

**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 provisional registration under section 14 and permanent registration issued under section 28;

(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) individual proprietorship or partnership firm

- (e) a local Public authority; and
- (f) a single doctor,

but does not include clinical establishments owned, controlled and managed by Armed forces.

Explanation – For the purposes of this clause ‘Clinical Establishment’ - Any dispute as to whether a procedure / establishment is to be covered under this definition shall be referred to state council for decision. State council, after giving a chance to the interested parties a chance to adduce evidence, shall give a decision on whether the clinical establishment carrying out the disputed procedure comes under the provision of the act.

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) or trauma 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) Appellate authority’ means the appellate authority for clinical establishments established under section 34

(g) Local registering authority means the registration authority for clinical establishments established under section 8

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

(i) “prescribed” means prescribed by rules made under this Act by the State Government;

(j) “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”

(k) “register” means the register maintained by the authority, State Government under sections 35, 36 of this Act containing the number of clinical establishments registered;

(l) “registration” means to register under section 9 and the expression registration or registered shall be construed accordingly.

(k) non registration means not applying or renewing temporary or permanent registration.

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

(n) “standards” means the conditions that the State Government may prescribe under section 12 for the registration of clinical establishments;

(o) “to provide basic emergency medical assistance” means, with respect to an emergency medical condition specified in clause (d), to provide basic emergency medical assistance, within facilities prescribed before the transfer of the individual from a clinical establishment where indoor facilities are available.

(p) “State register of Clinical establishments” means information in respect of clinical establishments of the state maintained in digital format and in such a form containing particulars as prescribed.

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 and Director AYUSH will be member.

(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.
- (vi) Maharashtra State Pharmacy Council constituted under Pharmacy Act, 1948
- (vii) Rehabilitation Council of India constituted under the Rehabilitation Council Act of 1992

(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); to be nominated by state government

(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.

Provided that the person nominated, shall hold office for such period till she/he holds appointment of the office by virtue of which She/he was nominated to the Council.

(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 such resources the state Government considers necessary for carrying out its functions and duties as provided for execution of act and rules and may give directions to the state council or local registering authority as it deem fit within the scope of act and rules made there under.

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 recognised 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 sub 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.
- (e) Notify the data relevant to public health information and statistics with its periodicity and formats to be mandatorily provided by clinical establishments and make it available in public domain as prescribed.
- (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 as second appellate body.
- (g) Sending periodic returns for updating National Register for

Clinical Establishments

- (h) Publication on annual basis a report on the status of implementation of the act.
- (i) 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 as prescribed.
- (j) Suggest the penalty to be levied on the concerned offence for the various categories of clinical establishments which would include the nature, size and location as prescribed.
- (k) perform any other function determined by the State Government from time to time.
- (l) In coordination with Public Health department state council would facilitate single window system for necessary legal clearances of clinical establishments which fall under its purview.

6. The State Council may associate or appoint any person or persons, organization or institution who are not members of the State Council or constitute committees 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 Rules for the consideration of particular matters.

Power to seek advice or assistance.

Provided the State council in exceptional circumstances may extend the term beyond 2 years.

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.

8. (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
 - 4. One representative nominated by Member Secretary Maharashtra Pollution Control board,
 - 5. One representative nominated by Director fire safety
 - 6. One representative nominated by Commissioner Food and Drugs administration
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- 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
 - 4. One representative nominated by Member Secretary Maharashtra Pollution Control board,

5. One representative nominated by Director fire safety
6. One representative nominated by Commissioner Food and Drugs administration

1. District Health Officer – Chairman Gram Panchayat
2. Additional District Health Officer – Member Secretary
3. Medical officer delegated this subject appointed by Chairman – Member
4. One representative nominated by Member Secretary Maharashtra Pollution Control board,
5. One representative nominated by Director fire safety
6. One representative nominated by Commissioner Food and Drugs administration

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional and final registration of clinical establishments under section 14 and 24 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) ensure that the registered institution maintains the minimum standards as long as the registration remains valid and call for periodic reports and/or inspect the institution to ensure the same.
- (g) 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.

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

Condition for registration and continuation

10. (A) The clinical establishment should be under the management of qualified and registered practitioner for the particular system and category.

For provisional registration

(i) owner on clinical establishment shall undertake to appoint qualified and registered person of concerned category to manage clinical establishment in case of single practioner clinical establishment.

(i) owner of clinical establishment shall undertake to appoint qualified and registered person of concerned category in case of multispecialty clinical establishment, and that clinical establishment will be under management of Registered Medical Practitioner.

(B) For permanent registration and continuation, every clinical establishment shall fulfil the following conditions, namely:—

(i) owner on clinical establishment shall undertake to appoint qualified and registered person of concerned category to manage clinical establishment in case of single practioner clinical establishment.

(ii) owner of clinical establishment shall undertake to appoint qualified and registered person of concerned category in case of multispecialty clinical establishment, and that clinical establishment will be under management of Registered Medical Practitioner.

(iii) the minimum standards of space, facilities and services as may be prescribed;

(iv) the minimum qualification and requirement of personnel as may be prescribed;

(v) provisions for maintenance of records, display and reporting as may be prescribed;

(vi) Observance of charter of patients' rights and responsibilities.

(vii) Display of notice regarding availability of rates of facilities and services.

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

(ix) Such other conditions as may be prescribed.

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

Classification of clinical Establishments.

12. 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. Every clinical establishment shall furnish to the authority or the State Council or the State government such information as may be prescribed

Standards of clinical establishments

CHAPTER IV PROCEDURE FOR PROVISIONAL AND PERMANENT REGISTRATION

13. (1) All clinical establishments in Maharashtra shall be registered with the authority under the provisions of this Act and the rules made there under. Where a clinical establishment is offering services in more than one category, it need not be registered separately however the local registering authority should ensure that qualified and registered medical practitioner of each concerned category is appointed and the location of the different clinical establishment are in the same premises.

Application for provisional certificate of registration.

(2) For the purposes of registration of the clinical establishment under section 8, an application in the prescribed proforma along with the prescribed fee shall be made to the authority as prescribed.

(3) The application shall be filed in person or by post or online.

(4) The application shall be made in such form and shall be accompanied by such details and fees 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 provisional registration shall be made within one month from the date of the notification of this Act and a clinical establishment which comes into existence after notification of this Act, shall apply for temporary registration before starting its functioning and for permanent registration after standards are finalized.

(6) 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.

14. 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 decided within 30 days, the clinical establishment shall be deemed to be registered.**

Provisional certificate.

15. (1) **Owner of clinical establishment will apply for provisional registration. The registering authority shall not conduct inquiry prior to grant of provisional registration, however registering authority has right to verify applications and make enquiry where felt necessary. In case of the clinical establishments owned by Government or a department of the Government, incharge of clinical establishment shall apply.**

Criteria of 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.

16. Subject to the provisions of section 22, 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. Clinical establishment should apply for renewal one month before date expiry.

Validity of provisional registration.

17. 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.

18. 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.

19. (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 the authority immediately and difference in registration fees as prescribed shall be paid to authority within thirty days.

Publication of expiry of registration.

20. The authority shall 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

21. The application for renewal of registration shall be made thirty days

provisional registration.

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, within a period the authority shall allow renewal of registration on payment of such enhanced fees, as may be prescribed.

Time limit for provisional registration.

22. 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.

23. (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. Where a clinical establishment is offering services in more than one category, it need not be registered separately however the local registering authority should ensure that minimum standards for each category for permanent registration are complied with and the location of the different clinical establishment are in the same premises.

Verification of the application for permanent registration.

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

Display of information.

25. 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. The information regarding services and facilities being provided need to be available in the public domain as prescribed.

Standards for permanent registration

26. Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration by the State council.

Allowing or disallowing of registration.

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

- (a) allowing the application for permanent registration; or
- (b) disallowing the application:

(c) No action on part of authority for sixty days will result in deemed registration of clinical establishment.

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

28. (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 24, 25, 26, 27 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. Process of deciding permanent registration should be completed within 30 days of application. During this period local registering authority should dispose application after due process as prescribed.

29. 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 24 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.

30. (1) If, at any time after any clinical establishment has been provisionally or permanently 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

(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 37 and 38. 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 30.

(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.

31. (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.

32. 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.

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

Appeal. and Grievance redressal

34. (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, appeal within 30 days and in such manner as may be prescribed, to the appropriate appellate body: 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 body as prescribed after making mutually agreed payment of dues.

(4) 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
 6. One representative from AYUSH - Member
 7. One representative from NGO working for health– Member
 8. One representative from women's organization– Member
- For
Municipal
corporation
area**

1. Collector – Chairman
 2. Assistant Director (Medical) from Deputy Director Office – Member Secretary
 3. Group A Class 1 Officer from Public Health Department– Member
 4. One representative of Indian Medical Association – Member
 5. One representative from the Medical consultants association.
 6. One representative from AYUSH - Member
 7. One representative from NGO working for health rights - Member
 8. One representative from women's organization - Member
- For other
than
Municipal
Corporation
area**

- 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.

35. (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 provide 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.

36. (1) State council 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 the state.

(2) State council shall provide in digital format to the national council, a copy of the state register of clinical establishments and shall inform the national council all additions to and other amendments in such register made, for a particular month by the 15th day of the following month.

CHAPTER VI

PENALTIES

Penalty.

37. 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. Thereafter if violation occurs, process of cancellation of registration and closure of clinical establishment may be initiated.

38. (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 second contravention with a monetary penalty which may extend to twenty five thousand rupees. For third contravention process of closure of clinical establishment should be started. Appeals if any may be disposed of before initiating the process as above.

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 39.

(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 filling the appeal referred to in sub-section (6) shall be such as may be prescribed.

39. (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 37, 38 and 39 shall be credited to such account as the state government may by order specify in this behalf.

Penalty for minor deficiencies.

40. 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.

41. (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

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

Offences by Government Departments.

42. (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.

43. 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

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

Protection of action taken in good faith.

(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. The amount collected by way of fees, fines, penalties collected for various purposes by the State Council and District Registration Authorities shall be utilized for the activities connected with the implementation of the provisions of the Act

45. 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.

46. 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.

47. 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.

48. (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.

Provision of
Basic
emergency
medical
assistance

49. a) Clinical establishment where indoor facilities are available should provide basic emergency medical assistance within facilities prescribed before the transfer of the individual from a clinical establishment.

b) In cases of basic emergency medical assistance given to unknown or unidentified patients, cost shall be reimbursed by the Government as per rates prescribed (Ref: As per recommendation of Law Commission report)

50. 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.

Laying of rules.

Power of State
Government to
make rules.

51. (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 space, facilities and services under section 10 B (iii);
5. the minimum number of personnel under section 10 B (iv);
6. the maintenance of records and reporting by the clinical establishment under section 10 B (v);;
7. other conditions for registration and continuation of clinical establishment under section 10 B (ix);
8. classification of clinical establishment under section 11;
9. the form and particulars to be contained in the register to be maintained under section 36.
10. the proforma and the fee to be paid for provisional registration under sub-section (4) of section 13;
11. the form manner and fees for application for permanent registration under sub-section (1) of section 23;
12. the particulars and information contained in certificate of provisional registration under section 14;
13. the manner of publication of all particulars of the clinical establishments proposed to be registered of section 25;
14. the fees to be paid to issue a duplicate certificate under section 18;
15. the change of ownership or management to be informed by the clinical establishment to the authority under sub-section (2) of section 19;
16. the manner in which the authority shall publish the names of the clinical establishments whose registration expired under section 20;

17. the manner of submitting evidence of the clinical establishments having complied with the minimum standards under section 26;
18. Manner and time of publication of expiry of registration specified in section 22;
19. period and manner within which an appeal shall be preferred under clause (a) of sub-section (1) (2) (3) (4) of section 34;
20. the manner of entry and search of clinical establishment under section 32;
21. the fees to be charged by the State Government for different categories of clinical establishments under section 33
22. the manner and the period within which an appeal may be preferred to the State Council under section 5 (g);
23. the form and the manner in which the register to be maintained under sub-section (1) of section 36;
24. the manner of providing information to National Council in digital format under sub- section (2) of section 36;
25. the manner of holding an inquiry by the authority under sub-section(3) (i) of sections 39;
26. the manner of filing the appeal under sub-section (7) of sections 39;
27. the manner and the time within which the information is to be furnished by the authority to state council under section 35 (2) or by State council to National Council section 36 (2) as the case may be, under section 48;
28. Descriptions of conditions where there is imminent danger to public health and the health and safety of patients and staff to cancel registration of such clinical establishments under section 5(i)
29. Suggest the penalty to be levied on the concerned offence for the various categories of clinical establishments which would include the nature, size and location under section 5(j)
30. difference in registration fees to be paid to authority within thirty days in the event of addition of facility to the clinical establishment under section 19(4)
31. prescribing due process to be adopted by local registering authority to dispose application for permanent registration under section 28 (4)
32. Manner in which multi-member inspection team to be formed and conduct inquiry in respect of a clinical establishment under section 31 (1)
33. Manner in which appeal is to be made by clinical establishment with prescription of fees for appeal under section 34 (1) (2).
34. proforma for complaint by patient or his / her next of kin for violation of charter of patients' rights under section 34(3)
35. Prescription of penalty for frivolous complaints under section 34(4)
36. any other matter which is required to be or may be prescribed by the State Government.

52. 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.

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

54. (i) Rights of patient Standard Charter of Patients' Rights and responsibilities

(1) Right to 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) Right of confidentiality of treatment and privacy during examination and

examination of female patient in presence of female attendant.

- (3) Right of non-discrimination about treatment and behaviour on basis of HIV Status.
- (4) Right to complain through complaint register which should be mandatory in Clinical establishment.
- (5) Right to access list of Specialists along with Qualifications display of which should be mandatory at prominent place in Clinical establishment.
- (6) Right to seek second opinion with due information to treating doctor. In such instance all copies of medical and diagnostic reports shall be made available to the patient or authorized person to facilitate second opinion.
- (7) Right to have an access to his / her clinical records during admission to Clinical establishment. In such instance patient and / or Person authorized by patient or guardian if patient is minor should receive photocopy of indoor papers on request within 72 hours.
- (8) Right to receive discharge card mentioning: Diagnosis, clinical findings, results of investigations, treatment given, the patient's condition at the time of discharge and advice to patient.
- (9) Right to choose registered pharmacy or recognised and registered diagnostic center at his / her own responsibility.
- (10) Right have protection ensured by statutory guidelines and legally enabled provisions applicable to Clinical Establishments which are conducting clinical research.
- (11) Right of informed consent prior to potentially hazardous tests / treatment.

(ii) 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 health care provider 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 clinical establishment 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.

Right to representation by counsel

55. Clinical establishment will have right to be represented by counsel in any of appellate bodies / registering authorities constituted under this act.

Repeal

56. Bombay Nursing Home Registration (Amendment 2005) Act is hereby repealed from date of enactment of this act.

AS PASSED BY VIDHAN SABHA

ON -----, 2014

Bill No. -----

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