The Orissa Clinical Establishments (Control and Regulation) Rules, 1994

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Rule
THE-ORISSA-CLINICAL-ESTABLISHMENTS-CONTROL-AND-REGULA
of 1994

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The Orissa Clinical Establishments (Control and Regulation) Rules, 1994Published vide Notification No. S.R.O.No.830/94, Orissa Gazette Extraordinary No. 1184/1.10.1994S.R.O.No.830/94. - Whereas the draft of the Orissa Clinical Establishments (Control and Regulation) Rules, 1993 was published as required by Section 20 of the Orissa Clinical Establishments (Control and Regulation) Act, 1990 (Orissa Act 8 of 1992), in the Extraordinary issue No. 112 of the Orissa Gazette dated the 29th January, 1994, under the Notification of the Government of Orissa in the Health and Family Welfare Department 43. 39344-ME.IM.-69/93-H., dated the 19th October, 1993, inviting objections and suggestions from all persons likely to be affected thereby till the expiry of a period of ninety days from the date of publication of the said notification in the Orissa Gazette.And whereas, the suggestion received in respect of the said draft have been duly considered by the State Government.Now, therefore, in exercise of the powers conferred by Section 20 of the said Act, the State Government do hereby make the following rules, namely :

1. Short title and commencement.

(1)These rules may be called the Orissa Clinical Establishments (Control and Regulation) Rules, 1994.

2. They shall come into force on such date as the State Government may by notification appoint, [w.e.f. 1.10.1994] [Published vide Orissa Gazette Extraordinary No, 1182/1.10.1994-Notification. No. 47/94/26.9.1994.].

2. Definition.

(1)In these rules, unless the context otherwise requires-(a)"Act" means the Orissa Clinical Establishments (Control and Regulation) Act, 1990 (Orissa Act 8 of 1992);(b)"Form" means a form appended to these rules;(c)"Registered Pharmacist" means a person whose name has been entered in the State Register of Pharmacists maintained by the State Pharmacy Council established under the Pharmacy Act, 1948;(d)"Schedule" means a Schedule appended to these rules;(e)"Section" means a section of the Act.(2)The words and expressions used herein, but not defined shall have the same meanings as respectively assigned to them in the Act.Chapter - I

3. Application for certification of Registration.

(1)Every person who intends to establish, maintain or renew the licence to maintain a clinical establishment shall make on an application to the supervising authority in Form 1.(2)The application shall be accompanied by a receipt of Treasury Challan showing payment of rupees one thousand towards grant/renewal of licence fee and rupees five hundred towards inspection fee into a Government Treasury under the head of account as specified in Form 1.(3)The application shall be accompanied with a site plan of the premises, document showing the educational qualification of the Directors, Proprietor and Partner, as the case may be, and such other relevant documents ancillary and incidental to the establishment/ maintenance/renewal as specified in Schedule 'A'.(4)A clinical establishment once started functioning in a particular place/building complex shall not be shifted to any other place before expiry of a period of five years from the date of its functioning :Provided that Government may in extraordinary situations like acquisition of the premises for public purpose or natural calamities, etc., give permission for such shifting.Note-The application for registration shall be accompanied by an undertaking to the effect that the clinical establishment once started functioning in a particular place/building complex shall not be shifted to any other place/premises before expiry of a period of five years from the date of its functioning.(5)The supervising authority after due consideration of application may grant registration, maintenance or renewal certificate in Form 2 or issue orders of rejection with reasons.(6)Certificate of registration shall remain valid for a period of two years from, the date on which it is granted.(7)A viva voce test as required under the first proviso to Sub-section (1) of Section 5 of the Act shall be conducted by the Chief District Medical Officer of the district within a period of six months from the date of grant of certificate of registration :Provided that the nurses or the midwives, as the case may be, shall qualify in the test within two chances.(8)The order of refusal to grant a certificate of registration shall be communicated to the applicant by registered post with acknowledgement due.(9)The order of revocation of the certificate of registration along with grounds for such revocation shall be communicated to the certificate holder by registered post with acknowledgement due.(10)Duplicate registration, maintenance or renewal certificate may be issued by the supervising authority if he is satisfied that the original certificate has been defaced/damaged/lost or destroyed on payment of fees of Rs. 500 (Rupees five hundred) only into a Government Treasury under the head of account as specified in Form 1 with an affidavit to the effect that the certificate was actually defaced/damaged/ lost or destroyed.Chapter-II

4. Inspection of clinical establishment.

(1)The supervising authority shall make such enquiries as may be deemed fit by himself or by any other officer not below the rank of Chief District Medical Officer of the area or may require such other Health authorities to inspect the premises and obtain a report which would cover all aspects as contained in Schedule 'A', relating to accommodation, equipments, instruments and qualifications of personnel employed therein (medical and paramedical personnel) and after being satisfied as regards the requirements of the Act, may grant a certificate of registration/maintenance/renewal, as the case may be.(2)The supervising authority or any officer authorised by him may, at any time enter, inspect and make spot enquiries so as to satisfy himself that the conditions specified in Form 2 are duly complied with and unless he is the supervising authority shall furnish a report to the supervising authority.(3)The supervising authority or the officers authorised by him shall inspect the clinical establishment or the local area at least twice a year.

5. Records.

(1)Every personal establishment to be registered under the Act shall maintain all records, in respect of inpatients and establishments in the manner provided under "Schedule B" and "Schedule C" respectively.(2)A free copy of the summary of treatment along with a copy of the record maintained by the clinical establishment concerned shall be supplied to inpatients admitted and outpatients treated in the said establishment while referring their case for treatment in Government hospital or other clinical establishment.(3)In the event of death of a patient in a clinical establishment the Director, Managing Partner or the Proprietor of the Establishment, as the case may be, shall furnish information to supervising authority in Form 3 forthwith.(4)The owner of the clinical establishment shall display the names of the visiting specialities to the establishment in a conspicuous place of the establishment for public information.

6. Appeal.

(1)Any person aggrieved by the order of the supervising authority in respect of rejection of grant, renewal, maintenance of certificate of registration, revoking certificate of registration may, within thirty days of receipt of such order make an appeal to the State Government in Form 4 accompanied by a fee of Rs. 500 (Rupees five hundred) only paid into a Government Treasury through challan under the Head of Account "0210-Medical and PH-020-Receipts from patients for Hospitals and Dispensary Services-9906480 -Other fees".(2)The State Government shall dispose of the appeal within a period of two months.

7. Cognizance of offence.

- Cognizance of offence under the Act shall be immediately taken by the Magistrate of First Class of the concerned local area on receipt of the prosecution report from the supervising authority or from the officer authorised by the supervising authority.

8. Miscellaneous.

(1)In case of difficulty in the implementation of or interpretation of these rules, the same shall be referred to the State Government for decision.(2)The State Government may after due consideration give necessary direction to the supervising authority for proper implementation or correct interpretation of these rules.Form 1[See Rules 3(1)(2) and (10)]Application for Grant/Maintenance or Renewal of Certificate of Registration of Clinical EstablishmentI/We.....of..... hereby apply for grant/maintenance/renewal of Certificate of Registration for the purpose of running a Physiotherapy Establishment/Maternity Home/Private Nursing Home/Clinical Establishment (Pathology)/Diagnostic Centre/Blood Bank/ Medical Termination of Pregnancy Clinics/X-Ray Institutes on the premises situated at.....

2. The Clinical aspect in the above establishment will be made under the supervision of the following technical persons :

Name(s).....Qualification.....Address(a)(b)(c)3. Name of Paramedical persons-Name(s).....Qualification .....Address(a)(b)(c)(d)4. Population of the local area (Town)Municipality/Panchayat Village).

5. Number of clinical establishments within the radius of one Kilometre of the proposed clinical establishment.

6. A fee of Rs. 1,500 (Rupees one thousand and five hundred) only has been credited to Government under the Head of Account "0210-Medical and P. H. 020-Receipt from patients for Hospital and Dispensary Service-9906480-Other fees".

7. Consent letters of the technical persons and paramedical persons to work for five years in your establishment duly signed by technical persons/paramedical persons is enclosed.

Date :Signature of applicant(Strike out whichever is not applicable)Form 2[See Rule 3 (5)]Grant/Renewal of Certificate of Registration to establish/maintain a Clinical Establishment).Messrs/Doctor.....are/is hereby issued the certificate of registration to run a Nursing Home/Clinical Establishment subject to the conditions stipulated herein at:

2. The Certificate of Registration shall be valid from.....to.....

3. The name(s) of the technical person(s) to remain in charge

4. Registration number of the certificate.....

Date of Issue.....Signature of Supervising AuthorityConditions of Registration

1. The certificate of registration shall be displayed in a prominent place in a part of the premises open to the public and inspecting authority.

2. The Registration certificate-holder shall comply with the provisions of the Orissa Clinical Establishments (Control and Regulation) Act, 1990 and Rules made thereunder for the time being in force.

3. The certificate-holder shall report to the Supervising Authority any change in technical staff within one month of such change.

4. No drugs shall be used in the establishment unless purchased with authorised bill from a licensed manufacturer and seller and should be handled only by registered Pharmacist in compliance with provision of Section 42 of the Pharmacy Act, 1948,

5. The certificate-holder shall inform the Supervising Authority in writing in the event of any change in the constitution of the management of the establishment where any change in the constitution of the management of the establishment takes place. The current certificate so issued shall be valid for a period of three months from the date of the change unless, in the meantime, a fresh certificate has been obtained from the approving authority, in the name of the new establishment with the changed constitution.

6. The fees to be charged for different medical treatment/laboratory test/X-fay, etc., realised shall be displayed in the part of premises for information of public and satisfaction of the Supervising Authority.

7. The clinical establishment shall function in the premises of Plot No.....Ward No.....Village/Town.....and shall not be shifted from this place till..

Form 3[See Rule 5 (3)]ToThe Director of Medical Education and Training,Orissa, Bhubaneswar(The Supervising Authority).Sir,I/We hereby bring to your kind notice that a death has occurred in our

establishment of one
Shri/Smt.....Address.....Date.....Time.....

2. The details of the history of the case and treatment given is enclosed herewith.

3. The matter may be intimated to other authorities at your level as may be deemed fit.

Yours faithfully,

Date.....Place..... Signature of the Director/ManagingPartner/Proprietor acting on behalf of the establishment

Form 4[See Rule 6 (1)]ToThe Secretary to the Government of Orissa, Health and Family Welfare Department, Bhubaneswar.Subject- In the matter of an appeal against the rejection of Application for grant/maintenance/renewal/revocation of Certificate of Regulation by the Supervising Authority under the Orissa Clinical Establishments (Control and Regulation) Rules, 1994.Sir,I/We.....had made an application to the Supervising Authority by complying to condition in appropriate form depositing requisite fees with all necessary documents on.....

2. The Supervising Authority after due enquiry have passed orders on dated.....rejecting grant or renewal of Certificate of Registration revoking the Certificate of Registration vide Order No .....dated.....(copy enclosed).

3. I/We have enclosed documents in support of reconsideration of the said order of the Supervising Authority.

4. I/We appeal that our application be duly examined and considered and orders passed.

5. A fee of Rs. 500 (Rupees five hundred) only in the appropriate head of account has been deposited.

Yours faithfullySignature of the applicantDate.....Place .....

'A'

[See Rules 3 (3) and 4]Details of accommodation, equipments and technical staff/ paramedical staff to be provided by the applicant seeking for issue of Certificate of Registration

1. Location-The premises shall be situated in a place which shall not be adjacent to open sewerage, drain, public lavatory or any, factory which produce an obnoxious odour or fumes. The premises shall be located in a sanitary place free from filthy surrounding and sound pollution.

2. Building-The building used for clinical establishment shall be constructed so as to allow maintenance of hygienic condition. They shall conform to the condition laid down in the Factory Act, 1948. The walls of the room shall be smooth, water proof. The flooring shall be smooth, washable and shall be such as not to permit retention of accumulation of dust.

3. Water-supply - (a) There shall be supply of wafer free from pathogenic organisms and shall be pure and of drinkable quality.

(b)Waste water and other residues from the premises shall be disposed off for suitable treatment to render them harmless for the health condition of the staff in the premises as well as people in the area.

4. Staff - The persons employed in the clinical establishment shall be free from contagious or obnoxious disease. They shall wear white or coloured uniforms which may be suitable to their nature of work and shall be cleaned. Adequate facilities for personal cleanliness such as cleaned towel, soaps shall be provided to each type of worker of different sex. The workers shall be required to change the cleaned footwear before entering into the premises

5. Medical services - The premises shall be provided with facilities for first-aid. Adequate precaution for industrial accident and fire shall be provided.

6. Requirement for Blood Bank - The relevant conditions as laid down in Drugs and Cosmetic Rules, 1945, Part XII-B shall be observed.

7. Medical termination of pregnancy clinic - The condition as laid down in the Medical Termination of Pregnancy Act, 1971 and rules made thereunder shall be observed.

Physiotherapy EstablishmentA. Rooms:(3 rooms) Each with at least 100 sq. ft. carpet area.B. Equipments:

1. Short wage diatherapy

2. Tractson- (a) Cervical, and

(b)Lumber,

3. Electrical stimulation

4. Shoulder wheel

5. Suspension frame

6. Tilt table

7. Dumbbell

8. Rowing machine

9. Static cycle

10. Pulleys

11. Paraffin wax bath

12. Refregerator and

13. Weigh machine

C. Qualification of technical persons :Diploma or Degree in PhysiotherapyNurses : 2 (two)D.N.A. - The rooms shall have good exhaust and ventilation system. Any establishment offering specialised service in such fields like Cardiotheracic, Geriaties or Electrotherapy shall have such equipments and technical persons as may be stipulated by supervising authorities from time to time.Clinical Laboratory InvestigationA. Rooms :

1. Waiting room reception (10' x 10')

2. Testing room (15' x 20')

3. Sterilisation room (10' x 10')

4. Room for preparation of culture media and incubation

B. Equipments :

1. Glass wares like test tube, slides, pipettes measuring Cylinder, etc.

2. Microscope-2 Nos. (a) One for Culture section

(b)Testing of samples other than culture

3. Photoelectric calorimeter (Double Photosell type) Range (200 mm to 600 mm)

4. Centrifuge machine

5. Hand lense

6. Haemoglobin meter

7. Haemocytometer

8. Laseet

9. Cuff

10. Disposable items for drawal of blood, etc.

11. Wester green ESR tube or wintrobe's tube for ESR and packed, cell volume determination

12. Gravitometer (for specific gravity)

13. Capillary tube for bleeding time and clotting time estimation

14. Auto clave

15. Incubator

16. Hot air ovan

17. Culture plates

18. Wire loop vectis

19. Flame photometer for determination of Sodium, Potassium and other electrolytes

20. Spirit lamp or gas burner

21. Gloves (Disposable)

C. Reagents and kitsBenedict's Solution, G. S. B. Stain Acetic AcidSodium CitrateW.B.C. diluting fluidR.B. C. diluting fluidPlatelet diluting fluidNormal salineIodine solutionBenzedine powderHydrogen peroxideRothra's test fluidSulphur powder, Pouchet's Reagent, Lelswan's StainKit for Blood Grouping and Rh. typingKit for Pheumatoid factorKit for detection of pregnancyKit for Comb's testKit for Montoux's testA. F. B. Stain (For detection of Leprosy and Fungal infection)Kit for Sputum testKit for determination of antistrophto lycine offitreKit for Creactive protein estimationKit for toxoplasma (to detect toxoplasma infection of eye)Kit for V. D. R. L. testingKit for Australia antigen testingD. Qualification and experience of Technical persons

1. Doctor with specialisation in Pathology and Bacteriology

2. 3 Trained Laboratory Technician

N. B. (I)-Disposal of waste material shall be done in such a way that the wastes shall be harmless and can cause no damage to the environment.N.B. (II)-Labs offering specialised testing facility shall have alternate source of power like generation, etc.Requirements For X-Ray InstitutionRoom : (1) Waiting-room-cum-Registration room for patient (10' x 12')(2)Radiologist's Chamber (10'x 10')(3)X-Ray machine room (15' x 10')(4)Dark Room

1. Waiting-room/Registration room

The room shall be furnished in such a way that the patients coming for diagnosis feel comfortable. Adequate numbers of bed should be provided for patients unable to sit or stand.

2. Radiologist's Chamber

The necessary requirement for giving a final diagnostic report to the patient should be provided to the Radiologist.

3. X-Ray Machine room

Requirements-(1)X-Ray machine(2)Lead gloves(3)Lead protected apron for technician(4)Walls of the room should be lead painted or such other protective measures are to be taken for taking adequate measures from radiation hazards.

4. Dark Room

The measures required for processing and developing X-Ray films are to be provided to the satisfaction of authorities.Technical person (Qualification)-M. D. in RadiologyX-Ray Technician-(one)

'B'

[See Rule 5(1)]Maintenance of Records in respect of Inpatients treated in the Clinical Establishment

1. Name of the patient .....

2. Date of treatment.....

3. Past history of the patient .....

4. Disease diagnosed .....

5. Drug regiment used.... .....

6. Name of the Doctor who treated.....

7. Length of treatment.....

8. Details of adverse reaction of drug, if noticed.....

9. Details of drugs administered..... ...

10. Frequency of drug changed in drug therapy.....

11. If the patient underwent operation, type of anaesthesia used.....

12. Name of the Anaesthesist.....

13. Name of the Surgeon.....

14. Date of discharge.....

15. Was Blood transfused.....

If so (a) What tests were performed.....(b)Source of Blood supply.....

Date.....Place..... Signature of the authoritySeal

'C'

[See Rule 5 (1)]Maintenance of Records in respect of Outpatients treated in the Clinical Establishment

1. Name of the patient.....

2. Date of treatment.....

3. Past history of the patient.....

4. Disease diagnosed.....

5. Drug regiment used.....

6. Name of the Doctor who treated.....

7. Length of the treatment.....

8. Remarks .....