

AS INTRODUCED IN THE RAJYA SABHA
ON 14TH MARCH, 2006

Bill No. XIV of 2006

THE PATHOLOGICAL LABORATORIES AND CLINICS
(REGULATION AND CONTROL) BILL, 2006

A

BILL

to provide for regulation and control of pathological laboratories and clinics by making their registration compulsory with an appropriate authority and prescribing norms and standards for setting up a pathological laboratory or clinic and for matters connected therewith or incidental thereto.

BE it enacted by Parliament in the Fifty-seventh Year of the Republic of India as follows:—

1. (1) This Act may be called the Pathological Laboratories and Clinics (Regulation and Control) Act, 2006.

Short title,
extent and
commencement.

5 (2) It extends to the whole of India.

(3) It shall come into force with immediate effect.

2. In this Act, unless the context otherwise requires,—

Definitions.

(a) ‘Authority’ means registration authority notified under section 4.

(b) ‘pathological laboratory or clinic’ means any laboratory or clinic carrying

out any kind of medical test of or on human body or its excreta for the purposes of diagnosing any disease or otherwise.

(c) 'prescribed' means prescribed by rules made under this Act;

Registration to be compulsory for pathological laboratory or clinic.

3. (1) With effect from such date as the Central Government may by notification in the Official Gazette appoint, no person or establishment shall run any pathological laboratory or clinic without prior registration with the appropriate authority in such manner as may be prescribed. 5

(2) Any pathological laboratory or clinic set up and running before the commencement of this Act shall apply for the registration with the appropriate authority within a period of thirty days from the date of commencement of this Act. 10

Establishment of Registration Authority.

4. (1) The Central Government shall by notification in the Official Gazette establish a Registration Authority for the purpose of registration of pathological laboratories and clinics under this Act.

(2) The Authority shall have its headquarters at Nagpur:

Provided that the authority may establish as many offices at other places in the country as may be necessary for performing functions under this Act. 15

(3) The Authority shall consist of a Chairperson and such other members not less than six, to be appointed by Central Government in such a manner as may be prescribed.

(4) The terms and conditions of service of the Chairperson and the members shall be such as may be prescribed. 20

(5) The Central Government shall provide such number of officers and staff as may be necessary to enable the authority to exercise its power and functions.

(6) The authority shall prescribe the norms and various standards to be followed for running a pathological laboratory or clinic. 25

Procedure for registration.

5. (1) On receipt of an application for registration, the Authority shall cause the application to be scrutinised and for the purpose may call for such other information from the applicant as may be necessary for registration.

(2) The authority shall cause the site of the pathological laboratory or clinic inspected to have a first hand information of the infrastructure available and the compliance of norms and standards prescribed by the authority in this regard. 30

(3) The authority on being satisfied about the various requirements shall, grant a registration certificate to the applicant in such manner as may be prescribed.

(4) The authority shall arrange to inspect the registered pathological laboratory or clinic at least once in every year. 35

Cancellation of Registration.

6. The authority may cancel the registration granted under this Act if such pathological laboratory or clinic fails to comply with the norms and standards prescribed by the authority for the purpose.

Central Government to provide money.

7. The Central Government shall, after due appropriation made in this behalf, provide such sums of money as it may think fit for being utilised for the purposes of this Act. 40

Penalty.

8. Whoever contravenes the provisions of this Act and rules made thereunder shall be punishable with imprisonment which may extend to three years or with fine which may extend to three lakhs rupees or with both.

Contravention by a Company.

9. Where a person committing a contravention of any of the provisions of this Act or of any rule, made there under is a company, every persons who, at the time the contravention was committed, was in charge of, and was responsible to, the company for the conduct of 45

business of the company as well as the company, shall be guilty of the contravention and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to punishment if he proves that the contravention took place without his knowledge or that
5 he exercised all due diligence to prevent such contravention.

Explanation.— For the purpose of this section:—

(i) "company" means any body corporate and include a firm or other association of individuals; and

(ii) "director", in relation to a firm, means a partner in the firm.

10 **10.** If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act, as appear to it to be necessary or expedient for removing the difficulty:
Power to remove difficulty.

15 Provided that no such orders shall be made after the expiry of the period of three years from the date of commencement of this Act.

11. The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force on the subject and save aforesaid the provisions of the Act shall be in addition to and not in derogation of any other law for the time in force.
Overriding effect of the Act.

20 **12.** The Central Government may, by notification in the Official Gazette make rules for carrying out the purposes of this Act.
Power to make rules.

STATEMENT OF OBJECTS AND REASONS

In recent years, there has been sudden spurt in the number of pathological laboratories and clinics in the country. There is, at present, no separate effective law to control and regulate the activities of these laboratories and clinics. Taking advantage of the situation, these laboratories are fleecing the innocent patients. Many of these laboratories are functioning without proper infrastructure, equipment and trained pathologists. Some of these laboratories are working in garages and tents under unhygienic conditions. In view of this, many of these laboratories and clinics are not carrying out the examination in proper way leading to wrong diagnosis. In fact, the persons running these laboratories are actually playing with the lives of the persons going to them for pathological tests and minting money in connivance with doctors who refer their patients to these laboratories/clinics. The plight of a patient can very well be imagined who gets himself treated for a diseases only to be informed later on that he was never suffering from that disease.

It is high time that the Government should step in and prescribe norms and standards for pathological laboratories/clinics and make provisions for their registration compulsory so as to save the people from this unhealthy business practice playing with their lives.

Hence this Bill.

VIJAY J. DARDA

FINANCIAL MEMORANDUM

Clause 4 of the Bill provides that there shall be an Authority for registration of pathological laboratories and clinics. Clause 7 provides that the Central Government shall provide funds for the purposes of the Bill. The Bill, if enacted, would involve expenditure from the Consolidated Fund of India. It is estimated that a recurring expenditure of rupees fifty crore would be involved from the Consolidated Fund of India.

A non-recurring expenditure of rupees five crore will also be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 12 of the Bill empowers the Central Government to make rules for carrying out the purposes of the Bill. As the matter will relate to details only, the delegation of power is of normal character.

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(Shri Vijay J. Darda, M.P.)