

**GOVERNMENT OF RAJASTHAN
MINISTRY OF HEALTH & FAMILY WELFARE**

**THE CLINICAL ESTABLISHMENTS REGISTRATION & REGISTRATION
BILL OF 2006.**

An act to provide for the registration and regulation of clinical establishment in the Rajasthan State and for matters connected therewith or incidental thereto.

Whereas, it is considered expedient and in the public interest to enact a comprehensive legislative framework for the registration and regulation of clinical establishments.

And whereas, it is considered expedient to prescribe among other minimum standards for facilities, and services provided with a view to standardizing health care services and for achieving improvement of public health as enjoined by article 47 of the constitution;

And whereas, it is expedient to have a state registry of clinical establishments in electronic format with a view to create a reliable database about the availability and service capacity of clinical establishments in the state;

Be it enacted by Assembly in the fifth-fifth year of the Republic of India as follows:-

PRELIMINARY

1. Short Title, Extent and Commencement
 - i. This Act may be called the Clinical Establishments Registration and Regulation Act, 2006.
 - ii. It extends to the whole of Rajasthan.
 - iii. It shall come into force on such date as the State Government may, by notification in the official Gazette, appoint:
Provided that different dates may be appointed for different categories of clinical establishments.
Provided further that different dates may be appointed for different provisions of this act.
2. Declaration as to Expediency of control by the union.
 - i. It is hereby declared that it is expedient in the public interest that the State Government should take the registration and regulation of clinical establishments under its control.

Definition

3. In this Act, unless the context otherwise requires:
- i. Authority means the registering authority appointed under section 7;
 - ii. Certificate means certificate of registration issued under section ----;
 - iii. Clinical Establishments means and includes:
 - a. A hospital, maternity homes, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities with beds requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine.
 - b. A place established as an independent entity or part of an establishment as defined in (a) above in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, o-chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on.
- Establishment and administered or maintained by any person or body of persons, whether incorporated or not, but does not include a clinical establishment established and administered or maintained by the State Government or a local authority.
- iv. Notifications means a notification published in the Official Gazette;
 - v. Prescribed means prescribed by rules or regulations under this act;
 - vi. Registration means to register under section 4 of this Act and the expression registration or registered shall be constructed accordingly;
 - vii. Standards means the conditions that the State Government may prescribe under section 5 for the registration of clinical establishments;
 - viii. State Council means State Council for Clinical Establishments.
 - ix. Rules means rules made under this Act; and
 - x. Regulations mean regulations made under this Act.
 - xi. Section means a section of the Act.
 - xii. Prescribed means prescribed by the Rules and Regulations made under this Act.
 - xiii. 'Register' means a register maintained under this Act and the expression 'Registered' and 'Registration' shall be constructed accordingly.

CHAPTER 1 REGISTRATION OF CLINICAL ESTABLISHMENTS AND STANDARDS FOR REGISTRATION

4. REGISTRATION ESSENTIAL FOR ALL CLINICAL ESTABLISHMENTS

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

Explanation: This expression 'carry on' means to receive patients in a clinical establishment for providing treatment, diagnosis or nursing care.

CLINICAL ESTABLISHMENTS TO BE MAINTAINED IN ACCORDANCE WITH PRESCRIBED CONDITIONS

5. EVERY Clinical Establishment shall fulfill for registration and continuation of it such conditions under this Act as the State Government may prescribe may among others include standards for facilities and services, qualification of personnel, maintenance of records, and incident reporting.

CLASSIFICATION OF CLINICAL ESTABLISHMENTS

6 (I) Clinical Establishments shall be classified into such categories as may be prescribed by the State Government from time to time.

(ii) Different standards may be prescribed for categories so classified in sub section (i) above.

CHAPTER II

AUTHORITIES FOR REGISTRATION

CLINICAL ESTABLISHMENTS REGISTRATION AUTHORITY

7. The Chief Medical & Health Officer of the districts or its equivalent would be the authority for purposes of grant of registration under this Act.

8. The Chief Medical & Health Officer of the district shall be the District Registrar of Clinical Establishments.

9. It shall be the responsibility of the District Registrar to send such returns as may be prescribed for regular updating of the State Register of Clinical Establishments and such other information as may be required by the State Council.

STATE REGISTRAR OF CLINICAL ESTABLISHMENTS

10. Every State Government shall designate the Director Medical & Health Services (H.A) or any other officer subordinate to him as the Registrar of Clinical Establishments.

11. It shall be the responsibility of the Registrar of Clinical Establishments to compile and update the State Register of Clinical Establishments and further to send monthly returns in digital format for updating the State register.

STATE COUNCIL FOR CLINICAL ESTABLISHMENTS

12 (I) There shall be a State Council for determining standards for Clinical Establishments to be constituted by the State Government for:

- a. The Classification of clinical establishment into different categories,
- b. Developing minimum standards and their periodic review;
- c. Compiling, maintaining and updating a State register of clinical establishments.
- d. Performing any other function determined by the State Government from time to time.

- (ii) The State Council shall consist of the following members:-
- (a) DM&HS - ex-officio, who shall be the chairman.
 - (b) One representative each to be elected by the Executive Committee of :
 - i. Rajasthan Medical Council
 - ii. Rajasthan Nursing Council
 - iii. Rajasthan Pharmacy Council
 - (c) Three representatives to be elected by the Executive of the State Council of Indian Medicine representing the Ayurveda, Sidha, and Unani systems of medicine.
 - (d) One representative to be elected by the State Council of the Indian Medical Association.
 - (e) One representative from the Hospital Owners Association.
 - (f) One representative of Bureau of Indian Standard.
 - (g) One representative from the line of paramedical systems.
 - (h) The State Government may nominate not more than three eminent representatives of other recognized systems of medicine of which no statutory regulatory authority has been set up.
 - (i) One representative from State level consumer groups. The nominated of the Council shall hold office for one year, but shall be eligible for re-nomination.

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

Provided that the person nominated or elected, as the case may be, under clause 13 (ii) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the council.

- (iv) The Council may, subject to the previous approval of the State Government, make byelaws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.
- (v) The Council may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding two years, as it may decided on temporarily for the consideration of particular matters, persons who are not members of the Council.
- (vi) The functions of the Council may be exercised notwithstanding any vacancy therein.
- (vii) The State Government shall appoint a person to be Secretary of the Council and may provide the Council such other secretarial and other staff as the State Government considers necessary.

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

SOURCES OF REVENUE

14. The State Council may charge as may be prescribed in the regulations from all registering authorities a fee for including into the State register details of any clinical establishment registered by such authority. Such fee shall however not exceed 2% of all fees charged by the Registering Authority from the Clinical Establishments for registration and renewal thereof.

STATE COUNCIL TO FOLLOW CONSULTATIVE PROCESS

15. The State Council shall follow a consultative process for determining standards and for classification of Clinical Establishments as per procedure to be prescribed in the regulations.

CHAPTER III PROCEDURE FOR REGISTRATION

APPLICATION FOR REGISTRATION

16. i. For the purpose of registration of the clinical establishment, an application in the prescribed Performa along with the prescribed fee shall be submitted to the prescribed authority.
- iii. The prescribed authority shall facilitate online submission of applications so as to minimize the interface between the authority and the applicant.
- iv. The application shall be made in such form and shall be accompanied with such details as may be prescribed under this Act or rules/regulations made There under.
- v. If any clinical establishment is in existence at the time of the commencement of this Act, as application for its registration shall be made within one year form the date of the commencement of this Act.
- vi. If any clinical establishment is already registered under any existing law requiring registration of such establishments, even then it would have to apply for registration as prescribed at (i) above.

CERTIFICATE OF REGISTRATION

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

NO ENQUIRY PRIOR TO PROVISIONAL REGISTRATION

18. i. The authority shall not be required to conduct any enquiry prior to the grant of provisional registration.
- ii. Notwithstanding the grant of the provisional certificate of registration, the authority shall within a period of forty-five days from the grant of provisional registration, cause to be published in such manner as may be prescribed, all particulars of the clinical establishment proposed to be registered

VALIDITY OF PROVISIONAL REGISTRATION

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

DISPLAY OF THE CERTIFICATE OF REGISTRATION

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

21. In case the certificate is lost, destroyed, mutilated or damaged, the authority will issue a duplicate certificate on the request of the Clinical Establishment and on the payment of such charges as may be prescribed.

CERTIFICATE TO BE NON TRANSFERABLE

22. The Certificate of registration shall be non-transferable. In the even of change of ownership or change of management or on ceasing to function as Clinical Establishment, the Certificate of registration shall be surrendered to the authority and the Clinical Establishment shall apply fresh for grant of Certificate of Registration.

RENEWAL OF REGISTRATION

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

24. The authority shall also cause to be sent either electronically or by post to every registered clinical establishment a computer generated notice sixty days onwards should apply prior to the expiry of the registration.

25. Application for renewal of registration shall be made thirty days before the expiry of the validity of the certificate of provisional registration to the authority.

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.

PERMANENT REGISTRATION

26. Permanent registration shall be granted only after the State Government has prescribed minimum standards for the registration of clinical establishments.

27. Clinical Establishments in respect of which standards have been notified by the **State** Government, provisional registration shall not be granted/renewed beyond a period of three years from the date of notification of standards.

APPLICATION FOR PERMANENT REGISTRATION

28. Application for permanent registration shall be made to the prescribed authority in such form and be accompanied with such fees as may be prescribed.

VERIFICATION OF THE APPLICATION

29. The applicant shall have to submit evidence of the clinical establishment being complaint of the prescribed minimum standard in such manner as may be prescribed in the rules.

30. As soon as the applicant submits the prescribed evidence of the clinical establishment being complaint with the prescribed minimum standards, the authority shall cause to be displayed in such manner as may e prescribed all such evidence submitted by the applicant for a period of thirty days before processing for grant of permanent registration.

31. If no objections are received within thirty days from the date of publication by the authority, permanent registration shall be granted.

32. If any objections are received within the prescribed period, these shall be communicated to the applicant for response within a period as may by prescribed.

33. Immediately after the expiry of the prescribed period and within the next thirty days thereafter, the authority shall pass an order of physical inspection of the institution:

- a. Allowing the application for permanent registration;
- b. Disallowing the application.

34. If the authority allows the application, it shall issue a certificate of permanent registration in such form and containing such particulars as may be prescribed.

35. If the authority disallows the application for permanent registration it would have to clearly state the grounds on which the application was disallowed.

36. The disallowing of an application for permanent registration shall not debar a clinical establishment from applying afresh for permanent registration under section 19 and after providing such evidence as may be prescribed, of having rectified the deficiencies on which grounds the earlier application was disallowed.

REVOCATION OF REGISTRATION

37. (i) If at any time after any Clinical Establishment has been registered, the authority is satisfied that:

- a. The conditions of the registration are not being compile with; or
- b. Any of the grounds that would have entitled the authority to reject the application for registration was suppressed at the time of the application; or
- c. The person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act.

It may issue a show cause notice as to why its registrations under this Act should not be cancelled for the reasons mentioned in the notice. 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 there under, it may, without prejudice to any other action that it may take against such Clinical Establishment, cancel its registration.

- (ii) Every order made under sub section (i) 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 provide that the authority after cancellation of registration for reason to be recorded in writing, may restrain the Clinical Establishment from carrying on if There is imminent danger to the health and safety of patients.

INSPECTION OF REGISTERED CLINICAL ESTABLISHMENTS

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

(ii) The authority shall communicate to the clinical establishment the views of that authority with reference to the results of such inspection or inquiry and many, after ascertaining the opinion of 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.

(iii)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. Such report shall be furnished within such time as the authority may direct.

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

INSPECTION OF UNREGISTERED CLINICAL ESTABLISHMENTS

39. (i) The authority or an officer authorized 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 and or inquiry and be entitled to be represented thereat.

APPEALS

40. all appeals against the orders of the registering authority shall like to the Joint Director Medical & Health having jurisdiction over the district.

CHAPTER IV REGISTERS OF CLINICAL ESTABLISHMENTS

REGISTER OF CLINICAL ESTABLISHMENTS

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

(ii) Each authority shall apply in digital format to the State Registrar of Clinical Establishments a copy of every entry made in the Register of Clinical Establishments in such a manner as may be prescribed to ensure that the State Register is constantly up to date with the Registers maintained by the Registering authorities in the State.

MAINTENANCE OF STATE REGISTER OF CLINICAL ESTABLISHMENTS

42. (i) The State shall maintain in digital format and in such form and containing such particulars as may be prescribed by the State Government a register to be known as the State Register of Clinical Establishments in respect of Clinical Establishments of that State.
- (ii) Each State shall supply in digital format to the Central Government, a copy the state Register of Clinical Establishments and shall inform the Central Government without delay of all additions to and other amendments in such register made from time to time.

MAINTENANCE OF ALL INDIA REGISTER OF CLINICAL ESTABLISHMENTS

43. The Central Government shall maintain in digital format an All India Register of Clinical Establishments that shall be an amalgam of the State Register of Clinical Establishments maintained by the State Governments.

CHAPTER V

OFFENCES, PENALTIES AND PROCEDURE

GENERAL PROVISION FOR PENALTIES

44. Whosoever, contravenes any provision of this Act or any Rule or notification, or order made there under shall be liable to such penalty as may be imposed by the authority.
45. Penalties to be imposed by the authority shall comprise of fines as may be prescribed but no fine shall exceed Rs. five lacs.
46. Whosoever contravenes any provision of this Act or any rule, regulation or notification made there under shall, if no penalty is provided for the offence, be punishable for the first offence with fine which may extend to ten thousand rupees, for any second offence with fine which may extend to fifty thousand rupees and for any subsequent offence with fine that may extend to five lacs of rupees.

OFFENCES RELATING TO NON-REGISTRATION

47. (i) Whosoever carries on a Clinical Establishment without registration shall on conviction for first offence be punishable with a fine up to fifty thousand rupees, for second offence (non-registration) with fine that may extend to two lakh rupees and for any subsequent offence with fine that may extend to five lakhs of rupees.
- (ii) Any person, who knowingly serves in a Clinical Establishment that is not duly registered under this act, shall be guilty of an offence and shall be punishable with fine that may extend to twenty five thousand rupees.

DISOBEDIENCE OF ORDER, OBSTRUCTION AND REFUSAL OF INFORMATION

48. (i) Whoever, willfully disobeys any direction lawfully given by any person or authority empowered under this Act to give such direction, or obstructs any person or authority in the discharge of any functions which such person or authority is required or empowered under this Act to discharge, shall be punishable with fine that may extend to five lakh rupees.
- (ii) whoever, being required by or under this Act to supply any information which he knows to be false or which he does not believe to be true, shall be punishable with fine that may extend to five lakh rupees.

DEFICIENCIES MINOR IN NATURE

49. (i) Whosoever contravenes any provision of this act or any rule, regulation or notification made there under 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 ten thousand rupees.

(ii) All offences under this section shall be compoundable and shall be tried summarily in accordance with the procedure provided for summary trials in the Code of Criminal Procedure, 1973.

OFFENCES BY COMPANIES

50. (i) Where any offence punishable under this Act has been committed by a company, every person who, at the time the offence was committed, was incharge of, and was responsible to the company for the conduct of its business, 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 sub-section shall render any such person liable to any punishment, if he provides that the offence was committed without his knowledge and that he had exercised all due diligence to prevent the commission of such offence.

(ii) Notwithstanding anything contained in sub-section (i), where any offence punishable under this Act has been committed by a company and it is provided that the offence has been committed 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 offence and shall be liable to be proceeded against and punished accordingly.

Explanation- For the purpose of this section.

- (a) 'Company' means any body corporate and includes a firm, society, trust or other association of individuals, whether incorporated or not, and
- (b) A society, trust or any association of individuals, means the person who is entrusted with the management of the affairs of the society, trust or association, as the case may be.

CHAPTER VI MISCELLANEOUS

PROTECTION OF ACTION TAKEN IN GOOD FAITH

51. (i) No suit, prosecution or other legal proceedings shall lie against any authority or any member of the State Council or any officer authorized in this behalf in respect of anything, which is in good-faith done or intended to be done in pursuance of the provision of this Act or any rules or regulations made there under.
- (ii) No suit or other legal proceedings shall lie against a State or the Central Government in respect of any loss or damage caused or likely to be caused by anything which is in good-faith done or intended to be done in pursuance of the provisions of this Act or any rules or regulations made there under.

BAR TO THE JURISDICTION OF COURTS.

52. No court shall entertain any suit, application or other proceeding in respect of any order made under this Act and no such order shall be called in question otherwise than by way of an appeal under this Act.

FURNISHING OF RETURNS ETC.

53. Every Clinical Establishment shall, within such time or within such extended time as may be prescribed on this behalf, furnish to the Authority or the Board or the Regulatory Council or the State Government or the Central Government such returns, statistics and other information in such manner as may be prescribed by the State Government or Central Government from time to time.

POWER TO ISSUE DIRECTIONS

54. Without prejudice to the foregoing provisions of this Act, 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.

AUTHORITY ETC. TO BE PUBLIC SERVANTS.

55. Every Authority, its officers and employees, National Council shall be deemed to, when acting or purporting to act in pursuance of any of the provisions of this Act, be public servants, within the meaning of Section 21 of the Indian penal Code (45 of 1860)

POWER OF THE CENTRAL GOVERNMENT TO MAKE RULES

- 56 (i) The Central Government may, by notification, make rules for carrying out all or any of the provisions of this Act.
- (ii) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters namely;
- a. Constitution of the National Council under Section 12 & 13.
 - b. Allowances of the members of the national council.
 - c. The manner in which to display the information under section 20.
 - d. The form of the applications to be made under section 16 & 27.
 - e. The form of the certificate of registration to be issued under sections 17 and 33
 - f. The registers to be maintained under sections 40, 41 and 42.
 - g. The conditions of registration under section
 - h. The information for facilities, services etc. under section 6.
 - i. The information to be displayed by the Clinical Establishment for public information.
 - j. The manner and period within which the reporting is to be done under section.
 - k. The procedure for inspection of Clinical Establishment under section 38 and 39.
 - l. Classification of clinical establishment under section 6.
 - m. Maintenance of District, State and All India register of clinical establishment under section 41, 42 and 43.
 - n. Returns and statistics to be submitted.
 - o. Any other matter which is required to be or may be prescribed by the Central Government.
57. Every rule made by the Central Government under this Act shall be laid, as soon as may be alter it is made, before each house of parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be or 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 TO REMOVE DIFFICULTIES

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

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

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

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