

## EXTRAORDINARY PUBLISHED BY AUTHORITY

No. 1355

FRIDAY, AUGUST 27, 2010

## <sup>1</sup>The Orissa Clinical Establishment (Control and Regulation) Act, 1990

#### ORISSA ACT 8 OF 1992

AN ACT TO PROVIDE FOR THE CONTROL AND THE REGULATION OF REGISTRATIONAND PROPER FUNCTIONING OF PRIVATE NURSHING HOMES AND OTHER CLINICAL ESTABLISHMENTS IN THE STATE AND FOR MATTER CONNECTED THEREWITH OR INCIDENTAL THERETO.

#### LAW DEPARTMENT NOTIFICATION The 1st February, 1992

No. 1642 Legis.—The following Act of the Orissa Legislative Assembly having been assented to by the Governor on the 11th December, 1991 is hereby published for general information.

Be it enacted by the Legislature of the State of Orissa in the Forty-second Year of the Republic of India as follows:—

- **1. Short title, extent, commencement and application :—**(1) This Act may be called the Orissa Clinical Establishments (Control and Regulation) Act, 1991.
  - (2) It extends to the whole of the State of Orissa.
- (3) It shall come into force on such date as the State Government may, by notification, appoint.
  - (4) It shall not apply to—
  - (a) a clinical establishment which owned, controlled, managed or maintained by Government or any authority or body established or constituted by an Act or Parliament or of the State Legislature;
  - <sup>2</sup>"[(b) Psychiatric Hospital or Psychiatric Nursing Home" established and licensed under the Mental Health Act, 1987."]
  - 1. Published in Orissa Gazette Extraordinary No. 102, dt. 3.2.1992.
- 2. Substituted by Orissa Gazette Extraordinary No. 2203 dt. 1.12.2016

- <sup>1[</sup>"(c) a clinical establishment established and maintained by a qualified Medical Practitioner only for treatment of outpatient care without any admission facility."]
- **2. Definitions**:— In this Act, unless the context otherwise requires.
  - (a) "Certificate of Registration" means a certificate of registration issued under Section 5;
  - <sup>2</sup>["(b) " 'Clinical Establishment' means -
    - (i) an establishment by whatever name called, that offers services, facilities requiring diagnosis, examination, tretment or therapy or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine;
    - (ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis, examination, analysis or treatment of diseases where, biological, pathological, bacteriological, genetic, radiological chemical, biochemical, investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment or the preparation of culture, vaccines, serum or other biological or bacteriological product are usually carried on;"]
- <sup>3</sup>["(c) 'Emergency Medical Condition' means a medical condition manifesting itself by acute symptoms of sufficient severity 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 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.]
  - (d) "Inspecting Authority" means such officer not below the rank of District Medical Officer, as may be appointed, or an

<sup>1.</sup> Substituted by Orissa Gazette Extraordinary No. 2203 dt. 1.12.2016

<sup>2.</sup> Substituted by Ibed

<sup>3.</sup> Substituted by Ibed

inspection team as may be constituted, by notification, by the State Government to carry out an inspection in accordance with the procisions of this Act;"

- <sup>1</sup>[(c) clauses (e) and (f) shall be omitted;]
- <sup>2</sup>[(g) "(g) ' Prescribed Authority' means the authority as may be prescribed in the rules to hear the appeals under this Act;";]
- (h) "Prescribed" means prescribed by rules;
- (i) "Qualified Medical Practitioner" means a medical practitioner registered in any State in India under a law for the registration of medical practitioners;
- (*j*) "Qualified Midwife" means a midwife registered in any State in India under a law for the registration of midwives;
- (k) "Qualified Nurse" means a nurse registered in any State in India under a law for the registration of nurses;
  - <sup>3</sup>["(k-a) 'Recognized System of Medicine' means allopathic, yoga, Naturopathy, Ayurveda, Homeopathy, Siddha and unani system of medicine or any other system of medicine as may be recognized by the Government;";]
- (l) "Registered Clinical Establishment" means a clinical establishment registered or deemed to be registered under this Act:
- (m) "Rules" means rules made under this Act;
  - <sup>4</sup>["(m-a) 'Standards' in relation to registration of clinical establishment, means the standard of facilities and services as may be prescribed;";]
- (n) "Supervising Authority" means the Director of Medical Education and Training or any other officer as the State Government may, by notification, specify in that behalf.

## 3. Clinical establishment not to be established or maintained without registration:— (1) On and after the commencement of this

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<sup>2.</sup> Inserted by Ibed

<sup>3.</sup> Inserted by Ibed

<sup>4.</sup> Inserted by Ibed

Act, no person shall establish or maintain a clinical establishment, unless he holds a valid certificate of registration and except under and in accordance with the terms and conditions as may be prescribed which shall be specified in the certificate of registration.

- (2) Notwithstanding anything contained in sub-section (1), a clinical establishment established an 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 commencement of this Act; or
  - (b) if an application for registration is made to the supervising authority within the period specified in clause (a) in accordance with Section 4, till the disposal of such application.
- **4. Application for Certificate of Registration:** (1) Every person, who continues to maintain, at the commencement of this Act, a clinical establishment, shall, if the said person intends to continue the maintenance of such establishment after the expiry of the period referred to in clause (a) of sub-section (2) of Section 3, make, at least one month before the expiry of such period, an application to the supervising authority for the grant of a certificate of registration.
- (2) A person , who intends to establish or maintain, after the commencement of this Act a clinical establishment, shall make an application to the supervising authority for the grant of a certificate of registration.
- (3) Every application under sub-section (1) or sub-section (2) shall be in such form and be accompanied by such fee as may be prescribed.
  - <sup>1</sup>[ **4-A.** Without prejudice to generality power and function of the supervising authority provided under this Act, he shall perform and following power and function namely:-
  - (a) to compile and update register of clinical establishment;
  - (b) to review and monitor implementation of the provisions of this Act and Rules.
  - (c) to send report or return relating to activities of clinical

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- establishment to the State Government and to such other authorities as required by or under anyy law for time being in force;
- (d) to publish annual report on the State implementation of Standard; and
- (e) any other power and functions as may be prescribed.",]
- **5.** Grant of Refusal of Certificate of Registration:— (1) On receipt of an application under Section 4, the supervising authority shall make such inquiries as it may deem fit and where it is satisfied that—
  - (a) the applicant or any person proposed to be employed or employed by him at the clinical establishment is a fit person to maintain or, as the case may be, to be employed at the clinical establishment named in the application; or
  - (b) the clinical establishment is under the supervision of a person who is a qualified medical practitioner, and that person or a qualified nurse is resident in the establishment, or there is adequate representation of qualified nurses among the persons having the superintendence of, or employed in, the nursing of the patients in such establishment; or
  - (c) in the case of maternity home, its staff includes a qualified mid wife and a qualified medical practitioner; or
  - (d) for reasons connected <sup>1</sup>["with any standard as may be prescribed, the situation"] construction, accommodation, staff of 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 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;

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:

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Provided that in the case of a clinical establishment referred to in clause (b) or a maternity home referred to in clause (c) which has been established prior to the commencement of this Act and continues to be maintained as such after such commencement, the supervising authority shall not refuse to grant a certificate of registration to the applicant on the ground that—

- (a) a qualified nurse is not resident in such clinical establishment; or
- (b) the staff of such maternity home does not include a qualified midwife; as the case may be, if—
  - (i) a nurse resident in such clinical establishment; or
  - a midwife included in the staff of such maternity home, (ii) as the case may be, is continuing therein as such, for a period not less than five years, subject to the condition that after the grant of a certificate of registration to the applicant, the nurse or, as the case may be midwife shall qualify in a test to be conducted by the Chief District Medical Officer of the district in such manner and within such period, as may be prescribed, and where any such nurse or midwife fails to qualify such test within the prescribed period the registration certificate shall be deemed to have revoked from the date when the said prescribed period expires, unless such nurse or midwife is substituted by a qualified nurse by the clinical establishment or, as the case may be, by a qualified midwife by the maternity home before the expiry of the said period:

Provided further that the supervising authority shall, before making any order refusing to grant a certificate of registration, give the applicant a reasonable opportunity of being heard 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.

<sup>1</sup>["(e) The clinical establihment has provided necessary fire prevention, life safety and such other measures in accordance

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with the provisions as provided by or under the provisions of any law for the time being in force".]

(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.

## **6. 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, as the case may be, the legal representative of such certificate holder shall forthwith report the matter in the prescribed manner to the supervising authority and, notwithstanding anything contained sub-section (1), the clinical establishment concerned may continue to be maintained shall be deem to be a 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 of 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 moth before the expiry of such period, an application to the supervising authority for the grant of a fresh certificate of registration for the maintenance of such establishment and the provisions of Section 5 shall apply in relation to such application as they apply in relation to an application made under Section 4.
- (4) Every certificate of registration shall, unless revoked earlier under Section 8 or deemed to be revoked under the first proviso to subsection (1) of Section 5 be valid for a period <sup>1</sup>[of five years] with effect from the date on which it is granted.

- <sup>1</sup>["Provided that the certificate holder who has been granted with certificate of registration before the commencement of the Odisha Clinical Establishments (Control and regulation) Amendment Act, 2016, irrespective of the fact whether validity period has expired or not shall apply within six months from the date of such commmencement for renewal of the certificate of registration for the remainder period on payment of such fee as may be prescribed."; and]
- (5) A certificate of registration may be renewed from time to time, on an application made in that behalf to the supervising authority, in such form and accompanied by such fee, as may be prescribed, and every such application shall be made <sup>2</sup>["not less than six months"] before the date on which the period of validity of the certificate of registration is due to expire:

Provided that the renewal of a certificate registration shall not be refused unless the supervising authority is satisfied that the certificate holder—

- (i) is not in a position to comply the requirements envisaged in Section 5; or
- (ii) has contravened any of the provisions of this Act or any rules made thereunder.
- 7. Transfer of Ownership of Clinical Establishment:— (1) in the case of transfer of ownership, proprietorship or management of a clinical establishment, the certificate of registration in respect thereof shall cease to have effect from the date on which such transfer is effected.
- (2) Within fifteen days from the date of every transfer referred to in sub-section (1) the transferor and the transferee shall jointly communicate the fact of such transfer to the supervising authority and the transferee shall, for the maintenance of the clinical establishment make an application for a fresh certificate of registration in accordance with the provisions of Section 4.
- (3) Where any transfer is effected as referred to in sub-section (1), notwithstanding any thing contained in this Act, the clinical establishment transferred shall be deemed to be a registered clinical establishment—
  - (a) for a period of thirty days form date when such transfer is effected, or
  - (b) if an application made in accordance with sub-section (2), for

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a fresh certificate of registration, is pending on the expiry of the period specified on clause (a) till the disposal of such application.

- **8. Revocation of Certificate of Registration:**—(1) The supervising 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 5; or
  - (b) if the clinical establishment, fails to comply with the requirements prescribed under Section 10; or
  - (c) if the certificate holder has been convicted of any offence in repsect of that establishment:

Provided that no such order shall be made except after giving the certificate holder a reasonable opportunity of being heard, 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) 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 direction) as to the care and custody of such inpatients pending such transfer.
- **9. Appeal:** (1) Any person, aggrieved by an order of the supervising authority to grant or renew a certificate of registration or revoking a certificate or registration may, in such manner and within such period as may be prescribed, prefer an appeal to <sup>1</sup>["prescribed authority"]

Provided that the State Government 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.

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(2) Every appeal under sub-section (1) shall be made in such form and be accompanied by such fee as may be prescribed.

# 10. Clinical Establishment to comply with certain requirement:— <sup>1</sup>["(1) Every clinical establishment registered or deemed to be registered under this Act shall comply with such requirements in relation to patient tretment, location, accommodation, equipment, instruments, personnel as may be prescribed;

(2) The clinical establishment shall provide for such minimum standard of services as may be prescribed including but not limited to minimum standard of accommodation, number and norms for service providers (like registered medical practitioner, registered nurse, other paramedical staff and other categories of staff with such qualification as may be prescribed), norms for emergency and referral care, norms for use of prescribed equipment, disposal of biomedical wastes and maintenance of such records and registers may be prescribed:

Provided that the clinical establishments which have not maintained the fire prevention and life safety measures and the standards to be prescribed after the date of commencement of the Odisha Clinical Establishments (Control and regulation) Amendment Act, 2016 shall, within six months of the date of commencement of such prescription, comply with such standard and the fire prevention and life safety measures:

provided further that for compliance of fire prevention and life safety measures, a further period not exceeding six months shall be allowed by the authority as may be prescribed.

- (3) The certificate holder shall maintain the fire prevention and life safety and such other measures in good condition at all times in accordance with the provisions as provided by or under the provisions of any law time being in force.
- (4) Every clinical establishment shall undertake to provide within the Staff and facilities available, such medical examination

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and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment and gives an undertaking by himself or by his attendant to be treated in the said clinical establishment.

Explanation - For the purpose of this section, the expression "to stabilize" with its grammatical variations and cognate expression, means eith respect to an emergency medical condition, to provide such medical treatment for improvement of the condition as be necessary.

- (5) The Clinical Establishments to which Government land has been provided such clinical establishment shall provide free treatment to presons below proverty Line as indoor and outdoor patients with such proportion as my be decided by the State Government, from time to time."]
- 11. Inspection of Clinical Establishment:—(1) the supervising authority or any officer empowered by it in that behalf may, subject to such general or special order as may be made by the State Government, at any time, enter and inspect any premises which are used or which the supervising authority or, as the case may be, <sup>1</sup>["the officer empowered by", the words "the Inspecting Authority"] it has reason to believe to be used for the purpose of a clinical estblishment and require the production of any records, which are required to be kept in accordance with the provisions of this Act or the rules, for inspection:

Provided that any personal records of a patient if inspected during the course of inspection shall be kept confidential except for the purpose of sub-section (4).

- (2) <sup>2</sup>[Ommited]
- (3) <sup>3</sup>["The supervising authority or the inspecting Authority,] may interview any private inpatient receiving treatment and care in the clinical establishment—
  - (a) for the purpose of inquiry into any complaint made by or on behalf of such patient as to the treatment and care; or
  - (b) in any case, where the supervising authority has reason to believe
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- 2. Omitted by Orissa Gazette Extraordinary No. 2203 dt. 1.12.2016
- 3. Substituted by Orissa Gazette Extraordinary No. 2203 dt. 1.12.2016

that any inpatient is not receiving proper treatment and care.

- (4) Where the supervising authority is satisfied that any inpatient in a clinical establishment is not receiving proper treatment and care, he may issue such directions as deemed fit to the certificate holder, and every such certificate holder shall be bound to comply with such directions.
- 12. Information as to change of Address of Clinical Establishment:—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 supervising authority <sup>1</sup>["not later than fifteen days"] after such change with specific mention as to the exact date when such change occurred.
- 13. Loss of Certificate of Registration:— (1) in the event of a certificate of registration being lost, damaged or destroyed, the holder thereof shall apply to the supervising authority for issue of a duplicate thereof and, on the receipt of such application, the supervising authority shall having been satisfied about the fact of such loss, damage or destruction and on payment, by the certificate holder, of such fee and in such manner as may be prescribed, issue such certificate.
- (2) Every certificate issued under sub-section (1) shall be marked "Duplicate".
- <sup>2</sup>[14. (1) There shall be maintained by the owner, proprietor or the management of every clinical establishment such register and records in such form and manner as may be prescribed:]
- <sup>3</sup>[14-A(1) Whoever refuses to allow the supervising authority or inspecting Authority to enter or inspect any premises or to inspect any record, register or obstructs such authority in exercise of his power under sub-section (1) of section 11 or willfully disobeys any direction of such authority or does not furnish the register and records or withhold any information required to be supplied under section 14 or gives information which he knows to be false, he shall be liable to pay fine which may

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extend to twenty-five lakhs rupees:

Provided that where any such person after being penalized under this sub-section (1), Commits it for the second or subsequent occasion, he shall be punishable with imprisonment for a term which may extend to six months and fine which may extend to twenty-five lakhs rupees.

- (2) For the purpose of imposing fine, the supervising authority shall hold an inquiry in the prescribed manner after giving the person concerned a reasonable opportunity of being heard.
- (3) While determining the quantum of fine the supervising authority shall take into account the category size and type of clinical establishment and local conditions of the area in which the establishment is situated.
- (4) The fine imposed under sub-section (1) shall, if the offender fails to pay the same, be recovered as if it were an arrear of land revenue and the fine so imposed and realized shall be credited to such account as the State Government may, by order, specify in this behalf.
- (5) Any person aggrieved by the decision of the supervising authority may prefer an appeal to the Prescribed Authority within a period of sixty days from the date of the said decision.
- <sup>1</sup>[14-B (1) During the time of inspection, if the Inspecting Authority finds any contraventions of the provision of this Act and Rules made thereunder, the Inspecting Authority shall have the power to seal the clinical establishment partially or fully, till the deficiencies are complied to the satisfaction of the Inspecting Authority.

(2) In case the clinical establishment is having admission facility, during such sealing, the provisions of sub-section (2) of section 8 shall apply mutatis mutandis."]

#### 15. Information of death occuring in clinical establishments:—

If any death occurs in a clinical establishment, the owner, propritor or the management thereof shall within twenty-four hours from the time of such occurence, furnish such informations in respect thereof in the prescribed form to the supervising authority and to such other authority or authorities as may be prescribed.

16. Penalty for Offences:— (1) Any person who establishes or maintains a clinical establishment in contravention of the provision of Section 3 or who, being a certificate holder, fails, without reasonable excuse, to keep or affix the certificate of registration in the clinical establishment in contravention of sub-section (2) of Section 5, shall on conviction, be punishable with fine which may extend to ten thousand rupees and where any such person, after being convicted under this section for any offence continues to commit the offence or commits it for the second or any subsequent time, he shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to twenty thousand rupees, or with both.

<sup>1</sup>[" (2) Any person who contravenes any of the provisions of this Act, other than those mentioned in sub-section (1) and section 14-A, shall, on conviction be punishable with fine which may extend to five lakhs rupees and in case, where any such person, after conviction, underthis sub-section for any offence, exontinues to commit the offence, he shall, on conviction, be punishable with further fine of one lakh rupees for

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every day after the first day during which the contravention is continued".]

17. Offences by Companies:— (1) Where an offence under this Act has been committed be a company, 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 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 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), 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 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 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 in the firm.
- **18.** Court competent to try Offences:— No Court inferior to that of a Magistrate of the first class shall try any offence punishable under this Act.
- 19. Protection of action taken in Good Faith:— (1) No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done in pursuance

of this Act or any rules or orders made thereunder.

- (2) No suit or other legal proceeding shall lie against the Government for any damage caused or likely to be caused for anything which is in good faith done or intended to be done in pursuance of this Act or any rules or orders made thereunder.
- **20. Power to make Rules:** The State Government may, subject to previous publication by giving notice for a period of not less than ninety days make rules for carrying out the provisions of this Act.
- 21. Effect of Act on other Laws:— The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for time being in force and to the extent of such inconsistency that other law shall be deemed to have no effect.
- **22. Power to remove Doubts and Difficulties:** If any doubt or difficulty arises in giving effect to the provisions of this Act, the State Government may, as occasion may require, by order, do anything not inconsistent with the provisions of this Act or the rules made thereunder, which appears to them necessary for the purpose of removing the doubt or difficulty:

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

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