

Bill Summary

The Clinical Establishments (Registration and Regulations) Bill, 2010

- The Clinical Establishments (Registration and Regulation) Bill, 2010 was introduced in the Lok Sabha on April 15, 2010 by the Minister of Health and Family Welfare, Shri Ghulam Nabi Azad. The Bill was passed by the Lok Sabha on May 3, 2010 and is pending in Rajya Sabha.
- 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.
- The Bill seeks to register and regulate clinical establishments. “Clinical establishment” is defined as hospitals and clinics and similar facilities that offer treatment for illness 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, 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 of Clinical Establishments 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 the Director General of Health Services (DGHS) and 22 other members (includes consumer groups and Associations of Indian Systems of Medicine).
- 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; and (b) minimum qualifications for the personnel. It may prescribe different minimum standards for each category of clinical establishment.
- National Register shall be compiled within two years from the date of commencement of the law and determine the first set of standards for clinical establishments within two years of setting up the Council.
- Every state government shall establish a State/Union Territory Council for clinical establishments. Members shall include Secretary, Health; Director of Health Services; elected representatives from state Medical Council, Nursing Council and Pharmacy Council, and state-level consumer groups or reputed NGOs etc.
- The state government shall set up a district registering authority for registering clinical establishments at district level. Members shall be the District Collector, the District Health Officer and 3 members with such qualifications to be prescribed by central government. However, the District Health Officer and Chief Medical Officer shall act as registering authority for provisional registration.
- The functions of the Council include compiling state registers and hearing appeals against orders of the authority for registration.
- The central government shall notify standards for each type of clinical establishment. The Bill provides for a system of provisional and permanent registration. Provision registration may be granted for a year. For clinical establishment whose minimum standards have been notified, provisional registration will only be granted for a specified time-limit. Permanent registration shall be valid for five years and application for renewal should be made six months before expiry of registration.
- A clinical establishment, applying for permanent registration, has to submit evidence of it having complied with the prescribed minimum standard.
- The registering authority may authorise an inspection or an inquiry of any clinical establishment through a multi-member inspection team to be prescribed. A show cause notice may be issued if the authority feels that a clinical establishment is not complying with the conditions of its registration. It may also cancel the registration. 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.



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- The Bill lists monetary penalties for any person violating the law, operating without registration or knowingly serving a clinical establishment which is not registered. It also outlines the inquiry and appeals process and states that while fixing penalty, the category, size and type of establishment should be considered.
- The provisions of this Bill shall not be applicable in nine states, which have laws related to clinical establishments. If these states adopt the 2010 Act, all provisions shall apply to them.

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