Chennai: HC court pulls up government on Clinical Establishment Act' (*Medical Dialogues*, 15 September 2016) <http://www.clinicalestablishments.gov.in/WriteReadData/9141.pdf> accessed 7 October 2023.
[101] Tamil Nadu Private Clinical Establishments (Regulation) Amendment Act, 2018, s 5 (amending s 2(a) of the principal Act).
[102] In Maharashtra, the private sector resisted regulation on the grounds that government facilities were so poorly run that the government should improve them before performing an oversight role. See Indira Chakravarthi and Benjamin M Hunter (eds), *Regulation of Formal Private Healthcare Providers in Maharashtra: Journey of Bombay Nursing Homes Registration Act and the Clinical Establishments Act* (SATHI 2019).

Furthermore, there are minor variations in the prescribed composition of the state councils:

- Goa alone prescribes representation from a **medical research institution** like the ICMR
- Tripura alone has representation from **local bodies**
- Goa alone has representation from **private sector interests**, like a chamber of commerce
- Punjab alone has representation from **consumer groups**
- Kerala alone has representation from **patient groups** and from **independent experts**

States having other state-level authorities

Followed by: **Meghalaya, Nagaland, Tamil Nadu, Andhra Pradesh, West Bengal**

Five states set up state level authorities which are distinct from the State Councils as envisaged under the CEA 2010. The Meghalaya Act, for instance, constitutes the Meghalaya Nursing Homes Licensing and Registering Authority. Its members include the Director of Health Services as the Chairperson, a medical and an environmental expert, and representatives of the urban development authority as some of the members.[103] This Authority receives applications[104] for grant of licences or for registration of nursing homes and instead of having different registering authorities at the district level, includes the Chief Executive Member of the Autonomous District Councils or their representative as members.

In Nagaland also the licensing and registering authority under the Act is the Nagaland Health Care Establishment Authority, which is a nine-member body and which includes a private practitioner.[105]

The Tamil Nadu Act only sets up a State Level Advisory Committee comprising members of the executive as well as the medical industry.[106] The function of this Committee is simply to advise the Government on matters related to the regulation of clinical establishments. Similarly, the Andhra Pradesh Act, as amended in 2006, provides for setting up of Registering Authorities in the state for different areas and these authorities are to be assisted by State and District Level advisory committees.[107]

The West Bengal Act permits the State Government to designate the Director of Health Services or any officer subordinate to him as the State Registrar for Clinical Establishments.[108]

States without a state-level authority

Followed by: **Maharashtra, Delhi, Madhya Pradesh, Odisha, Manipur, Karnataka, Chhattisgarh**

All seven of the state laws introduced before 1993, and the laws of Chhattisgarh and Karnataka do not establish a state level authority. Instead, all the functions under the Act are performed by the district level authority and the State Government directly.

[103] Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 4.
[104] Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 7.
[105] Nagaland Health Care Establishments Act 1997, s 4(i).
[106] Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 2-A.
[107] Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, ss 4 and 5A.
[108] West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, s 4.

Who licences healthcare facilities?

Establishment of registering authorities

The registration authority in nine states comprises multiple members of varying qualifications,[109] whereas in eight states, the registration authority may be an individual as well.[110] Amongst the latter eight states, only Odisha, Maharashtra and West Bengal prescribe that the appointed individual have a specific designation. In Tamil Nadu, while the registering authority can be an individual officer, they are assisted by a district committee.[111]

Most registering authorities are constituted at the district level

Meghalaya,[112] Nagaland[113] and Punjab[114] are the only states where a state level registration authority is constituted; most of the independent State Acts establish district registration authorities or more local authorities. Additionally, Punjab is the only state where both State and District Registering Authorities are constituted.[115] In Maharashtra, local supervising authorities can be below the district level.

Most registering authorities have a similar composition

Most State Acts prescribe a similar composition of registering authorities - they comprise government officials, the District Medical Officer or Health Officer, and a variety of members nominated by either the State Government or the District Collector. Some states have particularly distinctive members:

- The Registration and Grievance Redressal Authority of Karnataka must comprise a woman representative when the authority is "dealing with a grievance redressal."[116]
- The registering authorities in Nagaland and Kerala contain one healthcare practitioner as a member.[117]
- Meghalaya's Licensing and Registering Authority includes a representative from the State Urban Development Authority and an environmental expert appointed by the State Government.[118]

[109] Gujarat Clinical Establishments (Registration and Regulation) Act 2021, s 5; Goa Clinical Establishments (Registration and Regulation) Act 2019, s 7; Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 4; Karnataka Private Medical Establishments Act 2007, s 4; Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 14; Nagaland Health Care Establishments Act 1997, s 4; Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 4; Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 5; Punjab Clinical Establishments (Registration and Regulation) Act 2020, ss 7 and 9.
[110] West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, s 5; Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 2(a); Madhya Pradesh Upcharyagriha Tatha Rajopchar Sambandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973, s 2(k); Manipur Homes and Clinics Registration Act 1992, s 2(xii); Maharashtra Nursing Homes Registration Act 1949, s 2(2); Orissa Clinical Establishment (Control and Regulation) Act 1990, s 2(n); Delhi Nursing Homes Registration Act 1953, s 2(x); Chhattisgarh State Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Adhiniyam 2010, s 2(o).
[111] Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 2-F.
[112] Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 5(1).
[113] Nagaland Health Care Establishments Act 1997, s 5(1).
[114] Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 7.
[115] Punjab Clinical Establishments (Registration and Regulation) Act 2020, ss 7 and 9. The State Authority is empowered to grant registration to clinical establishments with 100 or more beds. The District Authority can grant registration to clinical establishments with less than 100 beds.
[116] Karnataka Private Medical Establishments Act 2007, s 4.
[117] Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 14; Nagaland Health Care Establishments Act 1997, s 4.
[118] Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 4.

The work by registering authorities is reviewed in only one state

Andhra Pradesh has State and District Advisory Committees to review the progress made by the district registering authorities.[119] No other independent State Act provides for a mechanism or authority to review the progress made by registering authorities.

What happens before a facility is registered?

Most of the separate state laws prescribe minimum standards for registration

Before being granted a certificate of registration, a facility is required to comply with certain terms and conditions prescribed by the governing Act or the respective Rules.[120] These terms and conditions include maintaining personnel of certain qualifications at all times; displaying rates in conspicuous places, furnishing the required information to the State Government or the State Council of Clinical Establishments, etc. A review of the legislation shows that 11 independent state Acts prescribe the categories of terms and conditions to be specified in the Rules,[121] and six state Acts leave the framing of terms and conditions entirely to the Rules.[122]

Such terms and conditions may include certain quantifiable minimum standards for infrastructure, services and personnel as well. Amongst the 17 separate state laws, 14 provide such minimum standards in their Acts or Rules.[123] Notably, no state Act accounts for the process of determining these terms and conditions for registration, with the exception of Kerala and Karnataka. The Kerala Act mandates that a consultative and transparent process, including public hearing, needs to be followed for altering the mandatory standards and classification of clinical establishments.[124] The Karnataka Act requires the state government to notify the minimum standards after receiving recommendations from an expert committee and considering any objections received from persons likely to be affected.[125]

[119] Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 5B.
[120] Provisional registration is an exception to this.
[121] Gujarat Clinical Establishments (Registration and Regulation) Act 2021, s 7; Goa Clinical Establishments (Registration and Regulation) Act 2019, s 9; Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010, s 7; Karnataka Private Medical Establishments Act 2007, s 6; Madhya Pradesh Upcharyagriha Tatha Ragopchar Samabandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973, s 4(5); Nagaland Health Care Establishments Act 1997, s 8; Orissa Clinical Establishments (Control and Regulation) Act 1991, s 5; Maharashtra Nursing Homes Registration Act 1949, s 5; Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 11; West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, s 7; Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 21.
[122] Andhra Pradesh, Delhi, Manipur, Kerala, Meghalaya, and Tamil Nadu.
[123] Gujarat, Kerala and Manipur do not provide such minimum standards. Section 20 of the Gujarat Clinical Establishments (Registration and Regulation) Act 2021 provides for the framing of minimum standards, but the Gujarat Clinical Establishments (Registration and Regulation) Rules 2022 do not enumerate any such standards. The Kerala Clinical Establishments (Registration and Regulation) Rules 2018 provide that the conditions for issuing registration would be notified by the government or the State Council of Clinical Establishments instead, and these minimum standards have been notified in 2023. We were unable to find any rules made under Manipur's Act.
[124] Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 7.
[125] Karnataka Private Medical Establishments Act 2007, s 9A(2).

Pre-registration inspection of documents

All state laws prior to the enactment of CEA 2010 provide only for one type of registration. State Acts that have been enacted after the CEA 2010 provide for both provisional and permanent registration, with the exception of West Bengal.

A notable difference between provisional and permanent registration has been that the registering authority is either expressly or implicitly prohibited from conducting any inquiry before issuing provisional registration.[126] However, for all State Acts prior to the CEA 2010, the registering authority is empowered to conduct inquiries before granting a certificate of registration.[127] Extensive records from Meghalaya and Nagaland, enclosed with their RTI replies, indicate that their pre-registration inspections are structured and comprehensive. For this reason, we undertook to examine their inspection strategies in particular.

Meghalaya's Nursing Home Licensing and Registering Authority and Nagaland's Licensing and Registering Authority conduct several documentary inspections before issuing registration. Such documents relate to

- the available personnel (such as specialists),
- infrastructure for the offered services (medical equipment and other requirements such as fire safety equipment and biomedical waste management), and
- the requisite clearances (such as no-objection certificate from the district council and the pollution control board).

Nagaland also forwarded an institution-specific inspection report template which contains fields for

- the types of services offered,
- the infrastructure details such as the number
- of beds,
- the necessary documentation like licences,
- the necessary elements of the quality management system, such as accreditations and whether it follows any internal and external quality control standards for the diagnostic services,
- the availability of facilities such as the display of service rates, the necessary equipment and facilities in specific departments such as the emergency and outpatient departments,
- the availability of certain drugs, etc.

[126] Gujarat Clinical Establishments (Registration and Regulation) Act 2021, s 11(1); Goa Clinical Establishments (Registration and Regulation) Act 2019, s 13(1); Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 12; Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 17(3); Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 15(1). While Kerala mandates that provisional registration would be deemed to have been granted if the application is not expressly granted or declined within 45 days, the registering officer would face disciplinary action if it is found that the provisional registration was not granted in accordance with law within such 45 days. See Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 17(4).
[127] Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010, s 6; Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 7; Delhi Nursing Homes Registration Act 1953, s 5; Karnataka Private Medical Establishments Act 2007, s 6; Nagaland Health Care Establishments Act 1997, s 8(ii); Orissa Clinical Establishments (Control and Regulation) Act 1991, s 5; Maharashtra Nursing Homes Registration Act 1949, s 5(1); Manipur Nursing Home and Clinics Registration Act 1992, s 5; Madhya Pradesh Upcharyagriha Tatha Ragopchar Samabandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973, s 4(4); Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 4; Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 11.

The report also requires listing of the available personnel with their qualification and registration details along with their performance indicators for that year (such as the numbers of OPD, casualties, deliveries, surgeries, and diagnostic tests). In case of any non-compliance, the Meghalaya authority usually issues a show cause notice or directs the applicant to give an undertaking. In one instance, an eye care centre was found to have been functioning without seeking registration in addition to other infrastructural deficiencies, and the authority resolved to send a show cause notice and then conduct a second inspection after the centre provided a compliance report. Some clinics and nursing homes were directed to give undertakings that they are not engaging any government doctors, nurses, paramedical personnel. The authority also issues registration subject to the production of certain licences.

How are records of registration maintained?

Maintaining a record of the registered clinical establishments is one of the primary responsibilities of a registering authority. However, four independent State Acts do not provide for the maintenance of a register of registered establishments.[128] Amongst the states that prescribe the maintenance of a register of clinical establishments,

- 5 state Acts provide for maintenance of both State and District Registers of clinical establishments.[129]
- 2 state Acts provide for maintenance of only a State Register of establishments.[130]
- 5 state Acts provide for only District Registers of establishments.[131]
- Meghalaya Rules mandate the publication of the list of registered establishments in the Official Gazette and the newspapers, but does not provide for the maintenance of a register.[132]

Additionally, we received substantive and clear responses from authorities in Goa and Tripura, who confirmed that they maintain a register. Punjab stated that they had not begun the registration process under their Act. Gujarat stated that the information was not available. Odisha rejected our application, claiming every exemption under the RTI Act.

[128] Karnataka, Nagaland, Manipur, Andhra Pradesh.
[129] Punjab Clinical Establishments (Registration and Regulation) Act 2020; West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017; Tripura Clinical Establishment (Registration and Regulation) Act 2018; Goa Clinical Establishments (Registration and Regulation) Act 2019; Gujarat Clinical Establishments (Registration and Regulation) Act 2021.
[130] Tamil Nadu Private Clinical Establishments (Regulation) Act 1997; Kerala Clinical Establishments (Registration and Regulation) Act 2018;
[131] Madhya Pradesh Upcharyagriha Tatha Ragopchar Sambandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973; Maharashtra Nursing Homes Registration Act 1949; Orissa Clinical Establishments (Control and Regulation) Act 1991; Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010; Delhi Nursing Homes Registration Act 1953.
[132] Meghalaya Nursing Home (Licensing and Registration) Rules 2015, r 9(5).

Are facilities regularly inspected?

Similar to the CEA 2010, every separate state law empowers authorities to enter and inspect the premises of a registered/licensed establishment to monitor compliance with the law.

In particular, we examine the following in this section:

1. Are the inspecting authorities established on a district-level or a state-level?
2. What is the composition of these authorities?
3. How many inspections have been carried out?
4. Are inspecting authorities allowed to inspect suo moto?
5. Can the inspecting authorities inspect the facility without prior notice?
6. Do the state laws mandate the publication of inspection reports?

Not all separate state laws establish district-level authorities

Inspecting authorities are expected to visit the premises of any clinical establishment and make observations on several aspects, such as the infrastructure, the staffing for different services, documents, etc. We expected that most independent state Acts would have prescribed the establishment of inspecting authorities on a district level so that they may inspect the establishments regularly and in a more resource-efficient manner. However, a review of the state laws reveals that

- Six state Acts constitute the inspecting authority on a state level,[133]
- Seven state Acts constitute the authority on a district level,[134] and
- Three state Acts permit the establishment of inspecting authorities on either the district or the state level or both.[135]

Most inspection authorities need not have multiple members

In light of the burden of physically inspecting different types of establishments and confirming their infrastructural and documentary compliance with the law, we expected that most of the independent state Acts would prescribe a multi-member inspection authority comprising members with different qualifications. On the contrary, we found from the state laws that

- Only five state Acts prescribe a multi-member authority for all inspections,[136]
- Five state Acts enable the inspecting authority to be an individual officer,[137]
- Seven state Acts provide for the establishments to be inspected by either a multi-member team or by an individual.[138]

[133] Tripura, Madhya Pradesh, Nagaland, Odisha, Meghalaya, Manipur
[134] Gujarat, Goa, Karnataka, Maharashtra, Tamil Nadu, West Bengal, Andhra Pradesh
[135] Chattisgarh, Kerala, Punjab.
[136] Punjab Clinical Establishments (Registration and Regulation) Act 2020, ss 30 and 33; Nagaland Health Care Establishments Act 1997, s 11; Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 13; Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 19(12); Kerala Clinical Establishments (Registration and Regulation) Rules 2018, r 26; Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 8.
[137] Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 18; Orissa Clinical Establishments (Control and Regulation) Act 1991, s 11; Maharashtra Nursing Homes Registration Act 1949, s 9; Madhya Pradesh Upcharyagriha Tatha Ragopchar Samabandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973, s 7; Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010, s 11.
[138] Karnataka Private Medical Establishments Act 2007, ss 7 and 21; Karnataka Private Medical Establishments (Amendment) Rules 2018, rule 7D; West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, ss 22 and 24; West Bengal Clinical Establishments (Registration, Regulation and Transparency) Rules 2017, rule 36(5); Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 6; Tamil Nadu Clinical Establishments (Regulation) Rules 2018, rule 5; Manipur Homes and Clinics Registration Act 1992, s 10; Delhi Nursing Homes Registration Act 1953, s 9; Goa Clinical Establishments (Registration and Regulation) Act 2019, ss 30 and 31; Gujarat Clinical Establishments (Registration and Regulation) Act 2021, ss 28 and 29.

Number of inspections - A Snapshot

In our RTI applications, we asked authorities about the number of inspections their respective authorities have conducted from 2012 till 2022. The responses are listed in the table below.

Table 4.1: Number of inspections of healthcare facilities conducted in different districts as per the RTI replies received

State	District (If the RTI reply is specific to a district)	Details of the replies
Chhattisgarh[139]	-	962 inspections wherein 935 establishments were sealed for being non-compliant with the Act. These included Ayurveda, Unani, Homoeopathy and illegally operating clinics. Under Section 11, the Nodal Officer from the Office of Chief Medical and Health Officer of Raipur responded that no information regarding this is available.
Delhi	-	More than 700 inspections have been conducted in the last two years
Goa	North Goa	Nil
	South Goa	Nil
Karnataka[140]	Bengaluru Urban	80 inspections/inquiries
	Kodagu	206 inspections
Maharashtra[141]	Latur City	236 inspections by the Municipal Corporation Health Department
	Amravati	• 2 yearly inspections are planned and conducted, according to the District General Hospital • Department of Health reply: six inspections • Municipality reply • 2010-13 - 145; • 2013-16 - 175; • 2016-19 - 215; • 2019-22 - 209; • In 2022, till date: 93
	Ahmednagar	The District Hospital stated that all 546 private hospitals in the district have been inspected, but no inquiry has been ordered at any hospital after the inspections. The Cantonment hospital reported their number of inspections as Nil.
	Thane	• District Family Welfare Office - DHO - 135 inspections and inquiries under s 9 • District General Hospital - 60 inspections
Maharashtra	Akola	• District Surgeon - 87 inspections conducted since 2012 • District Health Officer - 14 inspections and inquiries
	Buldhana	2 inspections
	Solapur	560 inspections and inquiries
	Bhandara	7 inspections and inquiries
	Panvel	379 inspections 117 inquiries regarding inspection of records to be maintained under the Act
	Dhule	119 hospitals inspected and inquired into by Taluka Health Officer Nil inspections reported by the Municipal Corporation
	Yavatmal	29 inspections
	Ratnagiri	The Zilla Parishad Health Department reported Nil inspections.
	Gadchiroli	9 private nursing homes registered under the Act and inspection of every establishment done once in 2022
	Navi Mumbai	The Municipal Corporation reported Nil inspections.
Manipur	Imphal West	192 inspections and inquiries
	Tamenlong	Nil
Meghalaya	-	33 inspections/inquiries
Odisha	Deogarh	7 inspections
Tripura	Gomati	43 inspections
	South Tripura	50 inspections/inquiries
	Sepahijila	58 inspections/inquiries

Nine districts have replied 'nil' or 'NA', and we interpret them to mean that these districts have not conducted any inspections of healthcare facilities.

[139] Minutes of the meetings
[140] Provided by the District Family Welfare Officer and the KPME Act Nodal Officer.
[141] Maharashtra empowers different authorities as the Local Supervising Authority within a district, and so there are multiple responses within a given district.

All state laws empower authorities to inspect suo moto

Since inspection of establishments is intended to ensure that they maintain compliance with the law, the inspecting authority may either conduct inspections *suo moto* or after receiving complaints from patients or any aggrieved person.

- All the state laws permit the inspecting authority to inspect establishments suo moto.
- Three state Acts specifically permit the authority to inspect after receiving complaints from aggrieved persons.[142]

Most state laws permit inspection without notice and do not prescribe a schedule

Since all the separate state laws permit the inspecting authority to conduct inspections *suo moto*, a concomitant provision would be to set a schedule for such inspections. These may be scheduled at regular intervals. Scheduled inspections are generally preferable when the aim is to help the healthcare facilities comply with the law. However, only two State Acts mandate periodic inspections.[143] The Kerala Act mandates inspection of all registered clinical establishments at least once every two years,[144] whereas the Maharashtra Act mandates periodic inspections at least twice a year.[145]

When the authorities apprehend or have received complaints about serious contraventions of the law, unscheduled inspections might be more effective.[146] However, under normal circumstances, providing notice for inspections can help facilities comply.[147] Amongst the seventeen state laws, we observed that

- Only two State Acts mandate that inspections be conducted only after providing a notice to the establishment.[148]
- Six State Acts allow all inspections to be conducted without notice and they empower the regulatory authority to enter the premises of the establishment for inspection at any reasonable time or opportunity.[149]
- Four State Acts allow the authority to inspect either with or without notice.[150] The West Bengal Act notes that the authority can inspect without notice only if the complaint received against the establishment is of a serious nature.[151]
- Surprisingly, five State Acts do not have any provision regarding the issuance of notice for inspection.[152]

[142] Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 8; Karnataka Private Medical Establishments Act 2007, s 7(7); West Bengal Clinical Establishments (Registration, Regulation and Transparency) Rules 2017, r 36.
[143] Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 19(11); Maharashtra Nursing Homes Registration (Amendment) Rules 2021, rule 11A.
[144] Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 19(11).
[145] Maharashtra Nursing Homes Registration (Amendment) Rules 2021, rule 11A.
[146] Julie Monk, 'Reform of Regulatory Enforcement and Inspections in OECD Countries' (OECD 2012) 36 <https://www.oecd.org/regreform/Reform%20of%20inspections%20-%20Web%20-%20Julie%20Monk.pdf> accessed 21 August 2023.
[147] ibid 37.
[148] Goa Clinical Establishments (Registration and Regulation) Act 2019, s 31; Goa Clinical Establishments (Registration and Regulation) Rules 2021, r 20(4); Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 37; Kerala Clinical Establishments (Registration and Regulation) Rules 2018, r 26.
[149] Gujarat Clinical Establishments (Registration and Regulation) Act 2021, s 29; Karnataka Private Medical Establishments Act 2007, s 21; , Orissa Clinical Establishment (Control and Regulation) Act 1990, s 11; Maharashtra Nursing Homes Registration Act 1949, s 9; Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 18. Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 33.
[150] Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 8(2); Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010, s 11; Madhya Pradesh Upcharyagriha Tatha Ragopchar Samabandi Sthapanaye (Ragistrikaran Tatha Anugyapan) Adhiniyam 1973, s 7; West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, s 22.
[151] West Bengal Clinical Establishments (Registration, Regulation and Transparency) Rules 2017, r 36(3).
[152] Tamil Nadu, Manipur, Meghalaya, Nagaland, Delhi.

Only two state Acts mandate the publication of inspection records

Publishing inspection records is another possible accountability mechanism as they might directly affect the reputation of the establishment. Only two state Acts mandate that inspection records be placed in the public domain.[153] These Acts mandate the public accessibility of inspection records regardless of the observations made by the authority.

Key Takeaways

We observe that the laws of Tripura, Odisha, Madhya Pradesh, Chhattisgarh and Manipur permit the appointment of an individual as the inspecting authority and also constitute these authorities on a state-level. A deeper on-ground examination would be needed to determine if these individuals possess the capacity to conduct inspections across the state.

The number of inspections differ vastly among states/UTs and even among districts. For instance, in Maharashtra, the authorities of Buldhana district have reportedly made two inspections between 2012 and 2022, whereas the authorities of Solapur district have made 560 inspections and inquiries during the same decade. While the number and frequency of inspections and inquiries would depend on the number of healthcare facilities in that territory, it is also likely that authorities across states/UTs and districts are operating with varied capacity and resources. It is essential to further examine the schedule of such inspections as well as whether they are unannounced or scheduled.

Most of the State Acts permit inspections to be conducted *suo moto* and without notice. Regardless of whether one method of inspection should be preferred to others, all State Acts must clarify whether inspections can be conducted with/without notice and also provide that inspections can be conducted upon receipt of a complaint.

As we observed, only two State Acts provide for the publication of inspection records for public accessibility. However, additional on-ground research is necessary to determine the impact of publication of inspection records, and the best ways in which they may effectively be used as accountability mechanisms.

[153] Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 19(11); Kerala Clinical Establishments (Registration and Regulation) Rules 2018, rule 20; Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010 , s 11(3)(e).

Are there grievance redressal mechanisms?

State laws differ in the degree to which they are patient-centric. As we have noted previously, earlier laws tended to focus on interactions between the state and the establishment. They were regulatory statutes. But more recent laws (and amendments and rules under old laws) give the patient a greater role as both the principal beneficiary and an actor within the regulatory scheme.

Grievance redressal mechanisms are a common way in which the patient is given a role in the regulatory scheme. In this context, a question may arise as to what happens when a patient finds that the healthcare provider is in breach of the prescribed minimum standards? Can a public-spirited individual take any step to check non-compliance by these establishments? What grievance redressal mechanisms exist for these purposes under the state law? We attempt to answer these questions in this section.

Seven states/UTs, namely, Delhi, Gujarat, Manipur, Meghalaya, Andhra Pradesh, Nagaland, and Odisha, do not accommodate the resolution of complaints or grievances within their laws.[154] The Odisha Act simply permits the interviewing of patients during inspections to look into their complaints regarding treatment.[155] However, the Odisha Act has no formal process for the filing or resolution of complaints.

States do not generally have constraints on who can file a complaint, but there are some exceptions. Karnataka restricts the scope to patients and their families. West Bengal's rules state that complaints may come from "(a) Any service recipient including Patient or Patient Party whose individual rights are alleged to be violated; or (b) Any person(s), as a potential service recipient whose collective community rights are alleged to be violated; or (c) any organization acting in public interest."

[154] These are Delhi, Gujarat, Madhya Pradesh, Maharashtra, Manipur, Meghalaya, Nagaland, Odisha, Tamil Nadu,
[155] Orissa Clinical Establishments (Control and Regulation) Act 1991, s 11(3).

Table 4.2: Details of grievance redressal or complaints mechanisms in the states with separate HFR legislation

State	Who is the grievance redressal body?	What are the grounds on which a complaint can be filed?	What is the time limit for resolving a complaint?
Maharashtra	Grievance redressal cell set up by local supervising authority	Violations of rights and responsibilities of patients as well as the rights and responsibilities of a registered nursing home.	Hearing within 24 hours
Madhya Pradesh	Supervising authority[157]	Not specified	Not specified
Tamil Nadu	District Committee[158]	Not specified	Not specified
Goa	Grievance Redressal Officer to be appointed by the clinical establishment[159]	Not specified	15 days
Karnataka	Registration and Grievance Redressal Authority[160]	1. non-compliance with the Patient's Charter or Private Medical Establishment's Charter 2. Violation of obligations under the Act	90 days
Kerala	Grievance Redressal Committee[161]	Violations of provisions of the Act or the rules	3 months
Punjab	State and District Grievance Redressal Cell, and public grievance redressal mechanism in every clinical establishment[162]	Treatment, improper billing, deficiency in service, attending staff's behaviour, non-compliance with any provision	Not specified
West Bengal	West Bengal Clinical Establishment Regulatory Commission,[163] and public grievance cell in every clinical establishment with two or more service providers[164]	Denial of assured services, which means and includes: a. non-provision of any of the assured services including non-provision of emergency treatment; or b. provision of defective or sub-standard quality of assured services; or c. any unethical or unfair trade practice, including but not restricted to recovery of money in excess of standard charges; or d. violation of patient rights specified in the Act and rules; or e. any such other deficiency, delay, defects, neglect or abuse as may be notified	A written preliminary response must be given by the grievance redressal officer within a period of seven days

[156] Maharashtra Nursing Homes Registration Rules 1973, r 11-B.
[157] Madhya Pradesh Upcharyagriha Tatha Ragopchar Sambandhi Sthapanaye (Ragistrikaran Tatha Anugyapan) Rules 1997, schs II and III.
[158] Maharashtra Nursing Homes Registration Rules 1973, r 5.
[159] Goa Clinical Establishments (Registration and Regulation) Act 2019, s 9(1)(iii).
[160] Goa Clinical Establishments (Registration and Regulation) Act 2019, s 4.
[161] Kerala Clinical Establishments (Registration and Regulation) Act 2018, s 36; Kerala Clinical Establishments (Registration and Regulation) Rules 2018, r 30.
[162] Punjab Clinical Establishments (Registration and Regulation) Act 2020, ss 21(2)(i) and 47.
[163] West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act 2017, s 2.
[164] West Bengal Clinical Establishments (Registration, Regulation and Transparency) Rules 2017, r 28.

Chhattisgarh	Appellate authority/ committee constituted under Section 7(1) of the Chhattisgarh Medicare Service Persons and Medicare Service Institutions (Prevention of Violence and Damage or Loss to Property) Act, 2010	Wilful negligence in treatment	Not specified
Tripura	District registering Authority	Not specified	15 days

In Goa, one of the conditions for registration is that every clinical establishment should appoint a grievance redressal officer and every complaint should be responded to within 15 days failing which the complainant may approach the district registering authority.[166]

Grievance redressal is deeply embedded in the Karnataka legislation with the district level authority being called the 'Registration and Grievance Redressal Authority'.[167] On receiving a complaint regarding non-compliance with the Patient's Charter or Private Medical Establishment's Charter, the authority can exercise powers similar to those of civil courts to dispose of the complaint summarily within 90 days.[168] Patients or their families can also file complaints with respect to non-compliance of obligations under the Act.[169] However, the complaints pertaining to negligence, non-adherence to standard protocols for treatments, procedures and prescription audit are to be referred to the Karnataka Medical Council.[170] In response, the Registration and Grievance Redressal Authority can impose penalties, or suspend or cancel the registration of the establishment.[171] Both the districts from Karnataka confirmed that such an authority has been set up for the district and the Bangalore Urban District reported that 80 complaints have been filed with the authority till date.

In Kerala, the State Council for Clinical Establishments has been mandated to set up a grievance redressal mechanism.[172] Accordingly, by way of rules, the Council has been mandated to set up a Grievance Redressal Committee with the following composition[173] -

- An officer retired from service by holding the post not below the rank of an Additional Secretary under the Government and has a degree in Law (Chairperson)
- A retired doctor from Government service after a minimum of twenty years of service
- A person who has expertised service of minimum fifteen years, in either one or more sectors of medical science, paramedical, emergency services, public health, law, finance, healthcare research, other medical branches, geriatric care, mental health, rights of differently abled persons and public health management.

The Grievance Redressal Committee is required to communicate its decision within three months.[174] Further, the State Council has been mandated to arrange for an online solution on its website for the submission of complaints and giving updates on the action taken.[175] Accordingly, a portal is available on the website of Kerala State Council for Clinical Establishments wherein a complaint can be filed under four categories: i) Consultation; ii) Fees and Charges; iii) Human Resources, and iv) Infrastructure.[176]

Under the Punjab Act, both the state[177] and district[178] registering authorities are required to establish a Grievance Redressal Cell. Further, each clinical establishment, as a condition for permanent registration, is mandated to maintain a Public Grievance Redressal Mechanism for lodging of any complaint regarding treatment, improper billing, deficiency in service, attending staff's behaviour etc.[179]

In Chhattisgarh, a person aggrieved by the wilful negligence of a nursing home or a clinical establishment with respect to the treatment of a person may make a complaint to the appellate authority. If the establishment is found guilty, then the Director of Health Services can order imprisonment of 6 months to 10 years and a fine of Rs. 10,000 to Rs. 50,000.[180] Further, the district level supervisory authority is required to maintain a register of complaints in a prescribed format.[181] In response to our RTI query, the district authority of Raipur confirmed that such a Complaint Register is maintained, however no complaints have been received till date.

In Tripura, the District Registering Authority is simply mandated to communicate to the clinical establishment any complaint or grievance against it, and seek an explanation within a period of fifteen days.[182]

The Maharashtra Rules provide for a Grievance Redressal Cell "having a toll free number to redress complaints of *violations of rights and responsibilities of patients as well as registered nursing home.*"[183] Hearings on the grievance must take place within 24 hours of the complaint if the patient is under treatment and within one month in other cases.[184]

In this section, we discussed the grievance redressal mechanisms available under state laws. While some GRM provisions explicitly talk about specific remedies, we presume that non-compliant institutions are usually dealt with using a traditional set of enforcement actions like monetary penalties, improvement notices, suspension/cancellation of licences, and imprisonment. Further, this is a purely legislative analysis (with the exception of the reply from Bangalore), and so further research is necessary to track the implementation of these laws on the ground.

[165] Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010, s 13.
[166] Goa Clinical Establishments (Registration and Regulation) Rules, 2021, s 9.
[167] The Karnataka Private Medical Establishments Act, 2007, s 4.
[168] The Karnataka Private Medical Establishments Act, 2007, s 8.
[169] The Karnataka Private Medical Establishments Act, 2007, s 11A.
[170] The Karnataka Private Medical Establishments Act, 2007, s 8.
[171] The Karnataka Private Medical Establishments Act, 2007, s 15.
[172] The Kerala Clinical Establishments (Registration and Regulation) Act, 2018 , s 36.
[173] The Kerala Clinical Establishments (Registration and Regulation) Rules, 2018, r 30.
[174] The Kerala Clinical Establishments (Registration and Regulation) Rules 2018, r 34.
[175] ibid.
[176] Department of Health and Family Welfare, Govt of Kerala, 'Grievance Registration' (Department of Health and Family Welfare, Govt of Kerala), <https://portal.clinicalestablishments.kerala.gov.in/Grievance/lodge_grievance> accessed 21 August 2023.
[177] The Punjab Clinical Establishments (Registration and Regulation) Act, 2020, s 8.
[178] The Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 10.
[179] The Punjab Clinical Establishments (Registration and Regulation) Act, 2020, s 21(2)(f).
[180] Chhattisgarh State Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Adhiniyam 2010, s 13.
[181] Chhattisgarh State Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Niyam 2013, r 18.
[182] The Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 27(3).
[183] The Tripura Clinical Establishment (Registration and Regulation) Act 2018, s 27(3).
[184] Maharashtra Nursing Homes Registration Rules 1973, r 11-B (emphasis on original).

What action is taken against non-compliant facilities?

All seventeen state laws empower authorities to take action against non-compliant clinical establishments by imposing monetary penalties, while the details of the grounds for imposing them vary.

Fine

Every separate state law contains a provision for exacting penalties from offenders. We asked authorities for the number of persons or establishments fined.

- In Chhattisgarh, Raipur fined 544 persons.
- In Odisha, Deogarh replied that a fine had been levied on six persons.
- In Tripura, South Belonia district reported that one fine had been levied.
- Delhi UT stated that figures on the number of people fined were not readily available.
- Meghalaya state replied that no fines had been levied.
- Six districts replied that no fines had been levied.[185]

Cancellation and Suspension

While all seventeen laws empower the competent authority to cancel the clinical establishment's registration, only eight of them allow for the suspension of registration.[186]

In our RTI applications, we asked authorities for a list of registrations cancelled under their respective Acts.

From the **state authorities** we received the following information:

- Meghalaya replied with "nil", which we interpret to mean that no registrations had been cancelled.
- Kerala reported that there have been 'nil' instances of cancellation or suspension of registration in the state.

From the **district authorities** we received the following information:

- We asked the Maharashtra Health Department how many licences had been cancelled under the Nursing Homes Act. They forwarded the question to each of their Local Supervising Authorities ("LSAs"), and we received replies from 21 of them. 17 LSAs reported that they had cancelled nil licences.[187] One LSA replied with "NA"[188] Ahmednagar District Hospital stated the name of one registration which had been cancelled. The Kolhapur Zilla Parishad reported 37 cancellations and Solapur (Rural) reported four.
- South Goa district replied stating that no cancellations had taken place.
- Manipur reported nil cancellations in Tamenglong and one cancellation in Imphal West.
- Kerala's Thiruvananthapuram district reported nil cancellations.
- In Karnataka, Bengaluru Urban replied with "NA" whereas Kodagu replied with "No."'
- In Tripura, South Belonia reported nil cancellations and Sepahijala replied with "No."
- In Odisha, Deogarh cancelled nil registrations.
- In Chhattisgarh, Raipur stated the name of one hospital whose registration had been cancelled.
- From Nagaland, we received copies of documentation relating to the cancellation of registrations. However, we received neither numerical figures nor assurances that this documentation was comprehensive.

Treating existing inpatients on cancellation

The legal regime surrounding cancellation of registrations is critical. They set out the circumstances and the procedure pursuant to which an establishment's registration may be cancelled. More importantly, the cancellation of registrations presents a logistical challenge: what happens to the inpatients? The solution must balance the desire for effective accountability with the needs of patient care and public health. Strangely, less than half (8) of the state laws address this question.

They take one of three separate approaches:

- Two states (Meghalaya and Andhra Pradesh) require the continuation of treatment for existing inpatients, and delay the shutdown of the establishment until such time as the last existing inpatient is discharged.
- Two states (Odisha and Karnataka) require that any order of cancellation also contain directions for the transfer of inpatients to another establishment.
- Four states (Kerala, Tripura, Goa, and Gujarat) adopt the approach of the CEA 2010 and do not require the immediate cessation of functions at an establishment except on a reasoned order in writing, on the grounds that there is imminent danger to the health and safety of patients. In other words, cancellation does not mean an immediate shutdown of the establishment unless the order explicitly requires it.

The other nine state laws do not make such provisions, and leave open the possibility that cancelling a registration could disrupt patient care even when it is not in their immediate interests.

Imprisonment

Ten states provide for the imprisonment of violators, whereas seven do not.

- Imprisonment is a penalty for contravention of the Act (as a first-time offender) only in Nagaland. In three states (Chattisgarh, Madhya Pradesh, and Odisha), a repeated contravention of the law attracts imprisonment.[189]
- In five of the states, only non-registration attracts imprisonment. In three of them (Karnataka, Maharashtra, and Manipur) imprisonment can be awarded on the first instance of non-registration, whereas in two states (Delhi and Tripura), only a repeated offence attracts imprisonment.
- In West Bengal, violation of the conditions of the licence attracts imprisonment.[190]

[185] Maharashtra Nursing Homes Registration Rules 1973, r 11-B(4).
[186] Andhra Pradesh Allopathic Private Medical Care Establishments (Registration and Regulation) Act 2002, s 9; Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Samabandhi Sthapanaye Adhiniyam 2010, s 9; Karnataka Private Medical Establishments Act 2007, s 15(5); Meghalaya Nursing Homes (Licensing and Registration) Act 1993, s 14(1); Nagaland Health Care Establishments Act 1997, s 12. Punjab Clinical Establishments (Registration and Regulation) Act 2020, s 29(2). Tamil Nadu Private Clinical Establishments (Regulation) Act 1997, s 5(2). West Bengal Clinical Establishments (Registration, Regulation, and Transparency) Act, 2017 , s 23.
[187] We include responses which report "Nil" cancellations as well as a response of "No." The relevant LSAs are Yavatmal, Amravati Municipal Corporation, Amravati DHO, Amravati Dist. Gen. Hospital, Jalgaon General Hospital, Thane Dist. Gen. Hospital, Thane DHO, Ratnagari Zilla Parishad Health Department, Panvel Municipal Corporation, Bhandara Zilla Parishad Health Department, Buldana District Hospital PCPNDT Department, Navi Mumbai Municipal Corporation, Dhule Municipal Corporation, Dhule Zilla Parishad, Latur City Municipal Corporation, Akola Zilla Parishad, Akola Dist Surgeon.
[188] Ahmednagar Cantonment Hospital.
[189] Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Adhiniyam 2010, s 12(B); Madhya Pradesh Upcharyagriha Tatha Ragopchar Sambandi Sthapanaye (Registrikaran Tatha Anugyapan) Adhiniyam 1973, s 8(ii); Orissa Clinical Establishments (Control and Regulation) Act 1991, ss 14A(1) and 16.
[190] Nagaland Health Care Establishments Act 1997, ss 14(1) and 15. West Bengal Clinical Establishments (Registration, Regulation, and Transparency) Act, 2017, s 34.

How are appeals handled?

All separate state laws permit the healthcare facility to appeal a denial of registration. The nature, structure, and composition of the appellate authority has a serious impact on how appeals are handled. For instance, multi-member bodies have the added advantage of deliberation and multiple points of view. This advantage is substantially enhanced if the multi-member body has representation from civil society and patient groups. Representation from professional associations of doctors and establishments is also useful in any body that seeks to be representative of stakeholders.

Generally, appeals are available only against refusal to grant registration, cancellation or suspension of the licence. Karnataka permits an appeal against any original order made under the Act. As the laws in Punjab and West Bengal allow for prohibition orders and improvement notices, appeals against them are permitted. The appellate authority is generally either a multi-member board, the State Government, a specified civil servant, or the State Council.

Of all the states from whom we requested details of the appeals received and disposed of since the relevant law was enacted, we received the following substantive information:.

Table 4.3 State-wise details of appeals received and disposed-of as per RTI replies

State	Reply
Delhi	Two appeals are pending before the Court of Financial Commissioner of Delhi
Madhya Pradesh	Nine appeals against the refusal of registration/licence have been disposed of wherein the prior decision was upheld in six cases and overturned in three cases. In one case, the appeal is pending.
Tripura	One appeal has been filed and is pending
Manipur	We do not have the number of filed or pending appeals in Manipur. However, we can confirm that no appeal has been disposed of.
Gujarat	Gujarat stated that the information was not available with them on record.
Chattisgarh	The State of Chhattisgarh has three appellate authorities, depending on the category of the institution. The authorities are the Director of Medical Education, the Director of Health Services, and the Director of AYUSH. The DHS required our physical presence for the purpose of inspecting the files as the information was not readily available. The DME stated that the information was not available with them. The Director of AYUSH stated that no appeals had been filed.

Patient Rights

Patient Rights

Since the CEA 2010 and the analogous state laws focus on the regulation of healthcare facilities and the infrastructure and services they provide, most of them do not have patient-centric provisions, i.e., provisions that acknowledge the rights of patients directly. This is perhaps due to the presumption that the provision of well-regulated healthcare services is in itself a patient-friendly outcome.[191] Accordingly, healthcare providers are viewed as active benefactors, and patients are viewed as passive beneficiaries.

The Charter of Patient Rights is not legally enforceable under any regulatory framework for healthcare facilities

Over time, there has been a significant increase in the recognition of patient rights and user perspectives in the legal and regulatory framework for health in India. This has been done by incorporating many of the patient rights from the Charter on Patient Rights within the body of regulatory law, within rules and regulations framed under the parent Act, and - in limited instances - in the form of a law recognising the right to health.

The National Human Rights Commission (**"NHRC"**) prepared the Charter of Patient Rights (**"Charter"**) in 2019. This is primarily a guiding document, which was disseminated by the Ministry of Health and Family Welfare to all states and UTs for adoption and implementation. However, no law, including the CEA 2010 and the rules thereunder, makes this Charter directly enforceable.

In 2021, the NCCE approved seven additional rights[192] for inclusion in minimum standards in addition to the existing thirteen rights in the charter. The NCCE also directed that this information should be widely disseminated by the respective State/UT Government among hospitals, doctors, patients and the general public. The implementation of the updated Patients' Rights Charter is within the remit of the respective State/UT Government, where the CEA 2010 is applicable.

Thus, it is to be seen if any steps are being taken at the state level towards the implementation of the Charter. Through the RTI replies we received, we observed that two State Councils have undertaken to spread greater awareness about the Charter:

- In 2021, the Mizoram State Council for Clinical Establishments passed a resolution that the newly added rights introduced in the Charter will be adopted.[193]
- In 2022, the Chandigarh Council of Clinical Establishments resolved to spread awareness about the Charter and the Chairperson directed that sensitisation of patient rights for the general public needs to be done and letters were to be sent to the President of the IMA, Chandigarh and private hospitals.[194]

However, there have been no concrete steps taken by any state/UT governments towards enforcing the Charter through law.

Certain state laws incorporate patient-centric provisions

Certain recent state laws governing healthcare facilities clearly acknowledge the position of the patient as an active stakeholder in the healthcare system and impose several patient-centric obligations on the healthcare facilities. For the purposes of this chapter, we focus on four states: Karnataka, West Bengal, Maharashtra and Rajasthan.

Karnataka

The Karnataka Act is interesting in that it lays down obligations beyond adherence to qualitative and quantitative standards relating to physical and human resources at clinical establishments.[195] For example, section 11 delineates the obligations of private medical establishments, including administering first aid and life-saving emergency measures in all medico-legal or potentially medico-legal cases, participating in the implementation of all national and state health programmes, performing statutory duties in respect of communicable diseases, and furnishing particulars with respect to non-communicable diseases.[196] Section 11A gives legal recognition to patient rights mentioned in the Schedule to the Act, and also provides for justiciability by making violation of such right a ground for raising a grievance under the Act.[197] Such violation may lead to the imposition of monetary penalty under section 15 by the Registration and Grievance Redressal Authority.[198]

[191] For instance, the Frequently Asked Questions for the CEA 2010 include a question about how the patients would benefit from the Act. The answer includes this excerpt: "Patients will be provided improved quality of healthcare and patient safety will be ensured through compliance to Minimum standards, Standard Treatment Guidelines and preventing unqualified persons from running Clinical Establishments." Evidently, this answer places the patient as simply a beneficiary with no other active or direct consideration towards their wellbeing. 'Frequently Asked Questions, <http://clinicalestablishments.gov.in/WriteReadData/847.pdf> accessed 27 August 2023.
[192] Right to protection and compensation for patients involved in clinical trials; RIght to protection and compensation for participants involved in biomedical and health research; Right to patient education; Right to be heard and seek redressal; and Right to proper referral and transfer free from perverse commercial influences.
[193] Mizoram State Council for Clinical Establishments, *Meeting Minutes of the 11th Meeting of the State Council for the Clinical Establishment Act, 2010* (26 October 2021).
[194] Chandigarh State Council for Clinical Establishments, *Minutes of the Meeting* (30 November 2022)
[195] Karnataka Private Medical Establishments Act 2007.
[196] Karnataka Private Medical Establishments Act 2007, s 11.
[197] Karnataka Private Medical Establishments Act 2007, s 11A.
[198] Karnataka Private Medical Establishments Act 2007, s 15.

West Bengal

The West Bengal Act adopts a slightly different approach by recognising patient rights as part of its Rules.[199] Rules 9 to 17 have detailed provisions on the right to dignity, privacy, and confidentiality; right to counselling and informed consent; rights to professional care; admission and in-patient care only if necessary and not otherwise; transparency standards in drugs, testing, and critical care; quality standards in drugs and nursing care; and right to proper referral and transfer.[200] Commendably, rule 15 mentions detailed rights pertaining to discharge, death, and terminal care, including right to advance directive for patients with terminal illnesses or conditions.[201] The grievance redressal system laid down in rule 28 includes the violation of mentioned patient rights within the meaning of 'denial of assured services', which is a ground for raising a grievance.[202]

Maharashtra

While the Maharashtra Act is austerely simple in its regulatory structure, and has not changed much since 1949, the patient-centric features of the Act have grown considerably through recent executive rulemaking. A 2021 amendment of rules originally made in 1973 inserted rules 11-A to 11-Q, substantially expanding the patient-centric features of the legislative framework.[203] Rule 11-Q provides for a Standard Charter of Patients' Rights, which includes the right of patients and their next of kin to receive relevant information about the illness, proposed care, expected results, possible complications, and expected costs; the right of female patients to be examined "in presence of female"; the entitlement of HIV/AIDS patients to treatment and care; the right to access clinical records and obtain a second opinion; the requirement to maintain a complaint register at the reception counter; as well as an obligation for the nursing home to display in a prominent place the rates for various treatments.[204] Interestingly, the charter also imposes obligations on patients and their next of kin to "settle the bill for the health service provided by the concerned nursing home", "abstain from violence in any form against health service provider and doctor", and to "adhere to sanitary, security norms of the nursing home."[205] Rule 11-B provides for grievance redressal in case of violations of patient rights and responsibilities.[206]

Similarly, Chhattisgarh recognises patient rights in the rules, through rule 17(2).[207] Interestingly, it directs clinical establishments to provide information, records, and discharge summaries to patients as part of rule 17(1) as a duty, and does not include these aspects under the next sub-rule on patient rights. It is not explicitly clear whether violation of rule 17 would be a ground to register a complaint using the grievance redressal procedure prescribed under rule 18.[208]

[199] West Bengal Clinical Establishment (Registration, Regulation and Transparency) Rules 2017.
[200] West Bengal Clinical Establishment (Registration, Regulation and Transparency) Rules 2017, rr 9-17.
[201] West Bengal Clinical Establishment (Registration, Regulation and Transparency) Rules 2017, r 15.
[202] West Bengal Clinical Establishment (Registration, Regulation and Transparency) Rules 2017, r 28.
[203] Maharashtra Nursing Homes Registration Rules 1973, rr 11-A to 11-Q, as amended by the Maharashtra Nursing Homes Registration (Amendment) Rules 2021.
[204] Maharashtra Nursing Homes Registration Rules 1973, r 11-Q.
[205] Maharashtra Nursing Homes Registration Rules 1973, r 11-Q.
[206] Maharashtra Nursing Homes Registration Rules 1973, r 11-B.
[207] Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Niyam 2013, r 17.
[208] Chhattisgarh Rajya Upcharyagriha Tatha Rogopchar Sambandhi Sthapanaye Anugyapan Niyam 2013, r 18.

Rajasthan

While the above laws recognise patient rights as part of a regulatory framework, the Rajasthan Right to Health Care Act adopts a rights-based language to recognise both rights and standards. Section 3 recognises a detailed set of rights, and section 5 lays down obligations of the government. It goes beyond the broadly recognised right to emergency medical care and provides for availing such care without prepayment, and simultaneously allows establishments to recover such payment through reimbursement from the government.[209] Section 4 allows room for prescribing further rights, duties, and responsibilities for patients, healthcare establishments, and healthcare workers in the Rules.[210] The current articulation of the Act suggests that the rights pertain only to residents of the state, although there is scope to expand the application of the rights to all users in the Rules that are yet to be notified. Section 11 lays down a mechanism for grievance redressal arising from the violation of these rights, the details of which are likely to be laid down in further detail through delegated legislation.[211]

The gradual turn towards centering patient/user rights in a variety of ways is commendable. Further research on the application of these provisions (and in the case of Rajasthan, the rules which are yet to be notified), would provide a deeper insight into the impact of such progression.

[209] Rajasthan Right to Health Care Act 2023, ss 3, 5.
[210] Rajasthan Right to Health Care Act 2023, s 4.
[211] Rajasthan Right to Health Care Act 2023, s 11.

Executive Summary

Executive Summary

Background

Healthcare facilities in India are regulated, among other approaches, through minimum standards legislation enacted by various states between the 1940s and the 2000s. These are laws that require facilities to be licensed, and which make licensing conditional on compliance with certain minimum standards. These laws traditionally focus on regulating the burgeoning private healthcare industry and often exclude government run facilities from their scope.

Dissatisfaction with these laws and their poor enforcement led to calls for a better legal regime. Consequently, Parliament enacted the Clinical Establishments (Registration and Regulation) Act, 2010 (CEA 2010), which provided a common regulatory structure and applied to government and private facilities. However, since facilities regulation is constitutionally within the exclusive competence of the states, the CEA 2010 applies directly only to Union Territories (with the exception of Delhi, which has its own legislative assembly) and to twelve states which have consented to its application. The remaining states have either continued with their pre-existing legislative frameworks, updated their legislation in line with the CEA 2010, or diverged from the CEA 2010 in significant ways.

There has emerged in recent years a sense that the CEA 2010 did not solve the issues with minimum standards legislation, with a 2021 NITI Aayog Report observing that it still remains to be seen whether the CEA 2010 will be more effective than the statutes that preceded it. Enforcement has continued to be unsatisfactory in various states that have adopted it. The Act also has various gaps, like the absence of grievance redressal systems, that prevent it from being an effective and patient-centric healthcare regulation.

Key Findings

Using a combination of desk research, legislative analysis, and data collection from authorities, this report examines minimum standards regulation for healthcare facilities in India. We provide a comparative legislative analysis of regulatory structure, the registration process, inspections, enforcement actions, appeals, and grievance redressal. This analysis is supplemented with some limited data obtained from the relevant statutory authorities in every state.

In territories where the CEA 2010 applies, we found several issues with implementation and enforcement; for instance: (a) the registration of clinical establishments is sporadic and uneven; (b) only one district authority stated that an application for permanent registration had been disallowed - raising the question of how stringently applications are being reviewed and compliance is being monitored; (c) based on data received from regulators, inspection and inquiries by authorities appear to be infrequent, with rare exceptions; and (d) the minimum standards for being granted permanent registration are yet to be notified. An analysis of the Act alongside the data on implementation, reveals an appellate mechanism (against decisions of regulators) that is underdeveloped and underutilised. Additionally, grievance redressal systems for patients are makeshift at best and non-existent at worst.

The central government has made efforts to persuade all states to adopt the CEA 2010 or enact similar laws. However, seventeen territories have not adopted the CEA 2010, and instead have their own laws in place. We do note, however, that several state laws enacted after the CEA 2010 include both private and public institutions within their scope, marking a departure from the pre-CEA 2010 laws that generally excluded government establishments from their application. In most states, registration of healthcare establishments takes place at the district level. Most of these laws prescribe clear minimum standards.

Most of the laws permit inspection without notice and do not require regular inspections. Only two states mandate the publication of inspection records. More than half of the laws provide for some form of grievance redressal or complaints mechanism for patients. Fewer than half of the laws envision a structured suspension or shut-down protocol by providing for what happens to inpatients when a facility's registration is cancelled. Ten states provide for imprisonment as a penalty, whereas seven do not. Every law permits facilities to appeal a denial of registration, but our data suggests that this mechanism is used very rarely.

Takeaways

Our data collection exercise suggests that either the maintenance of records or the actual implementation of facilities regulation statutes throughout the country is haphazard. In many cases, we found that states did not have or could not provide basic data regarding the enforcement of facilities regulation. Our legislative analysis suggests that the CEA 2010 has various lacunae which prevent it from being a patient-centric facilities regulation statute. As it stands, some states might benefit more from amending their existing laws and applying them to government facilities than from adopting the CEA 2010. There is a consensus that facilities regulation in India has not been particularly effective. However, further research is necessary to evaluate the *relative* effectiveness of different facilities regulation regimes. We hope this report is a helpful starting point, as well as a useful resource for policymakers, activists, academics, and others engaged in trying to understand and improve healthcare facilities regulation in India.

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