

**THE ODISHA CLINICAL ESTABLISHMENTS (CONTROL
AND REGULATION) AMENDMENT BILL, 2016**

A

BILL

**TO AMEND THE ODISHA CLINICAL ESTABLISHMENTS
(CONTROL AND REGULATION) ACT, 1991.**

BE it enacted by the Legislature of the State of Odisha in the
Sixty-Seventh Year of the Republic of India as follows: —

Short title.

1. This Act may be called the Odisha Clinical Establishments
(Control and Regulation) Amendment Act, 2016.

Amendment of
section 1.

2. In the Odisha Clinical Establishments (Control and Regulation)
Act, 1991 (hereinafter referred to as the principal Act), in
section 1, in sub-section (4),—

Odisha Act 8
of 1992.

(i) for clause (b), the following clause shall be substituted,
namely:—

“(b) psychiatric hospital or psychiatric nursing home”
 established and licensed under the Mental Health Act, 1987.”; 14 of 1987.
 and

(ii) for clause (c), the following clause shall be substituted,
 namely:—

“(c) a clinical establishment established and maintained by
 a qualified Medical Practitioner only for treatment of
 outpatient care without any admission facility.”.

Amendment
 of section 2.

3. In the principal Act, in section 2,—

(a) for clause (b), the following clause shall be substituted,
 namely:—

“(b)” ‘clinical establishment’ means —

(i) an establishment by whatever name called, that
 offers services, facilities requiring diagnosis,
 examination, treatment 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;”;

(b) for clauses (c) and (d), the following clauses shall be
 substituted, namely: —

“(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 Inspection team as may be constituted, by notification, by the State Government to carry out an inspection in accordance with the provisions of this Act;";
- (c) clauses (e) and (f) shall be omitted;
- (d) for clause (g), the following clause shall be substituted, namely;—
- "(g) 'prescribed authority" means the authority as may be prescribed in the rules to hear the appeals under this Act;";
- (e) after clause (k), the following clause shall be inserted, namely: —
- "(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;";
- (f) after clause (m), the following clause shall be inserted, namely:—
- "(m-a) 'Standards' in relation to registration of clinical establishment, means the standard of facilities and services as may be prescribed;".

Insertion of new section 4A.

"Power and functions of supervising authority.

4. In the principal Act, after section 4, the following section shall be inserted, namely:—

4A. without prejudice to generality powers and function of the supervising authority provided under this Act, he shall perform and following powers and functions 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 establishment to the State Government and to such other authorities as required by or under any law for time being in force;

(d) to publish annual report on the State implementation of Standard; and

(e) any other powers and functions as may be prescribed.”.

Amendment
of section 5.

5. In the principal Act, in section 5, in sub-section (1),—

(a) in clause (d), for the words “with the situation” the words “with any standard as may be prescribed, the situation” shall be substituted; and

(b) after clause (d), the following clause shall be inserted namely:—

“(e) the clinical establishment has provided necessary fire prevention, life safety and such other measures in accordance with the provisions as provided by or under the provisions of any law for the time being in force”.

Amendment
of section 6.

6. In the principal Act, in section 6,—

(a) in sub-section (4), for the words “of two years”, the words “of five years” shall be substituted;

(b) after sub-section (4), the following proviso shall be added, namely:—

“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, 2015, irrespective of the fact whether validity period has expired or not shall apply within six months from the date of such commencement for renewal of the certificate of registration for the remainder period on payment of such fee as may be prescribed.”; and

(c) in sub-section (5), for the words “not less than one month”, the words “not less than six months” shall be substituted.

Amendment
of section 9.

7. In the principal Act, in section 9, for the words “the State Government” wherever it occurs, the words “prescribed authority” shall be substituted.

Amendment
of section 10.

8. In the principal Act, for section 10, the following section shall be substituted, namely: —

“10.(1) Every clinical establishment registered or deemed to be registered under this Act shall comply with such requirements in relation to patient treatment, 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 as may be prescribed:

Provided that the clinical establishments which have not maintained the standards to be prescribed after the date commencement of the Odisha Clinical Establishment (Control and Regulation) Amendment Act, 2015 shall, within six months from the date of such prescription, comply with such standard.

(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 and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment.

Explanation. — For the purpose this section, the expression “to stabilize” with its grammatical variations and cognate expression, means with respect to an emergency medical condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability that no material deterioration of the condition is likely to result from, or occur during, the transfer of the individual from a clinical establishment.

(5) The clinical establishment to which Government land has been provided such clinical establishment shall provide free treatment to persons Below Poverty Line as indoor and outdoor

patients with such proportion as may be decided by the State Government, from time to time."

Amendment of section 11.

9. In the principal Act, in section 11,—

- (a) in sub-section (1), for the words "any officer empowered by it in that behalf" and for the words "the officer empowered by it", the words "the Inspecting Authority" shall be substituted;
- (b) sub-section (2) shall be omitted;
- (c) in sub-section (3), for the words "the supervising authority" wherever it occurs, the words "the supervising authority or the Inspecting Authority, as the case may be," shall be substituted; and
- (d) in sub-section (4), for the words "the supervising authority", the words "the supervising authority or the Inspecting Authority, as the case may be," shall be substituted.

Amendment of section 12.

10. In the principal Act, in section 12, for the words "not later than seven days", the words "not later than fifteen days" shall be substituted.

Amendment of section 14.

11. In the principal Act, for section 14 including the marginal heading the following section shall be substituted, namely:—

"Maintenanc
e of register,
records and
furnishing
information.

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:

Provided that the owner, proprietor or the management of every clinical establishment which requires to give free treatment to the persons belonging to Below Poverty Line under this Act and Rules, shall maintain separate register therefor.

(2) The supervising authority or any officer empowered by it may require any owner, proprietor or the management of any clinical establishment to furnish to it any register, record and other information within such period as specified in this behalf and such owner, proprietor or the management of the clinical establishment shall be bound to do so."

Insertion of new section 14A.

12. In the principal Act, after section 14, the following section shall be inserted, namely:—

"Penalty for disobedience of direction, obstruction and refusal of information.

14A-(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 penalty which may extend to 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 or fine which may extend to five lakhs rupees or with both.

(2) For the purpose of imposing penalty, 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 penalty 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 penalty 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 penalty 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.

Amendment of section 16.

13. In the principal Act, in section 16,—

(a) in sub-section (1), for the words "ten thousand rupees" and the words "twenty thousand rupees", respectively, the words "two lakhs rupees" and the words "five lakhs rupees" shall be substituted; and

(b) in sub-section (2), for the words "one thousand rupees" and the words "one hundred rupees", respectively, the words "two lakhs rupees" and "ten thousand rupees" shall be substituted.

STATEMENT OF OBJECTS AND REASONS

The Odisha Clinical Establishments (Control and Regulation) Act, 1991 was enacted during the year, 1990, to provide for the control and the regulation of Registration and proper functioning of private Nursing Homes and other Clinical Establishments in the State. Pursuant to the said Act, the Odisha Clinical Establishments (Control and Regulation) Rules, 1994 came into force.

The ambit of the Odisha Clinical Establishments (Control and Regulation) Act, 1991 is required to be broadened and deepened by defining Clinical Establishments in an objective manner. The penal provisions are required to be made stringent by incorporating monetary penalty and criminal liability.

In view of growing healthcare business and adoption of the provisions of the Clinical Establishments (Registration and Regulation) Act, 2010 in some other States, enacted by the Parliament there is a need for amendments of the Odisha Clinical Establishments (Control and Regulation) Act, 1991 so as to incorporate certain provisions in the line of the Central Act and guard against the foul play of the Clinical Establishments and to protect the interest of the public.

The Bill seeks to achieve the above objectives.

ATANU SABYASACHI NAYAK
Member-in-Charge

ANNEXURE

[Extract from the Odisha Clinical Establishments (Control and Regulation) Act, 1991 (Odisha Act 8 of 1992)]

Short title,
extent,
commence-
ment and
application.

1. (1) This Act may be called the Orissa Clinical Establishments (Control and Regulation) Act, 1991.

(4) It shall not apply to—

- (a) a clinical establishment which is owned, controlled, managed or maintained by Government or any authority or body established or constituted by an Act of Parliament or of the State Legislature ;
- (b) any asylum or mental hospital for lunatics established or licensed, if any, under the Indian Lunacy Act, 1912. 4 of 1912.
- (c) a clinical Establishment having four or less numbers of beds or a clinical laboratory established and maintained, in any area not included within any municipal or notified area, by a qualified Medical Practitioner for treatment of emergency patients or for diagnosis of disease of his own patients.

Definitions.

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

(a) "certificate of registration" means a certificate of registration issued under section 5;

(b) "clinical establishment" means a nursing home, a physical therapy establishment, a clinical laboratory or an establishment analogous to any of them, by whatever name called, and includes a maternity home, a blood bank, a private hospital, a dispensary, a place used for medical termination of pregnancy as approved under the Medical Termination of Pregnancy Act, 1971, an X-Ray institution or establishment and such other institutions or establishments as the Director of Health Services may, with the approval of the State Government, by notification from time to time, specify; 34 of 1971

- (c) "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 ;
- (d) "hospital" means any premises used for the reception of the sick and their treatment as indoor patient;
- (e) "maternity home" means an establishment where women are usually received or accommodated for the purpose of antenatal and postnatal care in Connection with child-birth ;
- (f) "nursing home" means an establishment or premises used or intended to be used for the reception of, and providing medical care including nursing care in any form to, persons suffering from sickness, injury or infirmity;
- (g) "physical therapy establishment" means a centre where persons are usually treated by physical means such as massage, electrotherapy, hydrotherapy, remedial gymnastics or the like ;
- (k) "qualified nurse" means a nurse registered in any State in India tinier a law for the registration of nurses ;
- (l) "registered clinical establishment" means a clinical establishment registered or deemed to be registered under this, Act ;
- (m) "rules" means rules ma Je under this Act ;
- (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.

Application
for certificate
of Registration.

4. (1) Every person, who continues to maintain, at the commencement of this Worthiest^o 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.

Grant of refusal
of certificate of
Registration.

5. (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 supervisions 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 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;

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 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 comment (intent, 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—

(l) a nurse resident in such clinical establishment; or

Duration and renewal of registration certificate.

6.

(1)	x	x	x	x
(2)	x	x	x	x
(3)	x	x	x	x

(4) Every certificate of registration shall unless revoked earlier under section 8 or deemed to be revoked under the first proviso to sub-section (1) of section 5 be valid for a period of two years with effect from the date on which it is granted.

(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 not less than one month before the date on which the period of validity of the certificate of registration is due to expire.

(6)	x	x	x	x
(7)	x	x	x	x

Apeal.

9. (1) Any person aggrieved by an order of the supervising authority refusing 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 the State Government ;

Provided that the State Government may entertain an appeal preferred after the expiry of the prescribed period if it is satisfied that the applicant was prevented by sufficient cause from preferring the appeal in time.

x x x x

x x x x

Clinical Establishment to comply with certain requirements.

10. Every clinical establishment registered or deemed to be registered under this Act shall comply with such requirements in relation to location, accommodation, equipments and instruments and personnel (Medical and Paramedical) as may be prescribed;

Provided that the State Government may relax any such requirements in respect of clinical establishments situated in rural areas.

Explanation – The expression “rural areas” shall mean area not included in any Municipal or Notified area within the meaning of the Orissa Municipal Act, 1950

Orissa Act 23 of 1950.

Inspection of Clinical Establishment.

11. (1) The supervising authority or any officer empowered by it in that behalf may, subject to such general or special order as may be ma be 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, the officer empowered by it has reason to believe to be used for the purpose of a clinical establishment 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) if any person refuses to allow the supervising authority or the officer empowered by it to enter or inspect any premises or to inspect any records under sub-section (1) or obstructs such authority or officer in the exercise of his powers under this section, he shall, on conviction, be punishable with imprisonment for a term which may extend to three months, or with fine which may extend to five hundred rupees or with both.

(3) The supervising 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 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.

Information as to change of address on clinical establishments.

12. 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 not later than seven days after such change with specific mention as to the exact date when such change occurred.

13.	x	x	x	x
	x	x	x	x

Maintenance of registers and records.

14. There shall be maintained by the worker, proprietor or the management of every clinical establishment such registers and records as may be prescribed.

x	x	x	x
x	x	x	x

Penalty for Offences.

16. 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 clinic 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.

(2) Any person who contravenes any of the provision of this Act other than those mentioned in sub-section (1), shall, on conviction be punishable with fine which may extend to one thousand rupees and in the case where any such person, after conviction under the sub-section for any offence, continues to commit the offence, he shall, on conviction, be punishable with further fine of one hundred rupees for every day after the first day during which the contravention is continued.