

THE CLINICAL ESTABLISHMENTS (REGISTRATION AND
REGULATION) BILL, 2007

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THE SCHEDULE.

Bill No. 71 of 2007

THE CLINICAL ESTABLISHMENTS (REGISTRATION AND
REGULATION) BILL, 2007

A

BILL

*to provide for the registration and regulation of clinical establishments in the country
and for matters connected therewith or incidental thereto.*

WHEREAS, it is considered expedient to provide for the registration and regulation of clinical establishments with a view to prescribe minimum standards of facilities and services which may be provided by them so that mandate of article 47 of the Constitution for improvement in public health may be achieved;

AND WHEREAS, Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

AND WHEREAS, in pursuance of clause (1) of article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

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

CHAPTER I

PRELIMINARY

Short title,
application
and com-
mencement.

1. (1) This Act may be called the Clinical Establishments (Registration and Regulation) Act, 2007.

(2) It applies, in the first instance, to the whole of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union territories; and it shall apply to such other State which adopts this Act by resolution passed in that behalf under clause (1) of article 252 of the Constitution.

(3) It shall come into force at once in the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union territories, on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (1) of article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, mean the date on which this Act comes into force in such a State or Union territory:

Provided that different dates may be appointed for different categories of clinical establishments and for different recognised systems of medicine.

Definitions.

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

(a) “authority” means the district registering authority designated under section 10;

(b) “certificate” means certificate of registration issued under section 30;

(c) “clinical establishment” means—

(i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities with beds requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or

(ii) a place established as an independent entity or part of an establishment referred to in clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not,

and shall include a clinical establishment owned, controlled or managed by,—

(1) the Government or a department of the Government;

(2) a Trust, whether public or private;

(3) a Corporation (including a cooperative society) registered under a Central, Provincial or State Act, whether or not owned by the Government;

(4) a local authority; and

(5) a single doctor establishment,

but does not include the clinical establishments owned, controlled or managed by the Armed Forces.

Explanation.— For the purpose of this clause “Armed Forces” means the forces constituted under the Army Act, 1950, the Air Force Act, 1950 and the Navy Act, 1957;

46 of 1950.
45 of 1950.
62 of 1957.

(d) “National Council” means the National Council for clinical establishments established under section 3;

(e) “notification” means a notification published in the Official Gazette;

(f) “prescribed” means prescribed by rules made under this Act by the Central Government or, as the case may be, the State Government;

(g) “recognised system of medicine” means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani Systems of medicines or any other system of medicine as may be recognized by the Central Government;

(h) “register” means the register maintained by the authority, State Registrar and the Central Government under sections 37, 38 and 39 respectively of this Act containing the number of clinical establishments registered and the expressions “registered” and “registration” shall be construed accordingly;

(i) “registration” means to register under section 11 and the expression registration or registered shall be construed accordingly;

(j) “rules” means rules made under this Act;

(k) “Schedule” means Schedule to this Act;

(l) “standards” means conditions that the Central Government may prescribe under section 12, for the registration of clinical establishments; and

(m) “State Government” in relation to a Union territory means the Administrator thereof appointed under article 239 of the Constitution.

CHAPTER II

THE NATIONAL COUNCIL

3. (1) With effect from such date as the Central Government may, by notification, appoint in this behalf, there shall be established for the purposes of this Act, a Council to be called the National Council. Establishment of National Council.

(2) **The National Council shall consist of—**

(a) **Director General of Health Services, Ministry of Health and Family Welfare, Central Government, *ex officio*, who shall be the Chairperson;**

(b) **one representative each to be elected by the—**

16 of 1948.

(i) **Dental Council of India constituted under section 3 of the Dentists Act, 1948;**

102 of 1956.

(ii) **Medical Council of India constituted under section 3 of the Indian Medical Council Act, 1956;**

48 of 1947.

(iii) **Nursing Council of India constituted under section 3 of the Indian Nursing Council Act, 1947;**

8 of 1948.

(iv) **Pharmacy Council of India constituted under section 3 of the Pharmacy Act, 1948;**

48 of 1970.

(c) **three representatives to be elected by the Central Council of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicine constituted under section 3 of the Indian Medicine Central Council Act, 1970;**

59 of 1973.

(d) **one representative to be elected by the Central Council constituted under section 3 of the Homoeopathy Central Council Act, 1973;**

102 of 1956.

(e) **one representative to be elected by the Central Council of the Indian Medical Association constituted under section 3 of the Indian Medical Council Act, 1956;**

(f) one representative of Bureau of the Indian Standards constituted under section 3 of the Bureau of Indian Standards Act, 1986; 63 of 1986.

(g) two representatives from the Zonal Councils set up under section 15 of the States Reorganisation Act, 1956; 37 of 1956.

(h) two representatives from the North-Eastern Council set up under section 3 of the North-Eastern Council Act, 1971; 84 of 1971.

(i) one representative from the line of paramedical systems;

(j) the Central Government may nominate not more than three eminent representatives of other recognized systems of medicine of which no statutory regulatory authority has been set up.

(3) The nominated members of the National Council shall hold office for one year but shall be eligible for re-nomination.

(4) The elected members of the National Council shall hold office for three years, but shall be eligible for re-election:

Provided that the person nominated or elected, as the case may be, shall hold office for so long as he holds appointment of the office by virtue of which he was nominated or elected to the National Council.

(5) The members of the National Council shall be entitled for such allowances as may be prescribed by the Central Government.

(6) The National Council may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(7) The National Council may constitute sub-committees and may appoint to such sub-committee, as it deems fit, consisting of members who are not members of the Council for such periods, not exceeding two years, for the consideration of particular matters.

(8) The functions of the National Council may be exercised notwithstanding any vacancy therein.

(9) The Central Government shall appoint a person to be the Secretary of the National Council and may provide the Council with such other secretarial and other staff as the Central Government considers necessary.

4. A person shall be disqualified for being appointed as a member of the National Council if he—

(a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government, involves moral turpitude; or

(b) is an undischarged insolvent; or

(c) is of unsound mind and stands so declared by a competent court; or

(d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or

(e) has, in the opinion of the Central Government, such financial or other interest in the Council as is likely to affect prejudicially the discharge by him of his functions as a member.

5. The National Council shall —

(a) determine the standards for ensuring proper health care by the clinical establishments;

(b) classify the clinical establishments into different categories;

Disqualifica-
tions for
appointment
as member.

Functions of
National
Council.

- (c) develop the minimum standards and their periodic review;
- (d) compile, maintain and update a national register of clinical establishments;
- (e) collect the statistics in respect of clinical establishments;
- (f) perform any other function determined by the Central Government, from time to time.

6. The National Council may associate with itself any person or body whose assistance or advice it may desire in carrying out any of the provisions of this Act.

Power to seek advice or assistance. National Council to follow consultative process.

7. The National Council shall follow a consultative process for determining the standards and for classification of clinical establishments in accordance with such procedure as may be prescribed.

CHAPTER III

REGISTRATION AND STANDARDS FOR CLINICAL ESTABLISHMENTS

8. Every State Government shall, by notification, designate the Director of Health Services (by whatever name called) or any other officer subordinate to him as the Registrar of clinical establishments.

State Registrar of clinical establishments.

9. It shall be the responsibility of the Registrar of clinical establishments to compile and update the State register of clinical establishments and further to send monthly returns in digital format for updating the national register.

Providing information to National Council.

10. The State Government shall, by notification, designate the District Health Officer or the Chief Medical Officer (by whatever name called) as an authority to be called the district registering authority for each district for registration of clinical establishments.

Authority for registration.

11. No person shall carry on a clinical establishment unless it has been duly registered in accordance with the provisions of this Act.

Registration for clinical establishments.

Explanation.— For the purposes of this section, “carry on” means to admit patients in a clinical establishment for providing treatment, diagnosis, or nursing care.

12. For registration and continuation, every clinical establishment shall fulfil—
- (i) the minimum standards of facilities and services as may be prescribed;
 - (ii) the minimum qualifications for the personnel as may be prescribed;
 - (iii) provisions for maintenance of records and reporting as may be prescribed;
 - (iv) such other conditions as may be prescribed.

Conditions for registration.

13. (1) Clinical establishment of different systems shall be classified into such categories, as may be prescribed by the Central Government, from time to time.

Classification of clinical establishments.

(2) Different standards may be prescribed for classification of different categories referred to in sub-section (1):

Provided that in prescribing the standards for clinical establishments, the Central Government shall have regard to the local conditions.

CHAPTER IV

PROCEDURE FOR REGISTRATION

14. (1) For the purposes of registration of the clinical establishment under section 10, an application in the prescribed proforma along with the prescribed fee shall be furnished to the authority.

Application for provisional certificate of registration.

(2) The application shall be furnished in person or by post or online.

(3) The application shall be made in such form and shall be accompanied by such details as may be prescribed under this Act or rules made thereunder.

(4) If any clinical establishment is in existence at the time of the commencement of this Act, an application for its registration shall be made within one year from the date of the commencement of this Act.

(5) If any clinical establishment is already registered under any existing law requiring registration of such establishments, even then it shall apply for registration as referred to in sub-section (1).

Provisional certificate.

15. The authority shall, within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in such form and containing such particulars and such information, as may be prescribed.

No inquiry prior to provisional registration.

16. (1) The authority shall not be required to conduct any inquiry prior to the grant of provisional registration.

(2) Notwithstanding the grant of the provisional certificate of registration, the authority shall, within a period of forty-five days from the grant of provisional registration, cause to be published in such manner, as may be prescribed, all particulars of the clinical establishment proposed to be registered.

Validity of provisional registration.

17. Every provisional registration shall be valid to the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable.

Display of the certificate of registration.

18. The certificate shall be kept affixed in a conspicuous place in the clinical establishment in such manner so as to be visible to every one visiting such establishment.

Duplicate certificate.

19. In case the certificate is lost, destroyed, mutilated or damaged, the authority shall issue a duplicate certificate on the request of the clinical establishment and on the payment of such fees, as may be prescribed.

Certificate to be non-transferable.

20. The certificate of registration shall be non-transferable and, in the event of change of ownership or change of category or change of management or on ceasing to function as a clinical establishment, the certificate of registration shall be surrendered to the authority and the clinical establishment shall apply afresh for grant of certificate of registration.

Publication of expiry of registration.

21. The authority shall also cause to be published in such manner, as may be prescribed, the names of clinical establishments whose registration would be expiring within the next forty-five days.

Renewal of registration.

22. Application for renewal of registration shall be made thirty days before the expiry of the validity of the certificate of provisional registration and, in case the application for renewal is made after the expiry of the provisional registration, the authority shall allow renewal of registration on payment of such enhanced fees, as may be prescribed.

Time-limit for provisional registration.

23. Where clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond a period of three years from the date of notification of standards.

Application for permanent registration.

24. Application for permanent registration by a clinical establishment shall be made to the authority in such form and be accompanied by such fees, as may be prescribed.

Verification of application.

25. The clinical establishment shall submit evidence of the clinical establishment having complied with the prescribed minimum standards in such manner, as may be prescribed.

Display of information for filing objections.

26. As soon as the clinical establishment submits the required evidence of the clinical establishment having complied with the prescribed minimum standards, the authority shall cause to be displayed for information of the public at large and for filing objections, if any, in such manner, as may be prescribed, all evidence submitted by the clinical establishment of having complied with the prescribed minimum standards for a period of thirty days before processing for grant of permanent registration.

27. If objections are received within the period referred to in the preceding section, such objections shall be communicated to the clinical establishment for response within a period, as may be prescribed.

Communication of objections.

28. Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration by the Central Government.

Standards for permanent registration.

29. The authority shall pass an order immediately after the expiry of the prescribed period and within the next thirty days thereafter either –

Allowing or disallowing of registration.

(a) allowing the application for permanent registration; or

(b) disallowing the application:

Provided that the authority shall record its reasons, if it disallows an application for permanent registration.

30. The authority shall issue a certificate of permanent registration in such form and containing such particulars, as may be prescribed, if the authority allows an application.

Certificate of permanent registration.

31. The disallowing of an application for permanent registration shall not debar a clinical establishment from applying afresh for permanent registration under section 24 and after providing such evidence, as may be required, of having rectified the deficiencies on which grounds the earlier application was disallowed.

Fresh application for permanent registration.

32. (1) If, at any time after any clinical establishment has been registered, the authority is satisfied that,—

Cancellation of registration.

(a) the conditions of the registration are not being complied with; or

(b) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act,

it may issue a show cause notice as to why its registration under this Act should not be cancelled for the reasons to be mentioned in the notice.

(2) If after giving a reasonable opportunity to the clinical establishment, the authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, without prejudice to any other action that it may take against such clinical establishment, cancel its registration.

(3) Every order made under sub-section (1) shall take effect—

(a) where no appeal has been preferred against such order immediately on the expiry of the period prescribed for such appeal; and

(b) where such appeal has been preferred and it has been dismissed from the date of the order of such dismissal:

Provided that the authority, after cancellation of registration for reasons to be recorded in writing, may restrain immediately the clinical establishment from carrying on if there is imminent danger to the health and safety of patients.

33. (1) The authority or an officer authorised by it, shall have the right to cause an inspection of, or inquiry in respect of any clinical establishment, its building, laboratories and equipment and also of the work conducted or done by the clinical establishment, to be made by such person or persons as it may direct and to cause an inquiry to be made in respect of any other matter connected with the clinical establishment and that establishment shall be entitled to be represented thereat.

Inspection of registered clinical establishments.

(2) The authority shall communicate to the clinical establishment the views of that authority with reference to the results of such inspection or inquiry and may, after ascertaining the opinion of the clinical establishment thereon, advise that establishment upon the action to be taken.

(3) The clinical establishment shall report to the authority, the action, if any, which is proposed to be taken or has been taken upon the results of such inspection or inquiry and such report shall be furnished within such time, as the authority may direct.

(4) Where the clinical establishment does not, within a reasonable time, take action to the satisfaction of the authority, it may, after considering any explanation furnished or representation made by the clinical establishment, issue such directions, as that authority deems fit, and the clinical establishment shall comply with such directions.

Power to enter.

34. The authority or an officer authorised by it may, if there is any reason to suspect that anyone is carrying on a clinical establishment without registration, enter and search in the manner prescribed, at any reasonable time and the clinical establishment, shall offer reasonable facilities for inspection or inquiry and be entitled to be represented thereat:

Provided that no such person shall enter the clinical establishment without giving notice of his intention to do so.

Finance and accounts.

35. (1) The State Government may charge fees for different categories of clinical establishments, as may be prescribed.

(2) The State Government shall remit two per cent. of the fees collected from the clinical establishments for registration and renewal to the National Council.

(3) It shall be the responsibility of the Registrar of clinical establishments to ensure that the amount referred to in sub-section (2), is remitted to the National Council, on time.

Appeal.

36. (1) Any person, aggrieved by an order of the registering authority refusing to grant or renew a certificate of registration or revoking a certificate of registration may, in such manner and within such period as may be prescribed, prefer an appeal to the State Government:

Provided that the State Government may entertain an appeal preferred after the expiry of the prescribed period if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

(2) Every appeal under sub-section (1) shall be made in such form and be accompanied by such fee as may be prescribed.

CHAPTER V

REGISTER OF CLINICAL ESTABLISHMENTS

Register of clinical establishments.

37. (1) The authority shall maintain in digital format a register of clinical establishments, registered by it and it shall enter the particulars of the certificate so issued in a register to be maintained in such form and manner, as may be prescribed by the State Government.

(2) Each authority, including any other authority set up for the registration of clinical establishments under any other law for the time being in force, shall supply in digital format to the State Registrar of clinical establishments a copy of every entry made in the register of clinical establishments in such manner, as may be prescribed to ensure that the State Register is constantly up-to-date with the registers maintained by the registering authority in the State.

Maintenance of State register of clinical establishments.

38. (1) Every State shall maintain in digital and in such form and containing such particulars, as may be prescribed by the Central Government, a register to be known as the State register of clinical establishments in respect of clinical establishments of that State.

(2) Every State shall supply in digital format to the Central Government, a copy of the State register of clinical establishments and shall inform the Central Government without delay of all additions to and other amendments in such register made, from time to time.

Maintenance of all-India register of clinical establishments.

39. The Central Government shall maintain in digital format an all-India register to be called as the national register of clinical establishments that shall be an amalgam of the State register of clinical establishments maintained by the State Governments.

40. Whoever contravenes any provision of this Act shall, if no penalty is provided elsewhere, be punishable for the first offence with fine which may extend to ten thousand rupees, for any second offence with fine which may extend to fifty thousand rupees and for any subsequent offence with fine which may extend to five lakh rupees. Penalty.

41. (1) Whoever carries on a clinical establishment without registration shall, on conviction for first offence, be punishable with a fine up to fifty thousand rupees, for second offence with fine which may extend to two lakh rupees and for any subsequent offence with fine which may extend to five lakh rupees. Penalty for non-registration.

(2) Whoever knowingly serves in a clinical establishment which is not duly registered under this Act, shall be punishable with fine which may extend to twenty-five thousand rupees.

42. (1) Whoever wilfully disobeys any direction lawfully given by any person or authority empowered under this Act to give such direction, or obstructs any person or authority in the discharge of any functions which such person or authority is required or empowered under this Act to discharge, shall be punishable with fine which may extend to five lakh rupees. Disobedience of order, obstruction and refusal of information.

(2) Whoever being required by or under this Act to supply any information wilfully withholds such information or gives information which he knows to be false or which he does not believe to be true, shall be punishable with fine which may extend to five lakh rupees.

43. Whoever contravenes any provision of this Act or any rule made thereunder resulting in deficiencies that do not pose any imminent danger to the health and safety of any patient and can be rectified within a reasonable time, shall be punishable with fine which may extend to ten thousand rupees. Penalty for minor deficiencies.

44. (1) Where a person committing contravention of any of the provisions of this Act or of any rule made thereunder is a company, every person who, at the time the contravention was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the contravention and shall be liable to fine: Contravention by companies.

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

(2) Notwithstanding anything contained in sub-section (1), where a contravention of any of the provisions of this Act or of any rule made thereunder has been committed by a company and it is proved that the contravention has taken place with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that contravention and shall be liable to fine.

Explanation.— For the purposes of this section,—

(a) “company” means a body corporate and includes a firm or other association of individuals; and

(b) “director”, in relation to a firm, means a partner in the firm.

45. (1) Where an offence under this Act has been committed by any Department of Government, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly: Offences by Government Departments.

Provided that nothing contained in this section shall render such Head of the Department liable to any punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Recovery of fine.

46. Whoever fails to pay the fine, the Registrar of clinical establishment may prepare a certificate signed by him specifying the fine due from such person and send it to the Collector of the District in which such person owns any property or resides or carries on his business and the said Collector, on receipt of such certificate, shall proceed to recover from such person the amount specified thereunder, as if it were an arrear of land revenue.

CHAPTER VI

MISCELLANEOUS

Protection of action taken in good faith.

47. (1) No suit, prosecution or other legal proceedings shall lie against any authority or any member of the National Council or any officer authorised in this behalf in respect of anything, which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder.

(2) No suit or other legal proceedings shall lie against a State Government or the Central Government in respect of any loss or damage caused or likely to be caused by anything which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder.

Furnishing of returns, etc.

48. Every clinical establishment shall, within such time or within such extended time, as may be prescribed in that behalf, furnish to the authority or the State Registrar or the National Council such returns or the statistics and other information in such manner, as may be prescribed by the State Government, from time to time.

Power to give directions.

49. Without prejudice to the foregoing provisions of this Act, the authority shall have the power to issue such directions, including furnishing returns, statistics and other information for the proper functioning of clinical establishments and such directions shall be binding.

Employees of the authority, etc., to be public servants.

50. Every employee of the authority and the National Council shall be deemed to, when acting or purporting to act in pursuance of any of the provisions of this Act, be public servants within the meaning of section 21 of the Indian Penal Code.

45 of 1860.

Power to remove difficulties.

51. (1) 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 may appear to it to be necessary or expedient for removal of the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the date of commencement of this Act.

(2) Every order made under this section shall, as soon as may be after it is made, be laid before each House of Parliament.

Power of Central Government to make rules.

52. (1) The Central Government may, by notification, make rules for carrying out all or any of the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

- (a) allowances for the members of the National Council under sub-section (5) of section 3;
- (b) the determination of standards and for classification of clinical establishments under section 7;
- (c) classification of clinical establishment under sub-section (1) of section 13;
- (d) the different standards for classification of clinical establishments under sub-section (2) of section 13;
- (e) the minimum standards for permanent registration under section 28;
- (f) the form and particulars to be contained in the register to be maintained under section 38.

53. Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Laying of rules.

54. (1) The State Government may, by notification, make rules for carrying out in respect of matters which do not fall within the purview of section 52.

Power of State Government to make rules.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—

- (a) the conditions for registration under section 12;
- (b) the proforma and the fee to be paid for registration under sub-section (1) of section 14;
- (c) the form and details of application under section 14(3);
- (d) the particulars and information contained in certificate of provisional registration under section 15;
- (e) the manner of publication of all particulars of the clinical establishment proposed to be registered under section 16(2);
- (f) the fees to be paid to issue a duplicate certificate under section 19;
- (g) the manner in which the authority shall publish the names of the clinical establishments whose registration would be expiring under section 21;
- (h) the enhanced fees to be charged for renewal after expiry of provisional registration under section 22;
- (i) the form of the application and fees to be charged by the State Government under section 24;
- (j) the manner of submitting evidence of the clinical establishments having complied with the minimum standards under section 25;
- (k) the manner of displaying information of the clinical establishments having complied with the minimum standards for filing objection under section 26;
- (l) the period within which the objections to be communicated to the clinical establishment under section 27;
- (m) the expiry of period specified in section 29;
- (n) the form and particulars of the certificate of registration under section 30;

(o) the manner of entry and inspection of clinical establishment under section 34;

(p) the fees to be charged by the State Government for different categories of clinical establishments under sub-section (1) of section 35;

(q) the manner and the period within which an appeal may be preferred to the State Government under sub-section (1) of section 36;

(r) the form and the fee to be paid for an appeal under sub-section (2) of section 36;

(s) the form and the manner in which the register to be maintained under sub-section (1) of section 37;

(t) the manner of supply to the State Registrar in digital format the entry made in the register of clinical establishments under sub-section (2) of section 37;

(u) the manner and the time within which the information is to be furnished under section 48;

(v) any other matter which is required to be or may be prescribed by the State Government.

Laying of rules.

55. Every rule made by the State Government under this section shall be laid, as soon as may be after it is made, before each House of the State Legislature where it consists of two Houses, or where such Legislature consists of one House, before that House.

Savings.

56. (1) The provisions of this Act shall not apply to the States in which the enactments specified in the Schedule are applicable.

(2) The Central Government may, as and when consider necessary, by notification amend the Schedule.

THE SCHEDULE

(See section 56)

1. The Andhra Pradesh Private Medical Care Establishments (Registration and Regulation) Act, 2002.
2. The Bombay Nursing Homes Registration Act, 1949.
3. The Madhya Pradesh Upcharya Griha Tatha Rujopchar Sambandhi Sthapnaye (Ragistrikaran Tatha Anugyapan) Adhinyam, 1973.
4. The Manipur Homes and Clinics Registration Act, 1992.
5. The Nagaland Health Care Establishments Act, 1997.
6. The Orissa Clinical Establishments (Control and Regulation) Act, 1990.
7. The Punjab State Nursing Home Registration Act, 1991.
8. The West Bengal Clinical Establishments Act, 1950.

STATEMENT OF OBJECTS AND REASONS

At present, the supervision and regulation of the quality of services provided by the health care delivery system to the people by both public and private sectors has largely remained a contentious and therefore, unresolved issue. The current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. The private sector health care delivery system in India has remained largely unregulated and uncontrolled. Problems range from inadequate and inappropriate treatment, excessive use of higher technologies, and wasting of scarce resources to serious problems of medical malpractice and negligence.

2. Despite many State Legislatures having enacted laws for regulating health care providers, the general perception is that current regulatory process for health care providers in India is inadequate or not responsive to ensure health care services of acceptable quality and prevent negligence. Concerns about how to improve health care quality have continued to be frequently raised by the general public and a wide variety of stakeholders, including Government, professional associations, private providers, agencies financing health care, National Human Rights Commission and also by judiciary.

3. Accordingly, a need has long been felt for a central legislation for ensuring uniform standards of facilities and services by the clinical establishments throughout the State where the Legislative Assemblies have passed resolutions under article 252 of the Constitution and the Union territories and the States which may adopt the legislation by such resolutions.

4. The salient features of the proposed legislation, *inter alia*, are as follows:—

(i) the proposed legislation provides for the constitution of a National Council consisting of representatives of the Dental Council of India, the Nursing Council of India, the Pharmacy Council of India, the Indian Medicines representing the Ayurveda, Siddha, Unani and Homoeopathy systems, the Indian Medical Associations, the Bureau of Indian Standards, the Zonal Councils set up under the States Reorganisation Act, 1956, the North Eastern Council, etc.;

(ii) the function of the National Council shall be to determine the standards for clinical establishments, classify the clinical establishment into different categories, develop the minimum standards and their periodic review, compile, maintain and update a national register of clinical establishments, perform any other function determined by the Central Government, from time to time;

(iii) the concerned State Government shall designate the Director of Health Services or any other officer subordinate to him as the Registrar of clinical establishments. The State Registrar of clinical establishments shall compile and update the State register of clinical establishments and further send the same in digital format for updating the national register;

(iv) the concerned State Government shall, by notification, designate the District Health Officer or the Chief Medical Officer as district registering authority for registration of clinical establishments;

(v) no person shall carry on a clinical establishment unless it has been registered in accordance with the provisions of the proposed Bill. The legislation would not apply to the clinical establishments of the Armed Forces;

(vi) it is proposed that clinical establishments already in existence may be allowed for provisional registration to carry out their business. There shall be no prior enquiry for provisional registration. But the Authority shall have power to make enquiry in accordance with such rules as may be prescribed;

(vii) the clinical establishment having provisional registration shall fulfil the standards which may be notified for the purpose. The provisional certificate shall not be granted or renewed beyond a period of three years from the date of notification of standards;

(viii) any clinical establishment may apply for permanent registration in such form and shall pay such fee as may be prescribed by the State Government. A detailed procedure for permanent registration is being provided in the proposed legislation;

(ix) the authority shall have power to cancel the registration of the clinical establishment which fails to comply with the conditions prescribed by the Central Government. The authority shall have power to inspect a registered clinical establishment. Any person aggrieved by an order of the registering authority shall prefer an appeal to the State Government;

(x) there shall be register of clinical establishments at the district level, State level and the National level;

(xi) if any person contravenes any provisions of the proposed legislation or any rules made thereunder, he shall be punished with fine. The maximum penalty being provided is rupees five lakh.

5. Legislation in respect of "Public health and sanitation, hospitals and dispensaries" are relatable to Entry 6 of List II-State List in the Seventh Schedule to the Constitution and Parliament has no power to make a law in the State (apart from the provisions of articles 249, 250 and 252 of the Constitution) under article 252 of the Constitution where the legislatures of two or more States pass resolutions in pursuance of article 252 of the Constitution empowering Parliament to pass the necessary legislation on the subject, a Bill may be introduced in Parliament. The legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim have passed such resolutions. The Bill is intended to give effect to the resolutions passed by the legislatures of the aforesaid States and to make also provisions in respect to Union territories.

6. The Bill seeks to achieve the above objective.

NEW DELHI;
The 7th August, 2007.

ANBUMANIRAMADOSS.

PRESIDENT'S RECOMMENDATION UNDER ARTICLE 117 OF
THE CONSTITUTION OF INDIA

[Copy of letter No. Z.28015/48/2000-H, dated the 22nd August, 2007 from Dr. Anbumani Ramadoss, Minister of Health and Family Welfare to the Secretary-General, Lok Sabha]

The President, having been informed of the subject matter of the proposed Clinical Establishments (Registration and Regulation) Bill, 2007 recommends to House the consideration of the Bill under article 117(3) of the Constitution.

Notes on clauses

Clause 1.—This clause provides for the short title of the proposed legislation, its extent and commencement. The proposed legislation shall first come into force at once in the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim which have already passed resolutions under article 252 of the Constitution and the Union territories and also in any other State which may adopt the Act by a resolution as aforesaid. Different dates may be appointed for different categories of clinical establishments and for different recognised system of medicine to come into force.

Clause 2.—This clause seeks to define certain expressions used in the Bill. The definitions of the terms — "authority", "certificate", "clinical establishment", "National Council", "notification", "prescribed", "recognised system of medicine", "register" "registration", "rules", "Schedule", "standards" and "State Government" are given in the clause.

Clause 3.—This clause provides for establishment of a Council to be called the National Council consisting of the Director General of Health Services who shall be the chairperson and one representative each of the (i) Dental Council of India, (ii) Medical Council of India, (iii) Nursing Council of India, (iv) Pharmacy Council of India, (v) Ayurveda, (vi) Siddha, (vii) Unani, (viii) Homoeopathy, (ix) Indian Medical Association, (x) Bureau of the Indian Standards, (xi) Line of paramedical and two representatives each of the (i) Zonal Councils and (ii) North Eastern Council.

Clause 4.—This clause provides for the disqualifications for appointment of a person as a member of the National Council if he—

(a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government, involves moral turpitude; or

(b) is an undischarged insolvent; or

(c) is of unsound mind and stands so declared by a competent court; or

(d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or

(e) has, in the opinion of the Central Government, such financial or other interest in the Council as is likely to affect prejudicially the discharge by him of his functions as a member.

Clause 5.—This clause seeks to specify the functions of the National Council.

Clause 6.—This clause empowers the National Council to seek advice or assistance of any person or body while carrying out any of the provisions of this Act.

Clause 7.—This clause provides that the National Council shall follow a consultative process for determining the standards and classification of clinical establishments.

Clause 8.—This clause provides that every State shall designate the Director of Health Services (by whatever name called) or any other officer subordinate to him as the Registrar of clinical establishments.

Clause 9.—This clause seeks to provide the responsibility of the Registrar of clinical establishments to collect and update the State register of clinical establishments.

Clause 10.—This clause provides that every State shall designate the District Health Officer or the Chief Medical Officer (by whatever name called) as the District Registering Authority for each district for registration of clinical establishments.

Clause 11.—This clause provides that no person shall carry on a clinical establishments unless it has been duly registered in accordance with the provisions of this Act.

Clause 12—This clause provides that every clinical establishment shall fulfil—

- (i) the minimum standards of facilities and services as may be prescribed;
- (ii) the minimum qualifications for the personnel as may be prescribed;
- (iii) provisions for maintenance of records and reporting as may be prescribed;
- (iv) such other conditions as may be prescribed.

Clause 13—This clause provides for classification of clinical establishments into different categories and their standards.

Clause 14—This clause provides for application for provisional certificate of registration for clinical establishments.

Clause 15—This clause provides for a time-limit within which provisional certificate for clinical establishment is to be issued.

Clause 16—This clause provides for conditions for issuing provisional registration for clinical establishment.

Clause 17—This clause provides for the validity of provisional registration for clinical establishment.

Clause 18—This clause provides that every clinical establishment should display the certificate of registration in a conspicuous place in the clinical establishment.

Clause 19—This clause seeks to provide for issuing duplicate certificate on the request of the clinical establishments and on the payment of requisite fees if the certificate is lost, destroyed, mutilated or damaged.

Clause 20—This clause provides that the certificate of registration shall be non-transferable and in case of change of ownership, category, management or ceasing to function as clinical establishment the certificate shall be surrendered to the authority.

Clause 21—This clause provides for publication of expiry of registration by the registering authority.

Clause 22—This clause provides for application for renewal of registration and procedure therefor.

Clause 23—This clause provides that a provisional certificate shall not be granted or renewed beyond a period of three years where the clinical establishments in respect of which standards have been notified.

Clause 24—This clause provides for application for permanent registration for clinical establishments.

Clause 25—This clause provides for verification of applications for registration of clinical establishments.

Clause 26—This clause provides for display of information for filing objections, if any, within a stipulated time.

Clause 27—This clause provides for communication of objections received by the authority to the clinical establishments.

Clause 28—This clause provides that registration shall be granted only when a clinical establishment fulfils the standards for grant of permanent registration.

Clause 29—This clause provides for time-limit of allowing or disallowing of registration for clinical establishments.

Clause 30—This clause provides for issuing certificate of permanent registration if the application for registration of clinical establishment is allowed.

Clause 31—This clause provides for applying fresh applications by clinical establishments for permanent registration if the earlier application for permanent registration is disallowed.

Clause 32—This clause provides for issuing a show cause notice for cancellation of registration if—

(a) the conditions of the registration are not being complied with; or

(b) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act.

Clause 33—This clause provides for inspection of registered clinical establishments by the registering authority or an officer authorised by it and intimating the inspection report to the clinical establishment.

Clause 34—This clause provides that the registering authority or an officer authorised by it may enter and search any clinical establishment suspecting of not being registered under the provisions of this Act.

Clause 35—This clause provides for fees to be charged from the clinical establishments by the registering authority and remittance of its two per cent. to the National Council.

Clause 36—This clause provides for an appeal to the State Government by any person aggrieved by an order of the registering authority.

Clause 37—This clause provides for maintenance of registers of clinical establishments in digital formats by the registering authority.

Clause 38—This clause provides that every State shall maintain register of clinical establishments in digital or in such other form and supply of information to Central Government.

Clause 39—This clause provides for maintenance of national register for clinical establishments in digital format by the Central Government.

Clause 40—This clause provides for penalty for contravention of any of the provisions of this Act.

Clause 41—This clause provides for penalty for non-registration of clinical establishments and also to any person who serves in such clinical establishment.

Clause 42—This clause provides for penalty for disobeying any direction given by any person or authority empowered under this Act and any person who withholds any information is required by or under this Act.

Clause 43—This clause provides for penalty for contravention of any provision of this Act resulting in deficiencies that do not pose any imminent danger to the health and safety of any patient and can be rectified within a reasonable time.

Clause 44—This clause provides for fixing responsibility for contravention of any of the provisions of this Act by companies.

Clause 45—This clause provides for punishment of offences committed by Government department.

Clause 46—This clause provides for recovery of fines imposed under the Act as an arrear of land revenue.

Clause 47—This clause protects any authority or any member of the National Council or any officer authorised in this behalf of having taken actions in good faith.

Clause 48—This clause provides that every clinical establishment should furnish such returns or the statistics and other information as may be prescribed by the State Government.

Clause 49—This clause empowers the authority to issue directions regarding furnishing returns, statistics and any other information for the proper functioning of the clinical establishment.

Clause 50—This clause provides that every employee of the authority and the National Council shall be public servants within the meaning of section 21 of the Indian Penal Code.

Clause 51—This clause empowers the Central Government to issue orders published in the Official Gazette making such provisions not inconsistent with the provisions of the proposed legislation for removing difficulties in giving effect to its provisions. Such orders could be issued within two years from the date of commencement of the proposed legislation. It also provides for laying of such orders before each House of Parliament.

Clause 52—This clause empowers the Central Government to make rules for carrying out the provisions of the proposed legislation.

Clause 53—This clause provides that every rule made by the Central Government under this Act shall be published in the Official Gazette and be laid before each House of Parliament.

Clause 54—This clause confers powers on the State Government to make rules for carrying out any of the provisions of the proposed legislation which do not fall within the purview of section 52.

Clause 55—This clause provides that every rule made by the State Government shall be published in the Official Gazette of the State and be laid before the State legislature.

Clause 56—This clause seeks to empower the Central Government to amend the Schedule to the Act as per legislative competence of Parliament.

FINANCIAL MEMORANDUM

Clause 3 of the Bill empowers the Central Government to establish a National Council for clinical establishments. It provides for allowance for the member of the National Council. It also empowers the Central Government to appoint a person to be the Secretary of the National Council. Clause 39 of the Bill empowers the Central Government to maintain in digital format an all-India Register to be called the national register of clinical establishments. The expenditure on account of procurement and maintenance of electronic equipments and setting up of network with the State Governments will have to be borne by the Central Government. The Bill, if enacted, could involve expenditure from the Consolidated Fund of India which may be of both recurring and non-recurring in nature. The estimated total expenditure per annum will be to the tune of Rs. 60 lakhs.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 51 of the Bill empowers the Central Government to issue an order for removal of any difficulty which may arise in giving effect to the provisions of the proposed legislation. Such an order will not be inconsistent with the provisions of the legislation and would not be made after the period of two years from the date on which the proposed legislation receives the assent of the President.

2. Clause 52 of the Bill empowers the Central Government to make rules for carrying out various provisions of the Bill and regarding—

- (a) allowances for the members of the National Council under sub-section (5) of section 3;
- (b) the determination of standards and for classification of clinical establishments under section 7;
- (c) classification of clinical establishment under sub-section (1) of section 13;
- (d) the different standards for classification of clinical establishments under sub-section (2) of section 13;
- (e) the minimum standards for permanent registration under section 28;
- (f) the form and particulars to be contained in the register to be maintained under section 38.

3. Clause 54 of the Bill empowers the State Governments to make rules for carrying out in respect of matters which do not fall within the purview of section 52 and regarding—

- (a) the conditions for registration under section 12;
- (b) the proforma and the fee to be paid for registration of clinical establishment under sub-section (1) of section 14;
- (c) the form and details of application under sub-section (3) of section 14;
- (d) the particulars and information contained in certificate of provisional registration under section 15;
- (e) the manner of publication of all particulars of the clinical establishment proposed to be registered under sub-section (2) of section 16;
- (f) the fees to be paid to issue a duplicate certificate under section 19;
- (g) the manner in which the authority shall publish the names of the clinical establishments whose registration would be expiring under section 21;
- (h) the enhanced fees to be charged for renewal after expiry of provisional registration under section 22;
- (i) the form of the application and fees to be charged by the State Government under section 24;
- (j) the manner of submitting evidence of the clinical establishments having complied with the minimum standards under section 25;
- (k) the manner of displaying information of the clinical establishments having complied with the minimum standards for filing objection under section 26;
- (l) the period within which the objections to be communicated to the clinical establishments under section 27;
- (m) the expiry of period specified in section 29;
- (n) the form and the particulars of the certificate of registration under section 30;
- (o) the manner of entry and inspection of clinical establishment under section 34;

(p) the fees to be charged by the State Government for different categories of clinical establishments under sub-section (1) of section 35;

(q) the manner and the period within which an appeal may be preferred to the State Government under sub-section (1) of section 36;

(r) the form and the fee to be paid for an appeal under sub-section (2) of section 36;

(s) the form and the manner in which the register to be maintained under sub-section (1) of section 37;

(t) the manner of supply to the State Registrar in digital format the entry made in the register of clinical establishments under sub-section (2) of section 37;

(u) the manner and the period within which the information is to be furnished under section 48;

(v) any other matter which is required to be or may be prescribed by the State Government.

4. The matters with respect to which rules may be made under the aforesaid provisions are procedure and detail and it is not possible to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

LOK SABHA

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BILL

to provide for the registration and regulation of clinical establishments in the country
and for matters connected therewith or incidental thereto.

(Shri Anbumani Ramadoss, Minister of Health and Family Welfare)

MGIPMRND—3355LS(S1)—22-08-2007.