

Legislative Brief

The Clinical Establishments (Registration and Regulation) Bill, 2007

The Bill was introduced in the Lok Sabha on August 30, 2007.

The Bill has been referred to the Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh), which is scheduled to submit its report within three months.

Recent Briefs:

[The Private Detective Agencies \(Regulation\) Bill, 2007](#)
November 2, 2007

[The Judges \(Inquiry\) Bill, 2007](#)
October 3, 2007

Kaushiki Sanyal
kaushiki@prsindia.org

November 13, 2007

Highlights of the Bill

- ◆ The Clinical Establishments (Registration and Regulation) Bill, 2007 seeks to register and regulate, and set standards for clinical establishments. It shall be applicable to all union territories and four states. Other states may adopt the Bill.
- ◆ A clinical establishment is defined as a hospital, maternity home, nursing home and any similar facility with beds. The definition also includes a laboratory that carries out pathological, bacteriological and other diagnostic services.
- ◆ The central government shall establish a National Council. Its main functions include prescribing standards for clinical establishments and maintaining a register of clinical establishments.
- ◆ Every clinical establishment will need to register. The Bill provides for both provisional registration and permanent registration upon satisfaction of prescribed conditions.
- ◆ The district registering authority is responsible for registering clinical establishments, inspecting such establishments and cancelling registrations in case of non-compliance with prescribed standards.

Key Issues and Analysis

- ◆ The definition of “clinical establishment” refers to dispensaries and clinics; however it also states that the facilities should have beds. This would arguably exclude clinics which only provide out-patient services.
- ◆ In case of change of ownership or management, the clinical establishment will need a new registration. This requirement differs from other sectors in which the registering authority is informed and the transfer is recorded in the register.
- ◆ The regulator for all clinical establishments (including government establishments) at the district level is also the administrator for government health services. This could lead to conflict of interest.
- ◆ The Bill stipulates that a register has to be maintained in digital format. This could prevent the use of new technologies which might not be digital in nature.
- ◆ The Bill is not applicable in areas where eight state Acts have jurisdiction. These Acts do not cover all the different types of clinical establishments listed in the Bill.

PART A: HIGHLIGHTS OF THE BILL¹

Context

Since “public health and sanitation, hospitals and dispensaries” fall under the purview of the State List in the Indian Constitution, only states can enact a law on the subject. Some states have enacted laws for regulating clinical establishments. For example, Delhi Nursing Homes Registration Act, 1953 and the Tamil Nadu Private Clinical Establishment Act, 1997. These laws either lack effective implementation or have varying minimum standards.² Also, some of them do not cover laboratories and diagnostic centres.

One of the goals of the National Health Policy 2002 was to enact a law to regulate minimum infrastructure and quality standards in clinical establishments by 2003.³ A working group set up by the Planning Commission also recommended the enactment of legislation for registration and regulation of clinical establishments.

The Clinical Establishments (Registration and Regulation) Bill, 2007 was introduced in Parliament to ensure uniform standards of facilities and services in clinical establishments. Four states, Arunachal Pradesh, Himachal Pradesh, Mizoram, and Sikkim, have passed resolutions empowering the Parliament to legislate on the issue. The Bill lists eight Acts⁴ and says that it is inapplicable in states where these laws are valid.

Key Features

Applicability

- The Bill shall be applicable to all union territories and four states (Arunachal Pradesh, Himachal Pradesh, Mizoram, and Sikkim). Other states may adopt the law by passing a resolution in the state legislatures.

Regulation of Clinical Establishments

- The Bill seeks to register and regulate clinical establishments. “Clinical establishment” is defined as hospitals and clinics and similar facilities with beds that offer diagnosis or treatment for illness or injury or pregnancy in any recognised system of medicine (allopathy, yoga, naturopathy, ayurveda, homoeopathy, siddha and unani). It also includes any laboratory which offers pathological, chemical and other diagnostic services. An establishment can be owned by the government, a trust, a corporation (including a cooperative society), a local authority and a single doctor establishment. The Bill does not apply to any clinical establishment owned or managed by the Armed Forces.
- The central government shall establish a National Council to (a) determine the minimum standards of health care by a clinical establishment; (b) classify them into categories; and (c) maintain a national register of clinical establishments. The Council shall be chaired by Director General of Health Services (DGHS), and have up to 18 other members (see Table 1).

Registration of Clinical Establishments

- Every clinical establishment has to be registered to admit patients for providing treatment. Norms required to be met prior to registration include (a) minimum standards of facilities; (b) minimum qualifications for the personnel; and (c) provisions for maintenance of records. The National Council may prescribe different minimum standards for each category of clinical establishment.
- Every state government shall designate the Director of Health Services or any other subordinate officer as the Registrar of clinical establishments. The Registrar shall compile the state register and monthly returns in digital format for updating the national register (maintained by the National Council). The state government shall designate the District Health Officer or the Chief Medical Officer as the district registering authority for clinical establishments.
- The central government shall notify standards for each type of clinical establishment. The Bill provides for a system of provisional and permanent registration. The provisional registration is valid for a period of one year. These may

Table 1: Composition of the National Council

Chairperson (DGHS)	1
Elected Members	
Dental Council of India	1
Medical Council of India	1
Nursing Council of India	1
Pharmacy Council of India	1
Central Council of Indian Medicine (Ayurveda, Siddha & Unani)	3
Central Council of Indian Medicine (Homoeopathy)	1
Central Council of the Indian Medical Association	1
Bureau of Indian Standards	1
Zonal Councils	2
North-Eastern Council	2
Paramedical System	1
Nominated Members (represent any system of medicine without statutory authority)	3
Total	19

Source: Clinical Establishments (Registration and Regulation) Bill, 2007

be granted till three years after the central government notifies minimum standards for that type of establishment. After that period, only permanent registration may be granted.

- Existing clinical establishments have to apply for registration within one year from the date of commencement of the Act. Irrespective of registration under any existing law, every clinical establishment has to register under the Act. The registering authority is required to grant provisional registration within 10 days of receiving the application. No inquiry is required before granting of such provisional registration.
- A clinical establishment, applying for permanent registration, has to submit evidence of it having complied with the prescribed minimum standard. The information shall be displayed for 30 days for any objection to be filed. Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration. A clinical establishment can reapply even if its application has been rejected.

Inspection of Clinical Establishments

- The registering authority may authorise an inspection or an inquiry of any clinical establishment. The clinical establishment shall have the right to be represented during the inspection or inquiry. The authority shall convey its views and may advise the establishment on the action to be taken.
- A show cause notice may be issued if the authority feels that a clinical establishment is not complying with the conditions of its registration or the person managing the establishment has been convicted of an offence punishable under the Act. The authority may cancel the establishment's registration if it feels there is a breach of the law. The authority may enter and search in the prescribed manner after giving notice of its intention to the clinical establishment, if it suspects that an establishment is operating without registration.

Appeal

- Any person aggrieved by the order of the registering authority refusing to grant or renew registration or revoking a certification of registration may appeal to the state government.

Penalties

- If anyone operates a clinical establishment without registration, he shall on first conviction be punishable with fine up to Rs 50,000, on second offence with fine up to Rs 2 lakh and for any subsequent offence with fine up to Rs 5 lakh. If someone knowingly serves in a clinical establishment which is not registered he shall be punishable with fine up to Rs 25,000. If any person violates the provisions of the Act and no penalty is provided elsewhere, he shall be punishable with fine up to Rs 10,000 for the first offence. For a second offence, the fine may extend to Rs 50,000 and for any subsequent offence it may extend to Rs 5 lakh.

Finances

- The expenditure to set up the machinery for enacting the provisions of the Act shall be borne by the Central Government. It could involve recurring and non-recurring expenditure from the Consolidated Fund of India. The estimated total expenditure per annum is Rs 60 lakh.

PART B: KEY ISSUES AND ANALYSIS

Exclusion of Out-Patient Clinics

Clause 2(c)(i) The Bill defines a “clinical establishment” as “a hospital, maternity home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, *facilities with beds* requiring diagnosis, treatment or care for illness...” [Emphasis added]

Clause 11 It also adds that “No person shall carry on a clinical establishment unless it has been duly registered in accordance with the provisions of this Act..” It defines “carry on” as the act of admitting patients in a clinical establishment for providing treatment, diagnosis, or nursing care.

The definition of a clinical establishment appears to exclude dispensaries, clinics etc without beds, i.e., those that deal only with out-patients. Since private out-patient facilities constitute 60-70 per cent of the private sector health care in India,² the purpose of the Bill to register and regulate all clinical establishments might not be served if such establishments are excluded from its purview.

Transfer of Ownership

Clause 20 The Bill requires a clinical establishment to apply for fresh registration in case of transfer of ownership or management. This requirement differs from the case of transfer of ownership in several other cases, in which the registering authority is

informed and the transfer is recorded in the register. (For example, if A sells a car to B, the registration number remains the same, but the ownership is changed by informing the registration office).

Furthermore, in case of a clinical establishment which is registered as a company and trades on the stock exchanges, the ownership structure changes every time the stock trades. This provision would imply that a new registration is required on each such instance.

Conflict of Interest

Clauses
2(c)(i), 10, 30,
32, 33

The National Council and state Registrar frame broad policies related to clinical establishments and maintain the register. The granting of registration, inspection and cancellation in case of non-compliance with the prescribed requirements of the law is undertaken by the district registering authority. The Bill designates the District Health Officer or the Chief Medical Officer as the district registering authority. This officer may also have administrative responsibilities for government health facilities. As his regulatory duties under the Bill include regulating these facilities, there could be a conflict of interest.

Format of register

Clause 37

The Bill stipulates that a register has to be maintained in digital format. This provision limits the technology that can be used to maintain the register to the digital format. New technologies which may not be digital in nature are thereby excluded.

The Information Technology (Amendment) Bill, 2006⁵ aims to amend the Information Technology Act by changing all references from “digital signature” to “electronic signature”. The reason is to keep the option open for newer technologies.

State Acts and the Bill

Clause 56;
Schedule

There are eight states where the Bill would not be applicable because of existing Acts. However, these Acts do not cover all the different types of clinical establishments covered by the Bill. For example, the Bombay Nursing Homes Registration Act, 1949 covers only nursing homes and maternity homes.

Notes

1. This Brief has been written on the basis of the Clinical Establishments (Registration and Regulation) Bill, 2007, which was introduced in the Lok Sabha on August 30, 2007. The Bill has been referred to the Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh). The Standing Committee is scheduled to submit its report within three months.
2. Report of the Working Group on Clinical Establishments, Professional Services Regulation and Accreditation of Health Care Infrastructure for the 11th Five-Year Plan, Planning Commission, Govt. of India, 2006.
3. National Health Policy 2002 (India).
4. The Andhra Pradesh Private Medical Care Establishment (Registration and Regulation) Act, 2002; The Bombay Nursing Homes Registration Act, 1949; Madhya Pradesh Upcharya Griha Tatha Rujopchar Sambandhi Sthapnaye (Ragistrikaran Tatha Anugyapan) Adhinyam, 1973; The Manipur Homes and Clinics Registration Act, 1992; Nagaland Health Care Establishment Act, 1997; The Orissa Clinical Establishment (Control and Regulation) Act, 1991; The Punjab State Nursing Home Act, 1991; and The West Bengal Clinical Establishments Act, 1950.
5. The Bill was introduced in the Rajya Sabha on August 23, 2006 and the Standing Committee on Home Affairs presented its report on September 7, 2007.

DISCLAIMER: This document is being furnished to you for your information. You may choose to reproduce or redistribute this report for non-commercial purposes in part or in full to any other person with due acknowledgement of PRS Legislative Research (“PRS”). The opinions expressed herein are entirely those of the author(s). PRS makes every effort to use reliable and comprehensive information, but PRS does not represent that the contents of the report are accurate or complete. PRS is an independent, not-for-profit group. This document has been prepared without regard to the objectives or opinions of those who may receive it.

