

The Bihar Clinical Establishments (Control and Regulation) Act, 2007

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Act 14 of 2007

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The Bihar Clinical Establishments (Control and Regulation) Act, 2007(Act 14 of 2007)Assented by Governor of Bihar on 13.4.2007 and published in Bihar Gazette (Extraordinary) dated 19.4.2007.Preamble :- An Act to provide provision for the control and the regulation and proper functioning of Private Nursing Homes and other Clinical Establishments in the State of Bihar to provide for better Medicare to the people of the State for matters connected therewith or incidental thereto.Be it enacted by the Legislature of the State of Bihar in the fifty eighth year of the Republic of India as follows:-

1. Short Title, Extent, Commencement and Application.

(1)This Act may be called The Bihar Clinical Establishments (Control and Regulation) Act, 2007.(2)It shall extend to the whole of the State of Bihar covering all Clinical Establishments.(3)It shall come into force at once.(4)It shall not apply to any Asylum or Mental Hospital for mentally ill patients established or licensed if any, under the Indian Lunacy Act.

2. Definitions.

- In this Act, unless the context otherwise requires:-(a)"Appellate Authority" means a body consisting of the following:-(1)[Secretary, Health - Chairman [Substituted by Bihar Act 5, 2008.](2)Two Doctors nominated by the State Government - Member](b)"Appropriate Authority" means the Civil Surgeon of the concerned District.(c)"Category" means any of the seven categories of "Clinical Establishments" according to the accreditation standard fixed by the Government under section-3(4) of this Act.(d)"Certificate" means a certificate of registration issued under this Act;(e)"Clinical Establishment" means a Nursing Home, Physiotherapy Establishment, A Clinical Laboratory or an Establishment analogous to any of these by whatever name called, and includes a

Maternity Home, a Blood Bank, a Private Hospital, a Dental Clinic/Hospital/Poly clinic/Consultation Chamber a place used for Medical Termination of Pregnancy as approved under the Medical Termination of Pregnancy Act, 1971, an X-ray and Imaging Centre or any Establishment as the Director-in-Chief of Health Services, Bihar with the approval of the Government, notifies for the specified period. Clinical Establishment would not include Government Establishments and Hospitals.(f)"Clinical Laboratory" means an Establishment where-(i)Biological, Pathological, Bacteriological, Radiological, Chemical, Biochemical or other tests, examinations or analysis; or(ii)The preparation of cultures, vaccines, serums or other biological or bacteriological products, in connection with the diagnosis or treatment of diseases, are or is usually carried on;(g)"Government" means the Government of Bihar;(h)"Hospital" means any premises used for the reception of the sick and their treatment as indoor patient;(i)"Maternity Home" means an establishment where women are usually received or accommodated for the purpose of antenatal, intranatal and postnatal care in connection with child-birth;(j)"Nursing Home" means, an establishment or premises used or intended to be used for the reception of and providing medical care; including Nursing Care Centre for treatment in any form to persons suffering from sickness, injury or infirmity;*(k) "other paramedical staff" means a staff trained in a licensed hospital, nursing home, maternity home for at least two years and duly certified to have been properly trained by the Doctor/Director/Superintendent of that institution;(l)"Physiotherapy Establishment" means a centre where persons are usually treated by physical means such as massage, electrotherapy, hydrotherapy, remedial gymnastics or the like;(m)"Prescribed" means prescribed by the Rules, Regulations and Notifications;(n)"Qualified Medical Practitioner" means a Medical Practitioner registered in any State of India under a law for the registration of Medical Practitioners;*(o) "Qualified Midwife" means a midwife registered under the law for the time being in force, for the registration of midwife or trained in a licensed hospital, nursing home, maternity home for at least two years and duly certified to have been properly trained by the Doctor/ Director/Superintendent of that institution;*(p) "Qualified Nurse" means a nurse registered under Indian Nursing Council Act, 1947 or trained in a licensed hospital, nursing home, maternity home for at least two years and duly certified to have been properly trained by the Doctor/Director/Superintendent of that institution;(q)"Registered clinical establishment" means a clinical establishment registered or deemed to be registered under this Act;(r)"Registration" means registration done under this Act;(s)"Rules" means rules made under this Act;(t)"Registration No." means registration no. issued under the Bihar Clinical Establishment (Control & Regulation) Act, 2007 in relation of the Clinical Establishment and issued by the Bihar Medical Council of Registration for doctors and for para-medics, registration no. issued by appropriate authority.* These will not be applicable for an initial period of three years from the commencement of this Act.

3. Establishment of Clinical Establishment.

(1)On and after the commencement of this Act, no person shall establish or maintain a Clinical Establishment unless he holds a valid Certificate of Registration.(2)Notwithstanding anything contained in sub-section (1) a Clinical Establishment maintained as such immediately before the commencement of this Act may continue to be maintained, and shall be deemed to be a registered Clinical Establishment under this Act:(a)For a period of three months from the date of commencement of this Act; or(b)If an application for registration is made to the Appropriate

Authority within the period specified in sub-clause (a) of this sub-section in accordance with section 4, will continue to be deemed as registered till the disposal of such application.(3)A person, who intends to establish or maintain, after the commencement of this Act, a Clinical Establishment, shall make an application to the Appropriate Authority for the grant of a Certificate of Registration;Every application to be given under this section shall be given in the prescribed form with a fee of rupees Five hundred,In case the Appropriate Authority is not able to take a decision on an application made under section 3(3) of this Act within a period of one month of application, the Clinical Establishment would deemed to have been registered under this Act and the prescribed fee is to be deposited as per section 3(4).(4)The Clinical Establishments shall be categorized in the following manner and the fee mentioned against each category, upon grant of certificate of registration, shall be deposited within one week thereof. The prescribed fee may be varied by the Government from time to time.The fee for five years for different categories will be as follows:-

Category 1 : Institutes of National Standard	- Rs. 15,000/-
Category 2 : Medical College Hospitals Standard	- Rs. 10,000/-
Category 3 : District Hospitals Standard Speciality Hospital	- Rs. 8,000/-
Category 4 : Sub-divisional Hospitals Standard	- Rs. 5,000/-
Category 5 : Referral Hospitals Standard	- Rs. 3,000/-
Category 6 : Block-level Hospitals Standard	- Rs. 2,000/-
Category 7 : Consultation Chamber	- Rs. 1,00/-

The fee so collected shall be deposited in a separate Fund created for the purpose. 50% of the deposits in this Fund shall be used for the welfare of doctors and para-medical staff in the Private Sector. The utilization of this fund shall be decided by a Committee headed by the Director in Chief, Health Services.The accreditation standard for the abovementioned categories shall be fixed by the Government.

4. Grant or refusal of certificate of registration.

(1)On receipt of an application under section 3, the Appropriate Authority shall make such inquiries as it may deem fit and where it is satisfied that(a)satisfies the accreditation and prescribed standard for the particular category;(b)for reasons connected with the situation, construction, accommodation, staff or equipment, the Nursing Home or any premises used in connection therewith is or are fit to be used for a Clinical Establishment of the description mentioned in the application or that the Clinical Establishment or any of its premises is or are used or to be used for purposes which are not in any way improper or undesirable;(c)Requirements as per Schedule-A are fulfilled and for general purpose specific requirements will be fixed by the Govt, from time to time.It shall grant a certificate of registration to the applicant in the prescribed form, and where it is not so satisfied, it shall, by order, refuse to grant the certificate of registration:Provided that the Appropriate Authority shall, before making any order refusing to grant a certificate of registration, give the applicant a reasonable opportunity of being heard, by the same authority and every order of refusal shall set out therein the reasons for such refusal and shall be communicated to the applicant in such manner as may be prescribed within three months from the date of application.(2)The certificate of registration issued under this section in respect of a Clinical Establishment shall be

kept or affixed in a conspicuous place in the clinical establishment.

5. Duration and renewal of registration certificate.

(1)A certificate of registration shall not be heritable.(2)Where the holder of a certificate of registration (hereinafter referred to as the certificate holder) is unable to function as such for any reason or where a certificate holder dies, the certificate holder or, as the case may be, the legal-representative of such certificate holder shall within 30 days from the date of occurrence report the matter in the prescribed form to the Appropriate Authority and, notwithstanding anything contained in sub-section (1) the Clinical Establishment concerned may continue to be maintained and shall be deemed to be registered Clinical Establishment:(a)for a period of three months from the date of such report or, in the . case of the death of the certificate holder, from the date of his death; or(b)If an application made in accordance with sub-section (3), for a certificate of registration, is pending on the expiry of the period specified in clause (a), till the disposal of such application.(3)The legal representative of the certificate holder referred to in sub-section (2) shall, if he intends to continue the maintenance of the Clinical Establishment after the expiry of the period referred to in sub-section (2), make, at least one month before the expiry of such period, an application to the Appropriate Authority for the grant of a fresh certificate of registration for the maintenance of such establishment and the provisions of section 4 shall apply in relation to such application as they apply in relation to an application made under section 3.(4)Every certificate of registration shall, unless revoked earlier under section 7 or deemed to be revoked under the proviso to sub-section (1) of section 4, be valid for a period of 5 years with effect from the date on which it is granted.(5)A certificate of registration will be renewed every 5 years, on an application made in that regard to the Appropriate Authority, in such form and accompanied by such fee, as may be prescribed, and every such application shall be made not less than one month preceding the date of expiry of the existing licence:Provided that the renewal of a certificate of registration shall not be refused unless the Appropriate Authority is satisfied that the certificate holder;(i)is not in a position to comply the requirements envisaged in section 4; or(ii)has contravened any of the provisions of this Act or the Rules, Regulations and Notifications made thereunder.

6. Transfer of ownership of Clinical Establishment.

- In case of transfer of ownership, proprietorship or management of a clinical establishment, the certificate of registration in respect thereof shall cease to have effect after thirty days from the date on which such transfer is effected:Provided that within thirty days from the date of such transfer referred above the transferor and the transferee shall jointly communicate the fact of such transfer to the Appropriate Authority and the transferee shall, for the maintenance of the clinical establishment for the remaining period of the certificate of registration in accordance with the provisions of this Act, make an application for change of ownership on payment of a token fee of rupees fifty only.

7. Revocation of Certificate of Registration.

(1)The Appropriate Authority may, without prejudice to any other penalty that may be imposed on the certificate holder, by order in writing, revoke the certificate of registration in respect of any clinical establishment:(a)on any ground which would entitle it to refuse an application for registration under section 4 of this Act; and/or(b)if the Clinical Establishment fails to comply with the requirement prescribed under section 9 of this Act; and/or(c)if the Clinical Establishment contravenes any provision of this Act or of any Rule, Regulation or Notification made thereunder; and/or(d)if the certificate holder has been convicted of any criminal offence in respect of that Establishment:Provided that no such order shall be made except after giving the certificate holder a reasonable opportunity of being heard by the appellate authority as mentioned above and every such order shall set out therein the grounds for the revocation of the certificate of registration and such grounds shall be communicated to the certificate holder in such manner as may be prescribed.(2)Every order made under sub-section (1) of this section shall contain a direction that the inpatients of the clinical establishment shall be transferred to such other clinical establishment as the patient or his attendant opts or where, it is not practicable to transfer the inpatient to the clinical establishment so opted, to the nearest Government Hospital, which shall be specified in that order and it shall also contain such provisions (including provisions by way of direction) as to the case and custody of such inpatients pending such transfer.

8. Appeal.

(1)Any person, aggrieved by an order of the appropriate authority refusing to grant or renew a certificate of registration or revoking a certificate of registration under this Act may, in such manner and within 3 months prefer an appeal to the Appellate Authority:Provided that Appellate Authority 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) of this section shall be made in such form as may be prescribed.

9. Clinical Establishment to comply with certain requirements.

- Every clinical establishment registered or deemed to be registered under this Act shall comply with such requirements in relations to locations, accommodation, equipments, instruments and personnel (Medical and Paramedical) as per the accreditation and prescribed standard:Provided that the Government may relax any such requirement in respect of clinical establishment situated in rural areas.Explanation. - The expression "rural areas" shall mean areas not included in any Municipal or Notified Area within the meaning of the [Bihar and Orissa Municipal Corporation Act] [Now See Bihar Municipal Act, 2007.] or any other law for the time being in force.

10. Inspection of Clinical Establishment.

- If any person refuses to allow the Appropriate Authority or its representatives empowered by it to enter or inspect any premises or to inspect any records as and when required or obstructs such

authority or its representatives in the exercise of their powers under this section shall, in addition to any other action under this Act, be punished with such fine which may extend to rupees one thousand.

11. Information as to change of address of Clinical Establishments.

- Any change in the address or situation of, or of staff belonging to, a clinical establishment shall be communicated by the owner, proprietor or management thereof to the Appropriate Authority not later than thirty days after such change with specific mention as to the exact date when such change occurred.

12. Loss of Certificate of Registration.

(1) In the event of a certificate of registration being lost, damaged or destroyed, as the case may be, the holder thereof shall apply to the Appropriate Authority for issue of a duplicate thereof and, on the receipt of such application, the Appropriate Authority as the case may be, shall, having been satisfied about the fact of such loss, damage or destruction and on payments of rupees fifty by the certificate holder re-issue such certificate in such manner as may be prescribed. (2) Every certificate issued under sub-section (1) of this section shall be marked "Duplicate" and would be valid for the remaining period of the original certificate.

13. [Maintains [maintenance] [Substituted by Bihar Act 5, 2008.] of registers and records and reporting requirements.

- The owner, proprietor or the management of every clinical establishment shall maintain such registers and records as may be prescribed. The rates for all various medical services provided by the clinical establishment shall be prominently displayed in front of the establishment. Every clinical establishment shall report the details of name/address of patients treated every day to the Civil Surgeon in the prescribed format on quarterly basis.]

14. Information of birth and death occurring in Clinical Establishment.

- The owner, proprietor or the management of every clinical establishment shall maintain registers of births and deaths in the prescribed form. These registers shall be made available to Appropriate Authority and to such other authorities for inspection as may be required under any law in force for the time being, on demand. The monthly report of births and deaths shall be sent by every clinical establishment to the Appropriate Authority in the first week of the following month in the prescribed form.

15. The Appropriate Authority shall have the following functions, namely.

(a) to grant, renew, suspend or cancel registration of a clinical establishment; (b) to enforce standards prescribed for a Clinical Establishment; and (c) to investigate complaint of breach of the provisions of

this Act or the rules made thereunder and take immediate action by first asking explanation and if not satisfied, by inspection by a specialists panel. In the first instance of breach of the provisions of this Act, the Appropriate Authority shall ask the concerned Clinical Establishment to take necessary action as per provisions of the Act, within a specified time period not exceeding one month. If the concerned Clinical Establishment does not take action as required by the Appropriate Authority as per provisions of the Act, the Appropriate Authority shall file a complaint before the Sub-divisional Magistrate as provided under section 16.

16. Penalty.

- (i) Whoever shall contravene any provision of this Act or Rules, Regulations or Notifications made thereunder shall be punishable for the first offence with fine which shall not be less than rupees ten thousand and may extend to rupees twenty five thousand. (ii) The person on conviction for second or subsequent contravention of any provision of this Act or Rules, Regulations or Notifications made thereunder shall be punishable with fine of not less than fifty thousand rupees, which may be extended to one lakh rupees. (iii) Offences mentioned in section 16(i) and 16(ii) shall be tried in the court of Sub-divisional Magistrate (including Executive Magistrate) of the concerned jurisdiction. Complaints in this regard may be made in the court of Sub-divisional Magistrate by the Appropriate Authority or any private person or individual. (iv) Any complaint by a private person under this section shall be made only after recourse to provisions under section 15 have been exhausted by the complainant. (v) The Appellate Authority, in such cases, shall be the District Magistrate of the concerned jurisdiction. (vi) All fines imposed under this section shall be recoverable as per provisions of the Public Demand Recovery Act, as a certificate proceeding. (vii) In case of second or subsequent contravention of section 3 of this Act by a Clinical Establishment who has not been registered under this Act, shall be punishable with imprisonment for a period which shall not be less than one month and may be extended to 6 months. The offence shall be non-bailable and triable by any Judicial Magistrate of the first class of concerned jurisdiction.

17. Offence by companies.

(1) Where an offence under this Act has been committed by a company, as defined below, every person who at the time the offence 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 offence and he 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 punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence. (2) Notwithstanding anything contained in sub-section (1) of this section where an offence under this Act has been committed by a Company 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 Director, Manager, Secretary, Agent, Officer or person concerned in the management of the Company, such Director, Manager, Secretary, Officer or person concerned, shall be liable to be proceeded against and punished accordingly. Explanation :- For the purposes of this section: (a) "Company" means a body corporate and includes a firm or other association of Individuals; and (b) "Director" in relation to a firm means a partner of an employee as

Director of the firm.

18. Protection to persons acting in good faith.

- No suit, prosecution or other legal proceedings shall lie or be instituted against any person for any thing done or intended to be done in good faith under this Act and its provisions.

19. [A person to be public servant. [Substituted by Bihar Act 5, 2008.]

- Every person appointed or acting under this Act, and its provisions shall be deemed to be a public servant within the meaning [meaning] of the Indian Penal Code (45 of 1860) and Prevention of Corruption Act, 1988 (49 of 1988) Provided that owner, proprietor or member of management of Clinical Establishment and staff, employees skilled or unskilled in employment of Clinical Establishment shall not be deemed to be public servant under this Act.]

20. Authorities under this Act to have powers of Civil Court.

- The Authorities under this Act shall have the same powers as are vested in a Court under the Civil Procedure Code, 1908 (V of 1908) in trying a suit, namely : (a) admission of evidence including that by affidavits; (b) summoning and enforcing the attendance of any person and examining him on oath; (c) compelling the production of documents; and (d) award of cost.

21. Power to make Rules, Regulations and issue Notifications.

- The Government may, subject to previous publication by giving notice for a period of not less than ninety days make Rules, Regulations and issue Notifications for the purpose of giving effect to the provisions of this Act.

22. Effect of this Act on other laws.

- The provisions of this Act shall be in addition to, and not in derogation to the provisions contained in any other law in force for the time being relating to the matters covered under this Act, connected therewith or incidental thereto.

23. Power to remove doubts and difficulties.

- If any doubt or difficulty arises in giving effect to the provisions of this Act, the Government may, as the occasion may require, by order, do anything not inconsistent with the provisions of this Act or the Rules, Regulations and Notifications made thereunder, which appears necessary for the purpose of removing the doubt or difficulty. This power shall be in addition to the general powers of the Government to issue directions or guidelines to the Appropriate Authority or the Appellate Authority with matters related to the implementation of the provisions of this Act.

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[See Sections 3(3) and 4]Details of accommodation, equipment and technical staff/para medical staff to be provided for the applicant seeking for issue of Certificate of Registration.Requirement of Clinical Establishment for Registration:-(i)The Clinical Establishment shall be situated in a place with easy accessibility.(ii)The building used for Clinical Establishment shall comply with relevant municipal bylaws in force from time to time.(iii)The rooms in the Clinical Establishment shall be well ventilated and lighted and be kept clean.(iv)There shall be adequate space for medicine, equipment and food articles.(v)The Clinical Establishment shall have facility for drinking water.(vi)In case of any calamity or disaster the Clinical Establishment would provide such reasonable assistance as may be requested by the Appropriate Authority.(vii)Name, address, qualification and registration no. of each Doctor and Para Medical Staff employed by the nursing home shall be furnished. Any changes made in the above personnel employed would have to be intimated to the Civil Surgeon within 3 days of making such changes. Doctor in position in the Clinical Establishment shall be permanently displayed.(viii)There shall be a standby generator in case of power failure.(ix)[No clinical establishment shall run from within the premises of residential accommodation. This provision shall not be applicable for consulting chamber provided the activity is in consonance with any other existing law Governing Regulation of land use and running of commercial establishment from residential accommodation. Provided that restriction under this clause shall apply prospectively to the Clinical Establishments to be set up after come [coming] [Substituted by Bihar Act 5, 2008.] into force of this Act.](x)All biological waste of Clinical Establishment shall be disposed off as per the prescribed procedure.(xi)Records of patients to be maintained as mentioned below:(a)Indoor patient Register;(b)Operation theatre Register;(c)Maternity Register;(d)Birth and Death Register;(e)Stock Register for emergency drugs.(xii)The Clinical Establishments shall have to conform to set of Ethical Practices to be notified separately in the rules.(xiii)[The Government also shall notify a set of 'Desirable rates' for various kinds of health for each type of Clinical Establishment shall display 'desirable rates' so notified prominently within the Clinical Establishment.] [Substituted by Bihar Act 5, 2008.](xiv)Any other requirement as prescribed by the Government.