

**THE MAHARASHTRA CLINICAL ESTABLISHMENTS  
(REGISTRATION AND REGULATION) BILL 2014 DRAFT**

**A BILL**

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

***Preamble** - 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 to safeguard rights of patients' and health care providers. So that mandate of article 47 of the Constitution for improvement in public health may be achieved;*

**CHAPTER I**

**PRELIMINARY**

Short title,  
application and  
commencement.

**1.** (1) This Act may be called the Maharashtra Clinical Establishments (Registration and Regulation) Bill, 2014.

(2) It applies to the whole of the State of Maharashtra.

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

Definitions.

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

(a) “authority” means the Local registering authority set-up under section 10;

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

(c) “clinical establishment” means—

(i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium, wellness clinics, day care centers or an institution by whatever name called that offers services, facilities requiring prevention, diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized 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 prevention, 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 Public authority; and

- (e) a single doctor,  
but does not include clinical establishments owned, controlled and managed by Armed forces.
- (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 women, 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) “Council” means the State 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 State Government;
- (h) “recognized system of medicine” means Allopathy, Ayurveda, Homoeopathy, Yoga, Naturopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognized by the Central or State Government and “registered medical practitioner” means qualified and registered personnel from “recognized system of medicine”
- (i) “register” means the register maintained by the authority, State Government under sections 37, 38 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) “standards” means the conditions that the State Government may prescribe under section 13 subsection (2), for the registration of clinical establishments;
- (m) “to provide primary emergency first aid measures means, with respect to an emergency medical condition specified in clause (d), to provide basic primary emergency first aid treatment, within facilities prescribed before the transfer of the individual from a clinical establishment.

## CHAPTER II

### STATE COUNCIL FOR CLINICAL ESTABLISHMENTS

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

Establishment of  
state council.

(2) The State Council shall consist of—

(a) Director of Health Services, Government of Maharashtra, ex officio, who shall be the Chairperson; Director of Medical Education and Research ex officio, who shall be the co chairperson ;

(b) One representative from each council nominated by the—

- (i) Maharashtra Dental Council constituted under section 3 of the Dentists Act, 1948;
- (ii) Maharashtra Medical Council constituted under section 3 of the Indian Medical Council Act, 1956;
- (iii) Maharashtra Nursing Council of India constituted under section 3 of the Indian Nursing Council Act, 1947;
- (iv) Maharashtra homeopathic Council constituted under Bombay Homeopathic practitioners Act 1959 amended 1980.
- (v) Maharashtra Council of Indian Medicine constituted under Maharashtra Medical Practitioners Act 1961.

(e) one representative to be nominated by the State Indian Medical Association;

(i) one representative from the line of paramedical systems excluding systems that have been given representation under clause (b);

(j) One representatives from Women's organization working in Health sector nominated by State Government

(k) Two representatives from NGO working in patients' rights nominated by State Government.

(l) one representative each from the Associations of Indian Systems of Medicines relating to Ayurveda, Naturopathy, Yoga, Siddha, Homeopathy and Unani to be nominated by the State Government;

(j) one representative from the Medical consultants association.

(k) Full time officer not below rank of Assistant Director to assist the system

(m) Joint Director (Hospitals) Member Secretary

(3) The nominated members of the State 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 members of the State council shall be entitled for such allowances as may be prescribed by the State Government.

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

(6) The functions of the State Council may be exercised notwithstanding any vacancy therein.

(7) The State Government shall provide the State Council with, financial assistance for manpower required and such other resources as the State Government considers necessary required for execution of act.

4. A person shall be disqualified for being appointed as a member of the State 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 State 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 removed by respective council.
- (e) has, in the opinion of the State 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 State Council shall —**

Functions of State Council.

- (a) classify the clinical establishments into different categories;
- (b) develop the templates for developing minimum standards and minimum standards of clinical establishments by appointing different committees and their periodic review;
- (c) determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the clinical establishments;
- (d) Safeguard the interests of patients and health care providers alike.
- (e) Develop the data relevant to Public Health and statistics with its periodicity and formats to be mandatorily provided from clinical establishments by appointing committee and collect the information in respect of clinical establishments;
- (f) compile and publish a State Register of Clinical Establishments within two years from the date of the commencement of this Act;
- (g) **Hearing of appeals from first appellate authority**
- (h) Sending periodic returns for updating National Register for Clinical Establishments
- (i) Publication on annual basis a report on the status of implementation of the act.
- (j) direct to cancel registration of such clinical establishments where there is imminent danger to public health and the health and safety of patients and staff;
- (k) Suggest to the State government the penalty to be levied on the concerned offence for the various categories of clinical establishments which would include the nature, size and location
- (l) perform any other function determined by the State Government from time to time.
- (m) Notify data relevant to Public Health which is mandatorily provided by clinical establishments including their periodicity and formats and make it available in Public domain.

**6.** The State Council may appoint any person or persons, organization or institution who are not members of the State Council or committee as it deems fit, for such periods, not exceeding two years whose assistance or advice it may desire in carrying out any of the provisions of this Act or for the consideration of particular matters .

Power to seek advice or assistance.

**7.** The State 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.

State Council to follow consultative process.

**CHAPTER III**

**CONDITIONS AND AUTHORITY FOR REGISTRATION**

Authority for registration.

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

### Local registering authority

1. Medical Officer Health of Municipal Corporation – Chairman **For Municipal Corporation area**
2. Deputy Medical Officer Health of Municipal Corporation – Member Secretary.
3. Medical officer delegated this subject appointed by Chairman - Member
1. Civil Surgeon – Chairman **For Municipality and cantonment area**
2. Additional Civil Surgeon – Member Secretary
3. Medical officer delegated this subject appointed by Chairman - Member
1. District Health Officer – Chairman **Gram Panchayat**
2. Additional District Health Officer – Member Secretary
3. Medical officer delegated this subject appointed by Chairman - Member

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional and final registration of clinical establishments under section 15 and 25, the Medical officer Health of corporation, District Health Officer or Civil Surgeon shall exercise the powers of the local registering authority as per procedure that may be prescribed.

(3) The local registering authority shall perform the following functions, namely:-

- (a) grant, renew, suspend or cancel registration of a clinical establishment;
- (b) enforce compliance of the provisions of the Act and the rules made thereunder;
- (c) investigate complaints of breach of the provisions of the Act or the rules made thereunder and take appropriate action;
- (d) prepare and submit reports periodically of such nature as directed by the state Council;
- (e) report to the state Council on a quarterly basis the action taken against non-registered clinical establishments;
- (f) perform such other functions as may be prescribed.

(4) The State Government shall provide the Local Registration Authority with required manpower, finances and such other resources as the State Government considers necessary for the proper functioning of the council and execution of the provisions of the act.

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 and continuation

**12. (A) For temporary registration and continuation every clinical establishment shall fulfil the criteria of**

- (i) minimum qualification and registration of concerned person under management of clinical establishment.
- (ii) owner on clinical establishment shall undertake to appoint qualified and registered person of concerned category to run clinical establishment. In case of noncompliance it will be responsibility of owner.

**(B) For permanent 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 qualification and requirement of personnel as may be prescribed;
- (iii) provisions for maintenance of records and reporting as may be prescribed;
- (iv) Observance of charter of patients' rights and responsibilities as may be

prescribed.

(v) Availability of rates of facilities and services.

(vi) Such other conditions as may be prescribed.

(vii) compliance with standards of safety, infection control and standard treatment guidelines as may be prescribed.

(C) Clinical establishment should provide basic primary emergency first aid treatment, within facilities prescribed before the transfer of the individual.

(D) In cases of advanced medical emergency treatment given to unknown or unidentified patients, cost shall be reimbursed by Government as per rates prescribed.

13. Clinical establishment of different systems shall be classified into such categories, as may be suggested by the State council, from time to time.

Classification of  
clinical  
Establishments.

14. The State Council shall within a period of two years from its establishment may prescribe first set of standards of clinical establishments. Provided that in prescribing the standards for clinical establishments, the State Government shall have regard to the local conditions.

Standards of  
clinical  
establishments

#### **CHAPTER IV PROCEDURE FOR PROVISIONAL AND PERMANENT REGISTRATION**

15. (1) All clinical establishments in Maharashtra shall be registered with the authority under the provisions of this Act and the rules made there under.

Application for  
provisional  
certificate of  
registration.

(2) 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.

(3) The application shall be filed in person or by post or online. In charge of clinical establishment who will apply for registration of clinical establishment should be minimum qualified and registered person of concerned council. In case of company, owner shall apply, however the qualified person to manage the clinical establishment is necessary. The application should contain details of the qualified and registered personnel where applicable and as prescribed.

(4) 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.

(5) 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.

(7) 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 section 15 sub-section (2).

(8) The Authority shall acknowledge the receipt of the application for

provisional registration or permanent registration as the case may be, in such form as may be prescribed.

**16.** The authority shall, within a period of thirty 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. If provisional registration is not granted within 30 days, the clinical establishment shall be deemed to be registered.

Provisional certificate.

**17. (1)** The authority shall not conduct any inquiry prior to the grant of provisional registration. However it should be verified by authority that incharge of clinical establishment who will be applying for provisional registration of clinical establishment shall be "registered medical practitioner." of concerned category of clinical establishment.

No inquiry prior to provisional registration.

(2) Notwithstanding the grant of the provisional certificate of registration, the authority shall publish in such manner, as may be prescribed, all particulars of the clinical establishment.

**18.** 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 for next one year.

Validity of provisional registration.

**19.** The provisional or permanent 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 the certificate of registration.

**20.** 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.

**21. (1)** The certificate of registration shall be non-transferable.  
(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.  
(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.  
(4) In the event of addition of facility to the clinical establishment, it should be informed to authority immediately after of such event. Difference in registration fees as prescribed may be paid to authority within thirty days.

Publication of expiry of registration.

**22.** 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 provisional and permanent registration has expired.

Renewal of provisional registration.

**23.** 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.

Time limit for provisional registration.

**24.** Where clinical establishments in respect of which standards have been notified by the state Government, provisional registration shall not be granted or renewed beyond

- (i) the period of three years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act;
- (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
- (iii) the period of six months from date of notification of standards for clinical establishments which come in to existence after standards have been notified.

Application for permanent registration.

**25.** (1) Application for permanent registration of a clinical establishment shall be made to the authority in form, manner and fees, as may be prescribed under the rules of this act.

(2) The application for permanent registration shall be filed in person or by post or online by the owner of the clinical establishment as the case may be. The application should contain details of the qualified and registered personnel where applicable and as prescribed.

Verification of the application for permanent registration.

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

Display of information.

**27.** As soon as the clinical establishment submits the required evidence of having complied with the prescribed minimum standards, the authority shall display information for a period of thirty days before processing for grant of permanent registration. The authority may cause inspection, if necessary.

Standards for permanent registration

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

Allowing or disallowing of registration.

**29.**

**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 25, 26, 27 and 28 shall also apply.

(4) The applications for renewal of permanent registration shall be made within three 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 provisional and permanent registration shall not debar a clinical establishment from reapplying after compliance for permanent registration under section 25 and after providing such evidence, as may be required, of having rectified the deficiencies on which grounds the earlier application was disallowed within 30 days. This will not involve additional fees within 30 days.

Compliance for provisional and permanent registration.

**32.** (1) If, at any time after any clinical establishment has been provisionally registered, registration may be cancelled or suspended by the authority or state Government if,—

Cancellation of provisional and permanent registration.

- (a) If criteria of qualification and registration of a person entrusted with the management of the clinical establishment are not complied with
- (b) If there is imminent danger to the safety of patients by the clinical establishment
- (c) the person entrusted with the management of the clinical establishment has been convicted of an offence under any medical acts.

(2) If, at any time after any clinical establishment has been permanently registered registration may be cancelled or suspended by the authority or state Government if,—

- (a) the conditions of the registration are not being complied with;
- (b) If there is imminent danger to the safety of patients by the clinical establishment
- (c) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act will be dealt with as per provisions of section 39. 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. This shall apply to Clinical Establishment who is given provisional and permanent registration as well.

(3) 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 as per provisions of section 39.

(4) Every order made under sub-section (3) 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, to be made by such multi-member inspection team as prescribed 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 there at with due notice.

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 Government.

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

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 appropriate appellate body as prescribed: Provided that the appropriate appellate body 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.

(3) If a patient is aggrieved by violation of charter of patients' rights such a patient or his / her next of kin may complain to appropriate appellate body as prescribed. **if patient / relatives have fulfilled their responsibility in terms of payment of agreed charges.**

(4) To be redrafted

(5) Frivolous complaints shall be entitled for penalty as may be prescribed.

#### **Appellate authority for clinical establishments-**

1) The Government shall by notification constitute *the Appellate Body* for clinical establishments in each of the districts of the State.

#### **Appellate authority**

1. Commissioner Municipal Corporation – Chairman
2. Assistant Director (Medical) from Deputy Director Office – Member Secretary.
3. Group A Class 1 Officer from corporation other than MOH – Member
4. One representative of Indian Medical Association– Member
5. One representative from the Medical consultants association - Member

**For  
Municipal  
corporation  
area**

6. One representative from AYUSH - Member
7. One representative from NGO working for health- Member
8. One representative from women's organization- Member

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| <ol style="list-style-type: none"> <li>1. Collector – Chairman</li> <li>2. Assistant Director (Medical) from Deputy Director Office – Member Secretary</li> <li>3. Group A Class 1 Officer from Public Health Department– Member</li> <li>4. One representative of Indian Medical Association – Member</li> <li>5. One representative from the Medical consultants association.</li> <li>6. One representative from AYUSH - Member</li> <li>7. One representative from NGO working for health rights - Member</li> <li>8. One representative from women's organization - Member</li> </ol> | <p><b>For other than Municipal Corporation area</b></p> |
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2) The appointed members of the Appellate authority shall hold office for a term of three years, but shall be eligible for re-appointment for maximum of one more term of three years.

Provided that the appointed person shall hold office for so long as he/she holds the appointment of the office by virtue of which s/he was appointed to the local Appellate Body.

3) The members of the Appellate authority shall be entitled for such allowances as may be prescribed by the Government.

4) The Appellate authority shall meet at least once in a two months or if necessary as and when required.

5) The functions of the Appellate authority may be exercised notwithstanding any vacancy therein.

6) The Government shall provide the Appellate authority with such other staff and budget as are

7) The Appellate authority may seek the assistance of any expert person or body whose assistance or advice it may desire in carrying out its function

8) Disqualifications for appointment as member of Appellate authority for clinical establishments – A person shall be disqualified for being appointed as a member of the District Appellate Body if the person—

(a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the 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 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.

**9. Functions of the Appellate authority –**

The Appellate authority shall hear and dispose of appeals by clinical establishments against the orders of local regulatory authority and complaint about violation of Charter of Patients' Rights, responsibilities and of minimum standards.

## 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 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.

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 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 15<sup>th</sup> day of the following month.

## CHAPTER VI

### PENALTIES

Penalty.

**39.** 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 five thousand rupees, for any second offence with fine which may extend to ten thousand rupees and for any subsequent offence with fine which may extend to fifty thousand rupees or process of closure of clinical establishment.

**40.** (1) Whoever carries on a clinical establishment without registration shall, on first conviction, be liable to a monetary penalty up to ten thousand rupees and for further contravention with a monetary penalty which may extend to twenty five thousand rupees or process of closure of clinical establishment. Appeals if any may be disposed of before initiating the process as above. Carrying out clinical establishment without registration means either not applied or not renewed registration.

Monetary penalty for non-registration.

(2) Any registered medical practitioner knowingly serves in a clinical establishment which is not duly registered under this Act, shall be liable to a 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 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 monetary 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 if desired shall prefer an appeal to the appropriate forum within a period of one month from the date of the said decision. During this period the decision of authority will be on hold.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

**41.** (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 liable to a monetary penalty which may extend up to twenty five thousand 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 liable to monetary penalty which may extend up to one lakh rupees.

(3) (i) 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.

(ii) While determining the quantum of monetary penalty, the Local 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 as prescribed.

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstance 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 monetary penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8)

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

(7) The manner of filing the appeal referred to in sub-section (6) 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.

**42.** 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 that may extend to one thousand rupees.

Contravention by companies.

**43.** (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 if authority is satisfied to that effect.

(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

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

Offences by  
Government  
Departments.

**44.** (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.

**45.** Whoever fails to pay the fine, Appellate authority 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

**46.** (1) No suit, prosecution or other legal proceedings shall lie against any authority or any member of the local registering authority or any

Protection of  
action taken in  
good faith.

officer authorised on his 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 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.

**47.** 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 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.

**48.** 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.

**49.** Every employee of the authority and the state Council or appropriate forums 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.

**50.** (1) If any difficulty arises in giving effect to the provisions of this Act, the State 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 State Legislature.

Laying of rules.

**51.** Every rule made by the State Government under this Act shall be laid, as soon as may be after it is made, before each State legislature, 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.

**52.** (1) The State 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.—

1. allowances for the members of the State Council under sub-section (4) of section 3;
2. Consultative process to be followed for determining standards and classification of clinical establishments under section 7;
3. the procedure under which the powers of the local registration authority may be exercised for the purpose of provisional registration of clinical establishment

4. the minimum standards of facilities and services under clause (i) of section 12;
5. the minimum number of personnel under clause (ii) of section 12; the maintenance of records and reporting by the clinical establishment under clause (iii) of section 12;
6. other conditions for registration and continuation of clinical establishment under clause (iv) of section 12;
7. classification of clinical establishment under section 13;
8. the different standards for classification of clinical establishments under sub-section (1) of section 13;
9. the minimum standards for permanent registration under section 28;
10. the form and particulars to be contained in the register to be maintained under section 38.
11. the proforma and the fee to be paid for registration under sub-section (1) of section 15;
12. the form and details of application under sub-section (3) of section 15;
13. the particulars and information contained in certificate of provisional registration under section 16;
14. the manner of publication of all particulars of the clinical establishments proposed to be registered under sub-section (2) of section 27;
15. the fees to be paid to issue a duplicate certificate under section 20;
16. the change of ownership or management to be informed by the clinical establishment to the authority under sub-section (2) of section 20;
17. the manner in which the authority shall publish the names of the clinical establishments whose registration expired under subclause (2) of section 21;
18. the enhanced fees to be charged for renewal after expiry of provisional registration under section 23
19. the form of the application and fees to be charged by the State Government for provisional registration under section 15 (1) for permanent registration under section 25;
20. the manner of submitting evidence of the clinical establishments having complied with the minimum standards under section 26;
21. Manner and time of publication of expiry of registration specified in section 22;
22. the form and particulars of the certificate of registration under section 30 (1);
23. period and manner within which an appeal shall be preferred under clause (a) of sub-section (1) (2) (3) (4) of section 36;
24. the manner of entry and search of clinical establishment under section 34;
25. the fees to be charged by the State Government for different categories of clinical establishments under section 35
26. the manner and the period within which an appeal may be preferred to the State Council under section 5 (g);
27. the form and the manner in which the register to be maintained under sub-section (1) of section 38;
28. 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;
29. the manner of holding an inquiry by the authority under sub-section (3) of sections 40;
30. the manner of filing the appeal under sub-section (7) of sections 41;
31. the manner and the time within which the information is to be



furnished to the authority Section 5 (f) or the State Council section 37 (2) or the National Council section 38 (2) as the case may be, under section 48;

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

**53.** Every rule made by the State Government under this act shall be laid, as soon as may be after it is made, before each House of the State Legislature. Laying of rules.

**54.** The state Government may, as and when consider necessary, by notification amend the Schedule. Savings.

**55. Rights of patient**

(1) The patients and / or Person authorized by patient shall receive the relevant information about the nature, cause of illness, proposed care, and the expected results of treatment, treatment options, possible complications and the expected costs.

(2) Confidentiality of treatment and privacy during examination. Examination of female patient should be carried out in presence of female attendant.

(3) Non-discrimination about treatment and behaviour on basis of HIV Status.

(4) Complaint register should be made available in Clinical establishment.

(5) List of Specialists along with Qualifications Should be displayed at prominent place in Clinical establishment.

(6) Patient has the right to seek second opinion with due information to treating doctor. All copies of medical and diagnostic reports shall be made available to the patient or authorized person to facilitate second opinion.

(7) Patient and / or Person authorized by patient or guardian if patient is minor has a right to have an access to his / her clinical records during admission to Clinical establishment and Photocopy of indoor papers should be made available on request within 72 hours.

(8) Discharge card should be issued to patient mentioning: Diagnosis, clinical findings, results of investigations, treatment given, the patient's condition at the time of discharge and advice to patient.

(9) Patient has right to choose registered pharmacy or recognised diagnostic center at his / her own responsibility.

(10) Protection ensured by statutory guidelines and legally enabled provisions applicable to Clinical Establishments which are conducting clinical research.

(11) Informed consent prior to potentially hazardous tests / treatment.

**Responsibilities of patient**

(1) To provide relevant health information and history to the doctor

(2) Share all information to health care provider in case of other treatment is being pursued simultaneously

(3) To fully cooperate with the doctor during the treatment and follow doctor's advice properly with follow up visits.

(4) To respect the dignity of the doctors and other staff as human being and professionals.

(5) To preserve and share the past medical records

(6) To undertake to pay hospital bills as agreed.

(7) Not to resort to unlawful methods such as violence against the doctor or clinical establishment, which is a nonbailable offence.

(8) Follow rules of clinical establishments for its smooth functioning.

(9) Cooperate with health care provider for complying with legal requirements like notifiable diseases, post mortem and such others.

Standard Charter  
of Patients'  
Rights and  
responsibilities

AS PASSED BY VIDHAN SABHA

ON -----, 2014

**Bill No. -----**

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