

Bill No. 43 of 2010

THE CLINICAL ESTABLISHMENTS (REGISTRATION AND
REGULATION) BILL, 2010

ARRANGEMENT OF CLAUSES

CHAPTER I

PRELIMINARY

CLAUSES

1. Short title, application and commencement.
2. Definitions.

CHAPTER II

THE NATIONAL COUNCIL FOR CLINICAL ESTABLISHMENTS

3. Establishment of National Council.
4. Disqualifications for appointment as member.
5. Functions of National Council.
6. Power to seek advice or assistance.
7. National Council to follow consultative process.

CHAPTER III

REGISTRATION AND STANDARDS FOR CLINICAL ESTABLISHMENTS

8. State Council of clinical establishments.
9. Providing information to National Council.
10. Authority for registration.
11. Registration for clinical establishments.
12. Conditions for registration.
13. Classification of clinical establishments.

CHAPTER IV

PROCEDURE FOR REGISTRATION

14. Application for provisional certificate of registration.
15. Provisional certificate.
16. No inquiry prior to provisional registration.
17. Validity of provisional registration.
18. Display of certificate of registration.
19. Duplicate certificate.
20. Certificate to be non-transferable.
21. Publication of expiry of registration.
22. Renewal of registration.
23. Time limit for provisional registration.

CLAUSES

24. Application for permanent registration.
25. Verification of application.
26. Display of information for filing objections.
27. Communication of objections.
28. Standards for permanent registration.
29. Allowing or disallowing of registration.
30. Certificate of permanent registration.
31. Fresh application for permanent registration.
32. Cancellation of registration.
33. Inspection of registered clinical establishments.
34. Power to enter.
35. Finance and accounts.
36. Appeal.

CHAPTER V

REGISTER OF CLINICAL ESTABLISHMENTS

37. Register of clinical establishments.
38. Maintenance of State register of clinical establishments.
39. Maintenance of National Register of clinical establishments.

CHAPTER VI

PENALTIES

40. Penalty.
41. Penalty for non-registration.
42. Disobedience of order, obstruction and refusal of information.
43. Penalty for minor deficiencies.
44. Contravention by companies.
45. Offences by Government Departments.
46. Recovery of fine.

CHAPTER VII

MISCELLANEOUS

47. Protection of action taken in good faith.
48. Furnishing of returns, etc.
49. Power to give directions.
50. Employees of the authority, etc., to be public servants.
51. Power to remove difficulties.
52. Power of Central Government to make rules.
53. Laying of rules.
54. Power of State Government to make rules.
55. Laying of rules.
56. Savings.

THE SCHEDULE

Bill No. 43 of 2010

**THE CLINICAL ESTABLISHMENTS (REGISTRATION AND
REGULATION) BILL, 2010**

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 Sixty-first Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

Short title,
application
and
commencement.

1. (1) This Act may be called the Clinical Establishments (Registration and Regulation) Act, 2010.

(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 State or Union territory:

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

Definitions.

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

(a) "authority" means the district registering authority set-up 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 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 sub-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—

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

(b) a trust, whether public or private;

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

(d) a local authority; and

(e) a single doctor,

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;

(d) "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in—

(i) placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; or

(ii) serious impairment to bodily functions; or

(iii) serious dysfunction of any organ or part of a body;

(e) "National Council" means the National Council for clinical establishments established under section 3;

(f) "notification" means a notification published in the Official Gazette;

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

(h) "recognised system of medicine" means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognised by the Central Government;

(i) "register" means the register maintained by the authority, State Government and the Central Government under sections 37, 38 and 39 respectively of this Act containing the number of clinical establishments registered;

(j) "registration" means to register under section 11 and the expression registration or registered shall be construed accordingly;

(k) "rules" means rules made under this Act;

(l) "Schedule" means the Schedule appended to this Act;

(m) "standards" means the conditions that the Central Government may prescribe under section 12, for the registration of clinical establishments;

(n) "State Government", in relation to a Union territory, means the Administrator thereof appointed under article 239 of the Constitution; and

(o) "to stabilise (with its grammatical variations and cognate expressions)" means, with respect to an emergency medical condition specified in clause (d), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

CHAPTER II

THE NATIONAL COUNCIL FOR CLINICAL ESTABLISHMENTS

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 for clinical establishments.

Establishment
of National
Council.

(2) The National Council shall consist of—

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

(b) four representatives out of which one each to be elected by the—

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

- (ii) **Medical Council of India constituted under section 3 of the Indian Medical Council Act, 1956;** 102 of 1956.
- (iii) **Nursing Council of India constituted under section 3 of the Indian Nursing Council Act, 1947;** 48 of 1947.
- (iv) **Pharmacy Council of India constituted under section 3 of the Pharmacy Act, 1948;** 8 of 1948.
- (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;** 48 of 1970.
- (d) **one representative to be elected by the Central Council of Homoeopathy constituted under section 3 of the Homoeopathy Central Council Act, 1973;** 59 of 1973.
- (e) **one representative to be elected by the Central Council of the Indian Medical Association;**
- (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 Council 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 excluding systems that have been given representation under clause (b);**
- (j) **two representatives from National Level Consumer Group to be nominated by the Central Government;**
- (k) **one representative from the Associations of Indian Systems of Medicines relating to Ayurveda, Siddha and Unani to be nominated by the Central Government;**
- (l) **the Secretary-General of the Quality Council of India, *ex officio*.**
- (3) The nominated members of the National Council shall hold office for three years but shall be eligible for re-nomination for maximum of one more term of three years.
- (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 such period till he holds appointment of the office by virtue of which he was nominated or elected to the 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 shall meet at least once in three months.
- (8) The National Council may constitute sub-committees and may appoint to such sub-committee, as it deems fit, persons, who are not members of the Council, for such period, not exceeding two years, for the consideration of particular matters.
- (9) The functions of the National Council may be exercised notwithstanding any vacancy therein.
- (10) The Central Government shall appoint such person to be the Secretary of the National Council as the Central Government may prescribe, and may provide the National 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—

Disqualifications for appointment as member.

(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—

Functions of National Council.

(a) compile and publish a National Register of clinical establishments within two years from the date of the commencement of this Act;

(b) classify the clinical establishments into different categories;

(c) develop the minimum standards and their periodic review;

(d) determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the 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.

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.

National Council to follow consultative process.

CHAPTER III

REGISTRATION AND STANDARDS FOR CLINICAL ESTABLISHMENTS

8. (1) Every State Government shall by notification constitute a State Council for clinical establishments or the Union territory Council for clinical establishments, as the case may be.

State Council of clinical establishments.

(2) The State Council or the Union territory Council, as the case may be, shall consist of the following members, namely:—

(a) Secretary, Health — *ex officio*, who shall be the Chairman;

(b) Director of Health Services — *ex officio* member-secretary;

(c) Directors of different streams of Indian Systems of Medicine—*ex officio* members;

(d) one representative each to be elected by the executive committee of—

(i) State Medical Council of India;

(ii) State Dental Council of India;

(iii) State Nursing Council of India;

(iv) State Pharmacy Council of India;

(e) three representatives to be elected by the Executive of the State Council or the Union territory Council, as the case may be, of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicine;

(f) one representative to be elected by the State Council of the Indian Medical Association;

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

(h) two representatives from State level consumer groups or reputed non-Governmental organisations working in the field of health.

(3) The nominated member of the State Council or the Union territory Council, as the case may be, shall hold office for a term of three years, but shall be eligible for re-nomination for maximum of one more term of three years.

(4) The elected members of the State Council or the Union territory Council, as the case may be, 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 the appointment of the office by virtue of which he was nominated or elected to the State Council or the Union territory Council, as the case may be.

(5) The State Council or the Union territory Council shall perform the following functions, namely:—

(a) compiling and updating the State Registers of clinical establishment;

(b) sending monthly returns for updating the National Register;

(c) representing the State in the National Council;

(d) hearing of appeals against the orders of the authority; and

(e) publication on annual basis a report on the state of implementation of standards within their respective States.

Providing information to National Council.

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

Authority for registration.

10. (1) The State Government shall, by notification, set-up an authority to be called the district registering authority for each district for registration of clinical establishments, with the following members, namely:—

(a) District Collector — Chairperson;

(b) District Health Officer — Convenor;

(c) three members with such qualifications and on such terms and conditions as may be prescribed by the Central Government.

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under section 14, the District Health Officer or the Chief Medical Officer (by whatever name called) shall exercise the powers of the authority as per procedure that may be prescribed.

Registration for clinical establishments.

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

Condition for registration.

12. (1) For registration and continuation, every clinical establishment shall fulfil the following conditions, namely:—

(i) the minimum standards of facilities and services as may be prescribed;

- (ii) the minimum requirement of 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.

(2) The clinical establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment.

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 made to the authority.

Application for provisional certificate of registration.

(2) The application shall be filed 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 and a clinical establishment which comes into existence after commencement of this Act, shall apply for permanent registration within a period of six months from the date of its establishment.

(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).

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.

Provisional certificate.

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

No inquiry prior to 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 so registered provisionally.

17. Subject to the provisions of section 23, 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.

Validity of provisional 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.

Display of certificate of registration.

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.

Duplicate certificate.

Certificate to be non-transferable.	<p>20. (1) The certificate of registration shall be non-transferable.</p> <p>(2) In the event of change of ownership or management, the clinical establishment shall inform the authority of such change in such manner as may be prescribed.</p> <p>(3) In the event of change of category, or location, or on ceasing to function as a clinical establishment, the certificate of registration in respect of such clinical establishment shall be surrendered to the authority and the clinical establishment shall apply afresh for grant of certificate of registration.</p>
Publication of expiry of registration.	<p>21. The authority shall also cause to be published within such time and in such manner, as may be prescribed, the names of clinical establishments whose registration has expired.</p>
Renewal of registration.	<p>22. The 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.</p>
Time limit for provisional registration.	<p>23. Where the clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond,—</p> <p>(i) the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act;</p> <p>(ii) the period of two years from the date of notification of the standards for clinical establishments which come into existence after the commencement of this Act but before the notification of the standards; and</p> <p>(iii) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified.</p>
Application for permanent registration.	<p>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.</p>
Verification of application.	<p>25. The clinical establishment shall submit evidence of having complied with the prescribed minimum standards in such manner, as may be prescribed.</p>
Display of information for filing objections.	<p>26. As soon as the clinical establishment submits the required evidence of 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.</p>
Communication of objections.	<p>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 of forty-five days.</p>
Standards for permanent registration	<p>28. Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration by the Central Government.</p>
Allowing or disallowing of registration.	<p>29. The authority shall pass an order immediately after the expiry of the prescribed period and within the next thirty days thereafter either—</p> <p>(a) allowing the application for permanent registration; or</p> <p>(b) disallowing the application:</p> <p>Provided that the authority shall record its reasons, if it disallows an application, for permanent registration.</p>

30. (1) The authority shall, if it, allows an application of the clinical establishment issue a certificate of permanent registration in such form and containing such particulars, as may be prescribed. Certificate of permanent registration.

(2) The certificate shall be valid for a period of five years from the date of issue.

(3) For the purposes of sub-section (1), the provisions of sections 18, 19, 20 and 21 shall also apply.

(4) The applications for renewal of permanent registration shall be made within six months before the expiry of the validity of the certificate of permanent registration and, in case the application of renewal is not submitted within the stipulated period, the authority may allow renewal of registration on payment of such enhanced fees and penalties as may be prescribed.

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 notice to the clinical establishment to show cause within three months' time 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, by an order, without prejudice to any other action that it may take against such clinical establishment, cancel its registration.

(3) Every order made under sub-section (2) 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 registered clinical establishment, its building, laboratories and equipment and also of the work conducted or done by the clinical establishment, to be made by such multi-member inspection team 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 within such time as indicated in the direction, 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.

Levy of fee by State Governments Appeal.

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

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 Council:

Provided that the State Council 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 within a period of two years from its establishment, compile, publish and 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 Council 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 Government 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 Government shall supply in digital format to the Central Government, a copy of the State Register of clinical establishments and shall inform the Central Government all additions to and other amendments in such register made, for a particular month by the 15th day of the following month.

Maintenance of National 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 and shall cause the same to be published in digital format.

CHAPTER VI

PENALTIES

Penalty.

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.

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

Monetary penalty for non-registration.

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

(3) For the purpose of adjudging under sub-sections (1) and (2), the authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstances of the case to give evidence or to produce any document which in the opinion of the authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8) of section 42.

(5) While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the authority may prefer an appeal to the State Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (5) shall be such as may be prescribed.

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 monetary penalty 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 monetary penalty which may extend to five lakh rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), the authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstances of the case to give evidence or to produce any document which in the opinion of the authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8) .

(5) While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the authority may prefer an appeal to the State Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (5) shall be such as may be prescribed.

(8) The monetary penalty levied under sections 41 and 42 shall be credited to such account as the State Government may by order specify in this behalf.

Penalty for minor deficiencies.

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.

Contravention by companies.

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:

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 purpose 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.

Offences by Government Departments.

45. (1) Where an offence under this Act has been committed by any Department of Government within a period of six months after the commencement of this Act, 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:

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 State Council of clinical establishment may prepare a certificate signed by an officer authorised by it 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 VII

MISCELLANEOUS

47. (1) No suit, prosecution or other legal proceedings shall lie against any authority or any member of the National Council or State 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.

Protection of action taken in good faith.

(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.

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 Council 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.

Furnishing of returns, etc.

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.

Power to give directions.

50. Every employee of the authority, the National Council and the State 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.

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

45 of 1860.

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:

Power to remove difficulties.

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.

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

Power of Central 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) allowances for the members of the National Council under sub-section (5) of section 3;

(b) appointment of such person to be the Secretary of the State Council by the Central Government under sub-section (10) of section 3;

(c) the determination of standards and for classification of clinical establishments under section 7;

(d) the qualification and the terms and conditions for the members of the authority under clause (c) of sub-section (1) of section 10;

(e) the procedure under which the powers of the authority may be exercised by the District Health Officer or Chief Medical Officer for the purpose of provisional registration of clinical establishment under sub-section (2) of section 10;

(f) the minimum standards of facilities and services under clause (i) of sub-section (1) of section 12;

(g) the minimum number of personnel under clause (ii) of sub-section (1) of section 12;

(h) the maintenance of records and reporting by the clinical establishment under clause (iii) of sub-section (1) of section 12;

(i) other conditions for registration and continuation of clinical establishment under clause (iv) of sub-section (1) of section 12;

(j) classification of clinical establishment under sub-section (1) of section 13;

(k) the different standards for classification of clinical establishments under sub-section (2) of section 13;

(l) the minimum standards for permanent registration under section 28;

(m) the form and particulars to be contained in the register to be maintained under section 38.

Laying of rules.

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.

Power of State Government to make 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.

(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 proforma and the fee to be paid for registration under sub-section (1) of section 14;

(b) the form and details of application under sub-section (3) of section 14;

(c) the particulars and information contained in certificate of provisional registration under section 15;

(d) the manner of publication of all particulars of the clinical establishment proposed to be registered under sub-section (2) of section 16;

(e) the fees to be paid to issue a duplicate certificate under section 19;

(f) the change of ownership or management to be informed by the clinical establishment to the authority under sub-section (2) of section 20;

(g) the manner in which the authority shall publish the names of the clinical establishments whose registration expired under section 21;

(h) the enhanced fees to be charged for renewal after expiry of the 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 expiry of period specified in section 29;

(m) the form and particulars of the certificate of registration under section 30;

(n) the period within which an appeal shall be preferred under clause (a) of sub-section (3) of section 32;

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

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

(q) the manner and the period within which an appeal may be preferred to the State Council 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 Council in digital format the entry made in the register of clinical establishment under sub-section (2) of section 37;

(u) the manner of holding an inquiry by the authority under sub-section (3) of sections 41 and 42;

(v) the manner of finding the appeal under sub-section (7) of sections 41 and 42;

(w) the manner and the time within which the information is to be furnished to the authority or the State Council or the National Council as the case may be, under section 48;

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

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. Laying of rules.

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

Provided that the States in which the enactments referred to in sub-section (1) are applicable, and such States subsequent to the commencement of this Act, adopts this Act under clause (1) of article 252 of the Constitution, the provisions of this Act shall, subsequent to such adoption, apply in that State.

(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 Delhi Nursing Homes Registration Act, 1953.
4. The Madhya Pradesh Upcharya Griha Tatha Rujopchar Sanbabdu Sthapamaue (Ragistikaran Tatha Anugyapan) Adhiniyam, 1973.
5. The Manipur Homes and Clinics Registration Act, 1992.
6. The Nagaland Health Care Establishments Act, 1997.
7. The Orissa Clinical Establishments (Control and Regulation) Act, 1990.
8. The Punjab State Nursing Home Registration Act, 1991.
9. 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. In view of the above, the Clinical Establishment (Registration and Regulation) Bill, 2007 was introduced in Lok Sabha on the 30th August, 2007 and the same was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare which made certain recommendations on the provisions of the said Bill. However, the said Bill was lapsed due to dissolution of the Fourteenth Lok Sabha.

5. It is now proposed to introduce the Clinical Establishments (Registration and Regulation) Bill, 2010 on the lines of above Bill incorporating therein certain recommendations made by the Department-related Parliamentary Standing Committee on Health and Family Welfare.

6. 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 Medical Council of India, Dental Council of India, Nursing Council of India, the Pharmacy Council of India, the Indian Systems of Medicines representing Ayurveda, Siddha, Unani and Homoeopathy systems, the Indian Medical Association, 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 the clinical establishment, 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 function of the State Council shall be to compile, maintain and update the State Registers of clinical establishments and to send monthly returns for updating the National Registers. The State Councils shall also publish reports on the implementation of standards within their respective States, annually;

(iv) the concerned State Governments shall, by notification, set-up an authority to be called the district registering authority under the chairmanship of District Collector 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 two 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 Council;

(x) the clinical establishments shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment;

(xi) the certificate of permanent registration issued by the authority is valid for a period of five years from the date of issue;

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

(xiii) 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;

(xiv) conferring power upon an authority, to levy monetary penalty for violation of the provisions of sections 41 and 42 of the proposed Bill;

(xv) any person aggrieved by the decision of authority may prefer an appeal to the State Council.

7. 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.

8. The Bill seeks to achieve the above objectives.

NEW DELHI;
The 10 March, 2010.

GHULAMNABIAZAD.

**PRESIDENT'S RECOMMENDATION UNDER ARTICLE 117 (3)
OF THE CONSTITUTION OF INDIA**

[Copy of letter No. Z.28015/48/2000-H dated the 15th March, 2010 from Shri Ghulam Nabi Azad, 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, 2010, recommends to the House the consideration of the Bill under article 117(3) of the Constitution.

Notes on clauses

Clause 2.—This clause defines certain words and expressions used in the Bill including 'clinical establishment', 'emergency medical condition', 'National Council', 'recognised system of medicine', 'standards', 'to stabilise', etc.

Clause 3.—This clause contains provisions for establishment of a council to be called the National Council for clinical establishments which would consist a chairperson and nineteen representatives drawn from the fields specified therein. The nominated or the elected members of the Council shall hold office for three years and shall be eligible for re-election or re-nomination, as the case may be and they shall be entitled for allowances as provided by rules to be made by Central Government. The Council, subject to the previous approval of the Central Government, make bye-laws fixing a quorum regulating its own procedure and conduct of business. It also provides that the council shall meet at least once in three months and may constitute sub-committees for consideration of particular matters. It further provides that the Central Government shall appoint a person to be the secretary of the council and provide other secretarial and other staff as considers necessary.

Clause 4.—This clause contains provisions for disqualifications for appointment as member of the National Council and specifies the circumstances for such disqualifications.

Clause 5.—This clause specify functions of the National Council which, *inter alia*, includes compiling and publishing a national register of clinical establishments, classify clinical establishments, develop minimum standards, collecting statistics in respect of clinical establishments, etc.

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

Clause 7.—This clause contains provisions for consultative process to be followed by the National Council for determining the standards and for classification of clinical establishments.

Clause 8.—This clause contains provisions for constitution of a State Council for clinical establishments or a Union territory Council for Clinical Establishments which would consist of a Chairman and thirteen members drawn from the fields specified therein. It also provides that the nominated or elected members of the State Council or the Union territory Council shall hold office for three years and shall be eligible for renomination or re-election as the case may be. It further provides that the State Council or Union territory Council shall perform, (a) compiling and updating the State Register of Clinical Establishment; (b) sending monthly returns for updating the National Register; (c) representing the State in the National Council; (d) hearing of appeals against the orders of the authority; and (e) publication on annual basis a report on the state of implementation of standards within their respective States.

Clause 9.—This clause fixes responsibility of the State Council for clinical establishments to compile and update the State register of clinical establishments and send monthly returns in digital format for updating the National Register.

Clause 10.—This clause provides that every State shall set up an authority to be called district registering authority for each district for registration of the clinical establishments which would consist of chairperson, convenor and three members as provided by rules to be made by the Central Government. It also provides that for the purpose of provisional registration, the District Health Officer or the Chief Medical Officer shall exercise the powers of the authority.

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

Clause 12.—This clause provides conditions for registration and continuation of clinical establishment. It provides the minimum standards of facilities and services, the minimum qualifications for the personnel, provisions for maintenance of records and reporting. It also provides that every clinical establishment shall provide staff, facilities for medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment.

Clause 13.—This clause empowers the Central Government to make rules to classify clinical establishments of different systems into categories and for different standards for different categories keeping in view the local conditions.

Clause 14.—This clause provides procedure for making application for provisional registration. The application to the authority shall be in the proforma along with such fees as may be provided by rules to be made by the State Government. It also provides that if any clinical establishment is in existence at the time of commencement of the proposed legislation, such application shall be made within one year from the date of the commencement of proposed legislation and a clinical establishment which comes into existence after commencement of this Act shall apply for permanent registration within a period of six months. It further provides that if any clinical establishment is already registered under any existing law even then it shall apply for registration under this clause.

Clause 15.—This clause provides that the authority shall within ten days from the date of receipt of application, issue provisional certificate for clinical establishments in such manner as may be provided by rules by the State Government.

Clause 16.—This clause provides that the authority shall not conduct any inquiry prior to the grant of provisional registration for clinical establishments. It also provides that the authority shall within a period of forty-five days from the grant of provisional registration, cause to be published all particulars of clinical establishments so registered provisionally.

Clause 17.—This clause provides that subject to the provision of clause 23 every provisional registration is valid for one year and such registration shall be renewable.

Clause 18.—This clause provides that every clinical establishment shall display the certificate of registration in a conspicuous place in the clinical establishment so as to be visible to every person visiting such establishment.

Clause 19.—This clause provides for issuing duplicate certificate by the authority 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 or management, the clinical establishment shall inform the authority of such change. It also provides that in the event of change of category or location of registration 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 of clinical establishments by the registering authority.

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

Clause 23.—This clause provides that where the clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond,—

(i) the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of the proposed legislation;

(ii) the period of two years from the date of notification of the standards in case of clinical establishments which come into existence after the commencement of the proposed legislation but before the notification of the standards;

(iii) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified.

Clause 24.—This clause provides procedure for making application for permanent registration. It provides that an application to the authority shall be made in the form and accompanied by such fees as may be provided by rules by the State Government.

Clause 25.—This clause provides that every clinical establishment shall submit evidence of having complied with the prescribed minimum standards in such manner, as may be provided by rules by the State Government.

Clause 26.—This clause provides that as soon as the clinical establishment submits the required evidence of having complied with the prescribed minimum standards, the authority shall display the same for information of the public for filing objections, if any, for a period of thirty days before processing for grant of permanent registration.

Clause 27.—This clause provides for communication of objections received by the authority within the period referred to in clause 26 to the clinical establishment for response within a period of forty-five days.

Clause 28.—This clause provides that permanent registration shall be granted only when a clinical establishment fulfils the standards for registration as may be provided by rules by the Central Government.

Clause 29.—This clause provides time limit to the authority for allowing or disallowing of registration and record its reasons for disallowing the application.

Clause 30.—This clause provides for issuing certificate of permanent registration in such form and containing such particulars as may be provided by rules by the State Government. It further provides that the certificate issued under the said clause shall be valid for a period of five years from the date of issue. It also provides for renewal of permanent registration and procedure therefor. However, the provisions of clauses 18, 19, 20 and 21 also apply to permanent registration.

Clause 31.—This clause provides for applying fresh application 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 the conditions of the registration are not complied with; or the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this proposed legislation. It also provides that the authority after giving a reasonable opportunity to the clinical establishment satisfied that there has been a breach of any of the provision of the proposed legislation or the rules; it may by an order cancel its registration and every such cancellation order shall take effect if no appeal has been preferred, on the expiry of the period prescribed for such appeal and if any appeal has been preferred and dismissed, from the date of the order of such dismissal. It further provides that such cancellation of registration shall be effective immediately if there is an imminent danger to the health and safety of general public.

Clause 33.—This clause provides for inspection or inquiry in respect of any registered clinical establishment, its buildings, laboratories and also of the work conducted or done by it and intimating the inspection report to the clinical establishment and advise that establishment upon the action to be taken. It also provides that the clinical establishment shall report to the authority, the action, if any, has been taken upon the results of such inspection. If no action is taken to the satisfaction of the authority, it may issue directions and the clinical establishment shall comply with such directions.

Clause 34.—This clause provides that the registering authority or an officer authorised by it after giving prior notice, may enter and search any clinical establishment suspecting of not being registered under the provisions of proposed legislation in the manner as may be provided by rules by the State Government. However, the clinical establishments shall offer reasonable facilities for such inspection or enquiry.

Clause 35.—This clause provides that fees may be charged for different categories of clinical establishments as may be provided by rules by the State Government.

Clause 36.—This clause contains provisions for appeal. Any person aggrieved by an order of the registering authority refusing to grant or renew a certificate of registration or revoking a certificate, can appeal to the State Council within such period and in such form accompanied by such fees as may be provided by rules by the State Government. However, the State Council may entertain an appeal after expiry of the period as said above, if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

Clause 37.—This clause provides that the authority shall within a period of two years from its establishment, compile, publish and maintain in digital format a register of clinical establishments in such form and manner as may be provided by rules by the State Government. It also provides that every authority set up for the registration of the clinical establishments shall in digital format supply to the State Council a copy of every entry made in the register of clinical establishments to ensure maintenance of up-to-date registers.

Clause 38.—This clause provides that every State Government shall maintain State register of clinical establishments in digital and in such form and containing such particulars, as may be prescribed by the Central Government. It also provides that every State shall supply a copy of the State register of clinical establishments in digital format to the Central Government.

Clause 39.—This clause provides for maintenance of National Register of clinical establishments in digital format by the Central Government. It also provides that the said Register shall be an amalgam of the State Register of clinical establishments and shall cause to be published in digital format.

Clause 40.—This clause contains provisions for penalties for contravention of any provisions of the proposed legislation, if no penalty is provided elsewhere. It provides punishment for the first offence with fine which may extend to ten thousand rupees; for 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.

Clause 41.—This clause contains provisions for monetary penalties for non-registration of clinical establishments. It provides punishment for the first offence with a monetary penalty which may extend to fifty thousand rupees, for second offence with monetary penalty which may extend to two lakh rupees and for any subsequent offence with monetary penalty which may extend to five lakh rupees. It further provides that if a person knowingly serves in a clinical establishment which is not duly registered under the proposed legislation, shall be punishable with monetary penalty which may extend to twenty-five thousand rupees. It also provides that for the purpose of adjudging the monetary penalty under this clause, the authority shall hold an inquiry after giving reasonable opportunities to the person concerned. It also provides that in determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated. It also provides that any person aggrieved by the decision of the authority may prefer an appeal to the State Council. The monetary penalty levied under this clause shall be credited to such account as the State Governments may by order specify.

Clause 42.—This clause provides for monetary penalty for disobeying any direction given by any person or authority empowered under the proposed legislation or obstructs any person or authority in discharge of any functions which that person or authority is required or empowered under the proposed legislation to discharge. It provides a monetary penalty which may extend to five lakh rupees. It also provides that for the purpose of adjudging the monetary penalty under this clause, the authority shall hold an inquiry after giving reasonable opportunities to the person concerned. It also provides that while determining the quantum of monetary penalty, the authority shall take into account the

category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated. It also provides that any person aggrieved by the decision of the authority may prefer an appeal to the State Council. The monetary penalty levied under this clause shall be credited to such account as the State Governments may by order specify.

Clause 43.—This clause provides for penalty for contravention of any provisions of the proposed legislation or any rule 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. It provides punishment with fine which may extend to ten thousand rupees.

Clause 44.—This clause contains provisions for contravention of any of the provisions of the proposed legislation or any rule by companies. It provides that a contravention under the proposed legislation has been committed by a company, every person directly in charge of, and responsible to, the company for the conduct of its business at the time of committing contravention shall be deemed to be guilty of the contravention and shall be liable to fine unless he provides that the contravention was committed without his knowledge or that he exercised all due diligence to prevent the commission of contravention. It also provides that where any contravention under the proposed legislation has been committed with the consent or connivance of, or 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. The explanation to the clause seeks to define the terms "company" and "director".

Clause 45.—This clause contains provisions for offences by Government Departments. It provides that where an offence under the proposed legislation has been committed by any Department of the Government within a period of six months after commencement of this Act, 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.

Clause 46.—This clause provides for recovery of fines as an arrear of land revenue. It provides that the State Council of clinical establishments may prepare a certificate specifying the fine due from such person and send it to the Collector of the district in which such person owns any property or carries on his business.

Clause 47.— This clause contains provisions for protection of action taken in good faith under the proposed legislation. It provides that no suit, prosecution or other legal proceedings shall lie against any authority or any member of the National Council or State Council or any officer authorised in this behalf in respect of anything done in good faith in pursuance of such proposed legislation or of any rule or order made, or direction issued, thereunder.

Clause 48.— This clause provides that every clinical establishment should furnish to the authority or the State Council or the National Council such returns or the statistics and other information as provided by rules to be made 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 establishments and such directions shall be binding.

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

Clause 51.— This clause contains provisions for power to remove difficulties. It provides that if any difficulty arises in giving effect to the provisions of the proposed legislation, the Central Government may, by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of the proposed legislation, as appear to it to be necessary or expedient for removing the difficulty. However, no such order can be made under this section after expiry of two years from the commencement of the proposed

legislation. It further provides that every order made under this section shall, as soon as may be after it is made, be laid 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 in respect of the matters specified in the said clause.

Clause 53.— This clause provides that every rule made by the Central Government under this Act as soon as may be after it is made, laid before each House of Parliament.

Clause 54.— This clause empowers the State Government to make rules for carrying out the provisions of the proposed legislation which do not fall within the purview of section 52 and in particular in respect of the matters specified in the said clause.

Clause 55.— This clause provides that every rule made by the State Government shall be laid as soon as may be after it is made, before each House of State Legislature.

Clause 56.— This clause provides that the provisions of this Act shall not apply to the States in which the enactments specified in the Schedule are applicable. However, it provides that the States in which the enactments referred to in sub-section (1) are applicable, and such States subsequent to the commencement of this Act, adopts this Act under clause (1) of article 252 of the Constitution, the provisions of this Act shall, subsequent to such adoption, apply in that State. It also provides that the Central Government may, by notification, amend the Schedule.

FINANCIAL MEMORANDUM

Clause 3 of the Bill empowers the Central Government to establish a National Council for clinical establishment. It provides for payment of allowance to the members 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 Government 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 rupees one crore.

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 the various provisions of the Bill and regarding—

(a) allowances for the members of the National Council under sub-section (5) of section 3;

(b) appointment of such person to be Secretary of the State Council by the Central Government under sub-section (10) of section 3;

(c) the determination of standards and for classification of clinical establishments under section 7;

(d) the qualification and the terms and conditions for the members of the authority under clause (c) of sub-section (1) of section 10;

(e) the procedure under which the powers of the authority may be exercised by the District Health Officer or Chief Medical Officer for the purpose of provisional registration of clinical establishment under sub-section (2) of section 10;

(f) the minimum standards of facilities and services under clause (i) of sub-section (1) of section 12;

(g) the minimum number of personnel under clause (ii) of sub-section (1) of section 12;

(h) the maintenance of record and reporting by the clinical establishment under clause (iii) of sub-section (1) of section 12;

(i) other conditions for registration and continuation of clinical establishment under clause (iv) of sub-section (1) of section 12;

(j) classification of clinical establishment under sub-section (1) of section 13;

(k) the different standards for classification of clinical establishments under sub-section (2) of section 13;

(l) the minimum standards for permanent registration under section 28; and

(m) 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 proforma and the fee to be paid for registration of clinical establishment under sub-section (1) of section 14;

(b) the form and details of application under sub-section (3) of section 14;

(c) the particulars and information contained in certificate of provisional registration under section 15;

(d) the manner of publication of all particulars of the clinical establishment proposed to be registered under sub-section (2) of section 16;

(e) the fees to be paid to issue a duplicate certificate under section 19;

(f) the manner in which the authority shall publish the names of the clinical establishments whose registration expired under section 21;

(g) the enhanced fees to be charged for renewal after expiry of provisional registration under section 22;

(h) the form of the application and fees to be charged by the State Government under section 24;

(i) the manner of submitting evidence of the clinical establishments having complied with the minimum standards under section 25;

(j) the manner of displaying information of the clinical establishments having complied with the minimum standards for filing objection under section 26;

(k) the expiry of period specified in section 29;

(l) the form and particulars of the certificate of registration under section 30;

(m) the manner of entry and search of clinical establishment under section 34;

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

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

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

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

(r) the manner of supply to the State Council in digital format the entry made in the register of clinical establishment under sub-section (2) of section 37;

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

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

4. The rules made by the Central Government under clause 52 shall be laid before each House of Parliament under clause 53 and the rules made by the State Government under clause 54 shall be laid before the State legislature under clause 55 of the Bill.

5. The matters in respect of which rules may be made are generally matters of administrative detail and procedure 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

A
BILL

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

(Shri Ghulam Nabi Azad, Minister of Health and Family Welfare)