Government of West Bengal
Department of Health & Family Welfare
Public Health Branch

The West Bengal Clinical Establishment Rules, 2012

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NOTIFICATION

No. : HF/O/PHP/57/4C-04/2….. dated,….., 20….. In exercise of the power conferred by section 57 of the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 (West Ben. Act XXVI of 2010), and in super session of all earlier rules on the subject, the Governor is pleased hereby to make the Following rules, namely:-

RULES

CHAPTER I
Preliminary

1. Short title and Commencement.

(1) These rules may be called the West Bengal Clinical Establishment (Registration and Regulation) Rules, 2012.

(2) They shall come into force on and from the date of their publication in the Official Gazette.

2. Definition.

(a) In these rules, unless there is anything repugnant in the subject or context,

(1) "The Act" means the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010;

(2) "applicant" means a person who has made an application under rule 31;

(3) 'care' means measures taken by a care provider or that are taken in a healthcare establishment in order to determine a service recipient's state of health or to restore or maintain it;

(4) 'Day care centre' means clinical establishment where persons to whom treatment of that kind or those kinds is provided are reasonably expected to be admitted and discharged on the same date;

(5) "Department" means the department of Health and Family Welfare of the Government of West Bengal if not mentioned otherwise;

(6) "diagnostic imaging laboratory" or "diagnostic imaging laboratory facilities" means any clinical laboratory used or intended to be used in production of images or visual display of structural or functional patterns of organs or tissues with the aid of any kind of electrical, electro-magnetic or sound wave for the purpose of diagnosis, treatment or research of diseases;

(7) "District Registrar means the licensing authority who shall be in-charge of generation, maintenance and safekeeping of the district register.

(8) 'Homoeopathy' means a system of Medicine as may be defined under the West Bengal Homeopathic System of Medicine Act, 1963 [WB Act XXXIII of 1963] or Act of similar kind;

(9) "Informed consent" means consent given by a person to a proposed specific intervention, without any force, undue influence, fraud, threat, mistake or misrepresentation, and obtained after disclosing to such person the adequate information including risks and benefits of, and alternatives to, the proposed intervention in a language and manner understood by such person with no binding to consent after being informed;

(10) "local authority" means (i) the Corporation, or Municipal Council concerned in any municipal area; (ii) the Notified Authority in notified area (iii) the Gram Panchayat concerned in rural area; or (iv) any such authority as may be notified

(11) "medically necessary" means a service or healthcare intervention that is scientific, appropriate and consistent with diagnosis and which, using accepted standard treatment protocol, standard operating procedures or any other standards of medical practice, could not be omitted without adversely affecting the patient's conditions

(12) "medical record" means any paper, film, print out, slide, solution or medium, or any documentation of services performed at the direction of a service provider as a part of treatment plan which can be deciphered or used to indicate and diagnose condition of the human body or a part of it or any material taken out of it and the course of treatment including nursing care administered to, or undergone by, the person;

(13) "near relative" means any of the following relatives of the deceased [or patient] namely, a wife, husband, parent, son, daughter, brother and sister and includes any other person who is related to the deceased or any other person;

(14) "New Establishment" means the clinical establishment registered under the Act after the date of commencement of these rules;

(15) "Old establishment" means the clinical establishment already registered prior to the date of commencement of these rules;

(16) "paramedical Professional" means any Technician like ECG Technician, Medical Laboratory Technician or Ophthalmic Assistant and includes such other technicians or any personnel, mentioned in the schedule who helps in providing health care services, teaching or practice of medicine by a registered medical practitioner.

(17) "patient" means a service recipient who has received any kind of service or care from any Clinical establishment being registered by the patient registration system of that CE and shall include any child born to a patient and is entitled to enjoy all the rights, responsibilities and obligation of being a patient;

(18) "Polyclinic" means a medical clinic having more than one Registered Medical Practitioner either of the same or of different specialty but practicing modern medicine excluding dentistry.

(19) "Primary Medical Attendant" means a registered Medical Practitioner as defined under rule 14;

(20) "qualified Nursing staff or technical staff" means any Nursing or paramedical professional who possesses a degree, diploma or certificate in any Nursing/ paramedical course of at least two years, conferred by any University established by law or any other institution recognized by the Department in this behalf.

(21) "schedule" means a Schedule appended to these rules;

(22) "Section" means a section of the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010;

(23) "Service" means health care related services and non-health care related services including but not limited to ambulance service therapeutic service, diagnostic services, in/out patient & emergency services, dietary services, palliative services, and rehabilitative services;

(24) "solo clinic" means a medical clinic having only one Registered medical practitioner practicing any recognized system of medicine excluding dentistry.

(25) "Staff" or "employee" means a person working in or employed by a clinical establishment and includes those working on part-time, contractual, consultancy, honorary or on any other basis;

(26) "telemedicine" means the practice of medicine using audio, visual and data communications;

(27) "Unani" means a system of medicine as may be defined under the Paschim Banga Unani System of Medicine Act, 1979 [WB Act XLV of 1979] or Act of similar kind;

(28) "university" means a University defined under clause (f) of section 2 of the University Grants Commission Act, 1956 and includes an institution declared to be a deemed University under section 3 of the said Act.

(29) "Yoga and Naturopathy" means a system of medicine as may be defined under section 2 of The West Bengal Yoga and Naturopathic System of Medicine Act, 2010 [WB Act VI of 2010] or Act of similar kind.

(b) The words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meaning respectively assigned to them in the Act.

3. License for Single Doctor Establishment

(1) Notwithstanding anything contained in chapter II to chapter VII, in order to provide the registration and regulation of the single doctor establishment, the following provisions shall be complied with in exercise of the power conferred by section 8 of the act.

Explanation. – 'single doctor establishments' means a medical clinic having only one Registered medical practitioner practicing any recognized system of medicine excluding dentistry who is the owner of that clinic

(2) Notwithstanding anything contained in rule 30, an application in Statutory CE Form I shall be submitted by the Doctor to obtain a license or renewal thereof for a single doctor establishment along with the following documents:

(a) Self declaration and undertaking in the form of Affidavit as per Statutory CE Form III;

(b) Copy of Certificate of qualification

(c) copy of certificate of Registration

(d) copy of existing license in case of renewal

(e) an undertaking in the form of a self declaration that the doctor shall follow the provisions of Bio-Medical Waste (Management and handling) Rules, 1998

(f) Any other additional document as may be notified.

Explanation. – "Doctor" means the licensee as well as the sole Registered medical practitioner of the single doctor establishment.

(3) After processing the application under rule 34, the Licensing Authority if satisfied that the clinical establishment has maintained the standards and fulfilled other terms and conditions as mentioned under rule 7, shall grant the a license or renewal, as the case may be, without collecting any license fee within 30 days of receipt of such application without causing any inquiry or inspection under rule 34 and such License shall be valid for 5 years.

4. Standards for Single Doctor Establishment

(1) Notwithstanding anything contained in rule 9, the Doctor shall provide adequate accommodation for the purpose of providing such healthcare appropriate for it.

Explanation: 'adequate accommodation' means that the medical clinic has provided (i) a space for Patient examination; (ii) sitting arrangement for doctor and patient; (iii) waiting space for patient; (iv) access to toilet, and drinking water; and (v) adequate lighting and ventilation arrangement.

(2) Notwithstanding anything contained in rule 14, in order to maintain the dignity and privacy of the patient, the Doctor shall take appropriate measures and shall carry out the examination or any health care intervention of a female patient preferably in presence of another female person.

(3) Notwithstanding anything contained in rule 23, if bio-medical waste is generated by him, the doctor shall handle those wastes as per the provisions of Bio-Medical Waste (Management and handling) Rules, 1998.

(4) Notwithstanding anything contained in rule 25, the Doctor shall generate and maintain records as per MCI Act or similar Acts; records related to medicolegal cases; and any other records or registers as may be notified.

(5) Notwithstanding anything contained in rule 26, the Doctor shall cause to display the name of the Establishment along with the license Number; the system(s) of Medicine practiced along with specialty, if any; the Hours of availability; display as per MCI Act or similar Acts or any other information as may be notified

(6) Notwithstanding anything contained in rule 27, the Doctor shall submit (a) the reports on National or state health programmes such as immunization as per requirement of State or District Programme Officers when applicable and (b) reports of Notifiable disease when applicable.

(7) The Doctor shall (a) provide such emergency treatment as mentioned under rule 20; (b) participate in public health related activities as per rule 45 and shall (c) comply with any other terms and conditions as may be notified.

5. Name of the Clinical Establishment.

(1) Notwithstanding anything contained in any law for the time being in force, no person shall use, or continue to use any name for the purpose of commencing, keeping or carrying on that clinical establishment or display and advertisement thereof without the prior registration of that clinical establishment with such name as per sub-rule (2).

(2) The licensing authority shall allow the clinical establishments to be registered with name for that clinical establishment subject to fulfillment of the following terms and conditions:-

(b) Such name is not identical with or too nearly resembling with Name of a clinical establishment already registered with that Licensing Authority;

(c) Such name is not containing the word "Hospital" or any of its variation unless that clinical establishment is having more than 30 (thirty) beds and having separate earmarked facilities or department for providing emergency medical services round the clock

(d) Such name is not containing the word "RESEARCH" or any of its variation unless that clinical establishment has got prior approval under the rule 24 and submitted evidence thereof along with the application;

(e) Such name is not stating, suggesting, or implying a false or misleading claim.

(f) any other terms and conditions as may be notified

6. Classification.

(1) The Clinical establishments shall be classified depending upon the following criteria namely (a) Location of the clinical establishment; (b) System of Medicine practiced by the clinical establishment; (c) Service facilities offered by the clinical Establishment or (d) any other criteria as may be notified by the Government from time to time.

(2) Depending upon the nature of Service facilities offered by the Clinical establishment shall be classified into following mutually exclusive categories: (a) Outpatient based Service Facilities; (b) Inpatient based service Facilities; (c) Pathology Laboratory service Facilities; (d) Diagnostic Imaging laboratory service Facilities; or (e) Any other type (to be specified by the applicant).

(3) Depending upon the nature of service sub-facilities offered, such Outpatient based Facilities mentioned in sub-rule (2), shall be further classified into following mutually exclusive sub-categories (i) Solo clinic; (ii) Polyclinic; (iii) Dental Clinic; (iv) Physiotherapy Clinic; (v) Occupational therapy Clinic; (vi) Counseling Centre; (vii) Wellness/Fitness centre/clinic (viii) Infertility Clinic; (x) Dialysis Centre; (x) MTP clinic; (xi) any other clinic or OPD based service centre without beds (to be specified by the applicant); or (xii) any other Day care centre or any other OPD based service facility with beds (to be specified by the applicant);

(4) Depending upon the nature of sub-facilities offered, such Inpatient based Facilities mentioned in sub-rule (2) shall be further classified into following mutually exclusive sub-categories: (i) Maternity Home; (ii) Nursing Home/Hospital; or (iii) Any other IPD based service centre (to be specified by the applicant).

(5) Depending upon the nature of sub-facilities offered, such Pathology Laboratory Facilities mentioned in sub-rule (2) shall be further classified into mutually exclusive sub-categories: (i) Collection centre; (ii) Small Laboratory; (iii) Medium Laboratory; (iv) Large Laboratory; (v) Genetic Laboratory; (vi) any other pathology laboratory (to be specified by the applicant).

Explanation 1: The term 'Collection centre' means a Pathology Laboratory, other than Genetic laboratory providing services regarding collection of samples or specimen for the purpose of pathological, bacteriological, chemical, biological or other tests, examination, or analysis.

Explanation 2: The term 'Small Laboratory' means a Pathology Laboratory, other than Genetic laboratory performing only the Routine Clinical Pathology and Haematology tests e.g. Hb, TC, DC, ESR, BT, CT, PT, Routine examination of stool, urine, sugar (blood and urine), urea, and cholesterol.

Explanation 3: The term 'Medium Laboratory' means a Pathology Laboratory, other than Genetic laboratory performing all the clinical pathology and haematology tests in addition to tests performed by the small laboratory but excluding Microbiology, and Morphological Pathology test.

Explanation 4: The term 'Large Laboratory' means as a Pathology Laboratory, other than Genetic laboratory performing all the Microbiology, and Morphological Pathology tests in addition to tests performed by the medium laboratory.

(6) Depending upon the nature of sub-facilities offered, such Diagnostic Imaging laboratory Facilities as mentioned in sub-rule (2) shall be further classified into mutually exclusive sub-categories: (i) X-Ray laboratory (Conventional) (ii) X-Ray laboratory (Digital); (iii)Mamography laboratory; (iv) Bone Densitometry laboratory; (v) Ultrasonography laboratory; (vi) Colour Doppler Imaging laboratory; (vii) CT Scan laboratory; (viii) Magnetic Resonance Imaging (MRI) laboratory; (ix)Positron Emission Tomography (PET) Scan laboratory; (x) Echo laboratory; (xi) Electro-cardiography laboratory; (xii) Electro-encephalography laboratory; (xiii) Electromyography laboratory; or (xiv) Other Clinical Physiological test laboratory or (xv) Any other Imaging laboratory (to be specified by the applicant)

Explanation 5: 'Other Clinical Physiology' shall include (i) Heart function tests; (ii) Blood volume estimation; (iii) Lung Function tests & spirometry; (iv) Estimation of basal metabolism.

(7) Services provided by the Pathology laboratory shall include (a) Morphological Pathology; (b) Clinical Pathology/biochemistry; (c) Microbiology; and (d) Haematology.

Explanation 1: 'Morphological Pathology' shall include: (i) Histopathology and histochemistry; and (ii) Exfoliative cytology except Morbid anatomy (autopsy);

Explanation 2: 'Clinical Pathology'/'biochemistry' shall include (i) Estimation of carbohydrate, lipid protein and electrolyte constituents of blood, urine and other body fluids, and their metabolites; (ii) Determination of endocrine levels and enzyme reactions; and (iii) Levels of drugs and toxic substances etc.

Explanation 3: 'Microbiology' shall include (i) Bacteriology; (ii) Parasitology; (iii) Mycology; (iv) Virology; and (v) Immunology;

Explanation 4: 'Haematology' shall include (i) the study of blood, bone marrow, the reticulo-endothelial system, and those disease associated with alterations of its cytological constituents; (ii) The study of the physico-chemical features associated with haemorrhages and blood dyscrasias; (iii) Immuno-haematology; and (iv) Laboratory procedures associated with blood transfusion

7. Standards & License.

(1) Any person intending to commence, keep or carry on a clinical establishment shall have to obtain a valid license after compliance with the terms and conditions mentioned under section 7 of the Act, and different

provisions of rules applicable to such clinical establishment by submitting an application to the Licensing Authority as mentioned under rule 30.

(2) The license shall be issued in duplicate in statutory CE Form VII mentioning the period of validity and other particulars and no Clinical Establishment shall be permitted to offer services or facilities other than those mentioned under that License:

(3) Subject to sub-rule (1), no person shall keep or carry on any clinical establishment in any district unless he possesses a valid license obtained from the licensing authority and the district registrar of that district failing which shall attract penalty under section 27 of the Act.

(4) Any person carrying on an old clinical establishment under a valid license on the date of commencement of these rules, shall have to obtain a new license after complying with the terms and conditions mentioned under section 7 of the Act, and different provisions of rules applicable to such clinical establishment by submitting an application to the Licensing Authority as mentioned under rule 30, immediately.

Provided that no application fee shall have to be submitted along with such application.

Provided further that, no license fee shall have to be submitted for the remaining period of the validity of the earlier license or registration.

Explanation: 'immediately' means a period of 90 (ninety) days from the date of coming into force of these rules which can be extended for another 90 (ninety) days on the request from the concerned Clinical establishment.

(5) In case of difficulty, the licensing authority with the prior approval of the State Government may relax any of those terms and conditions in exercising the power under section 8 of the Act while granting license to applicant as mentioned in sub-rule(1) and sub-rule (4)

Provided that, before relaxing any specific term or condition, the licensing authority has to determine the consequences of such relaxation keeping in view the need to ensure safety of patient and public and the standard of healthcare services.

(6) The clinical establishment offering Services in more than one category as specified in Rule 6, need not apply for separate registration for each type of category but shall have to submit application as per Rule 30 clearly mentioning those service facilities to obtain a composite license against a composite fee.

(7) If a clinical establishment with existing valid license intends to change or bring out any expansion, modifications or additions or changes in name, service category, ownership,, address or any other particulars mentioned in the license, he has to be obtained a new license after surrendering the old one as per section 18 of the Act

Explanation: Expansion may be in form of addition of more service facilities including enhancement of bed strength or expansion in any other forms

(8) If a clinical establishment with existing valid license intends to change or bring out any modifications or additions or changes in situation of, layout or of staff belonging to, or any other particulars under sub-section (2) of section 12 of the Act or any other information based on which the license was granted, it has to convey such information to the Licensing Authority with specific mention as to the exact date (s) on which such changes have taken place immediately and in any case not later than 30 (thirty) days after such change.

Explanation: Such changes shall include but not limited to closure, or temporary suspension of a service or any such changes as may be notified.

(9) After considering all the relevant aspects of the desired modifications or additions or deletion or changes mentioned in the application under sub-rule (7), the licensing Authority, if satisfied, may approve and issue a new license incorporating such changes in registration within 90 (Ninety) days from the date of receipt of such application with requisite fee and surrender of the duplicate copy of the existing License:

CHAPTER II
Input Standards

8. Accommodation Standard.

(1) The clinical establishment shall be located at a suitable place as specified in schedule I and depending upon the nature of Location, those shall be classified into mutually exclusive classes like: (a) Metropolitan meaning a locality under Corporation or Urban Local body having more than 5 lakh population; (b) Rural meaning a locality under Panchayat; or (c) Urban meaning a locality which is not metropolitan or rural.

(2) No clinical establishment or any service-provider attached to it shall render any service at a place other than a place registered under this Act:

Provided that, any service-provider attached to clinical establishment, being called for, may attend such house-call and provide service to the service-recipient confined there who is unable or unwilling to attend the Clinical establishment to receive such service which shall include collection of sample or specimen.

Provided further that, clinical establishment or any service-provider attached to it may render service at a medical camp which has got approval from the respective licensing authority under such terms and conditions as may be notified.

Explanation. – For the purpose of this rule, 'house' means a home, hostel, hotel, vehicle, or any place or premises where the patient is confined to.

Explanation. – 'Medical camp' means a transient or interim gathering of service-recipient in a shelter or enclosure on a site other than the place registered under this rule. The shelter or enclosure may be of portable nature that is not permanently attached to the ground.

(3) The clinical establishment shall provide such reception and accommodation to the patient and patient party which shall be reasonably adequate and suitable enough to render the service facilities offered by that type of clinical establishment as per and shall not allow any unwanted person to stay there overnight.

Provided that, a patient party may be allowed to stay only if approved by the Primary Medical Attendant or DMO.

(4) To ensure adequate reception and accommodation as per sub-rule (1) and (2), the Clinical establishment shall comply with the minimum accommodation standard as may be specified in schedule I:

Provided that, to accommodate the patient, suffering from an infectious disease, the clinical establishment shall provide isolation cabin, or ward or any such arrangement including but not limited to negative pressure ventilation and air-conditioning as may be medically necessary for that type of disease;

Provided further that the clinical establishment may officer different standards of accommodation based upon the amenities attached to such accommodation;

Provided furthermore that, the clinical establishment may provide different standards of accommodation to accommodate such patient who needs such special therapy/care as mentioned under rule 17;

Provided finally, that, the clinical establishment may determine and declare differential rate of user-charges for such different standard of accommodation

Explanation: Amenities means arrangements to provide physical comfort and conducive atmosphere which cannot be described as medically necessary.

(5) The clinical establishment shall take necessary precaution so guarding that the building or premises clinical establishment is not being used for unsocial or immoral purpose or both and shall not allow the use of the building, premises or equipment for use by a person who is not an employee or staff of that establishment:

9. Manpower Standard.

(1) The Clinical establishment shall provide such manpower who are qualified enough and suitable enough to render the services offered by that type of clinical establishment and to ensure such manpower standard, the clinical establishment shall comply with the minimum qualification norms in respect of health service providers as specified in schedule II and service rendered by an unqualified or underqualified person shall be considered as major deficiency under section 29 of the Act.

(2) The Clinical establishment shall ensure that any service provider engaged or empanelled by it-

(a) has valid registration certificate under any law regulating their registration and, in the absence of such law, hold such qualifications and possess such experience as are recognized by the Government; and

(b) has such qualification, training, experience and skill to (i) practice in their particular specialty or subspecialty in the field of medicine or dentistry, nursing or other health care profession as are recognized by the Government and (ii) provide necessary health care service as expected and applicable of him.

(c) has submitted all the particulars relating to his registration, qualification, training, experience and skill along with the certificates of registration and certificate of qualification and other supporting documents thereof.

Explanation 1: 'Certificate of registration' means the registration certificate awarded by the respective council in case of Registered Medical Practitioner, Registered Nurse or Midwife, and Registered Paramedical Technician.

Explanation 2: 'Certificate of qualification' means the certificate, diploma or degree awarded by university or any such competent authority.

(3) Each such engagement or empanelment shall be substantiated by an offer letter issued by the clinical establishment and an acceptance letter by the service provider.

(4) The Clinical establishment shall retain copies of such certificates of Registration and certificate of qualification and copies of such offer letter or acceptance letter under sub-rule (3) as long as necessary and shall produce such documents at the time of inspection or enquiry under rule 35 or on demand by the authority and shall submit such copies along with the application.

(5) The Clinical establishment shall provide such manpower which is reasonably adequate and suitable enough to render the services offered by that type of clinical establishment and to ensure such manpower standard, the clinical establishment shall comply with the minimum number norms in respect of health service providers as specified in schedule II.

(6) The licensee could be a non-medical person but every Clinical establishment shall ensure that all healthcare related services are being rendered under the supervisory management of a registered medical practitioner.

(7) To ensure the availability of staff as per norm, the clinical establishment shall generate and maintain the following registers as a part of mandatory record keeping:

(a) an up-to-date Staff Register in which names, designation, present and permanent addresses, qualification(s), date of engagement etc. of all staff of the clinical establishment are to be entered; and

(b) an up-to-date Register in which attendance of all staff of the clinical establishment are to be recorded daily.

Provided that the clinical establishment may maintain any bio-metric or electronic attendance system with the approval of the Licensing authority.

(8) Notwithstanding anything contained in Rule 21, no person, other than the person whose name and particulars is entered in the register as per sub-rule (7) shall be allowed to provide healthcare services.

(9) Notwithstanding anything contained in PC-PNDT Act and other laws, each service-provider shall be permitted to be engaged as a part-time staff with a certain numbers of clinical establishments within a district as per following norms:

(a) In case of registered medical practitioner, such maximum numbers of clinical establishments are 5 (five);

(b) In case of nursing professional, such maximum numbers of clinical establishments are 2 (two);

(c) In case of paramedical professional, such maximum numbers of clinical establishments are 2 (two):

Provided that, the state government shall have the power to relax such norms as may be notified.

(10) Subject to the provision of sub-rule (2), the clinical establishment may engage part-time staff depending upon the services offered such type of clinical establishment:

Provided that before any such engagement, the clinical establishment shall obtain a self-declaration in the form of affidavit from that service-provider related to his compliance of sub-rule (9) as the case may be and shall submit a copy of the same along with the application.

(11) The clinical establishment shall issue proper photo-identity badges under the signature of the licensee for the staff which shall be worn by the staff when he is in the premises.

10. Engagement of Govt employees

(1) No clinical establishment shall engage or empanel any person already engaged by the Government of West Bengal, without obtaining express permission from the DHS or DME or any other officer authorized for this purpose, as the case may be, in the form of a 'No objection certificate' mentioning the period of validity of such certificate.

Explanation: 'Person' means any service provider, or other staff engaged in the agencies even as honorary or stipendiary basis or who are bound under bond-cum-agreement executed with or under Contract with the agencies and shall include any House-staff, Internee or student.

(2) The clinical establishment shall submit the copy of NOC along with the application and shall display the Name and designation of such person(s) as a part of mandatory display which may be published in the website/public domain by the Government.

11. Equipment, Drugs and Medical Supplies Standards.

(1) The Clinical establishment shall ensure the provision of such equipment, machineries, medical devices medical supplies as specified in schedule III of acceptable standard and it shall permit the use of medical supplies only after being reasonably satisfied about the quality of such medical supplies and the use of unsafe

equipment machineries, medical devices medical supplies shall be treated as a major deficiency under section 29 of the Act.

(2) All the medical supplies necessary for the patient accommodated in a clinical establishment shall be supplied from the stock of that clinical establishment at a reasonable cost not exceeding MRP and the cost of such medical supplies shall be recovered from the patient presented in form of an itemized bill issued by that Clinical establishment:

Provided that the patient receives and uses the goods such medical supplies so procured by the clinical establishment as service provider in patient's capacity as pure agent of the recipient of service.

(3) The patient or the party shall be given an option by the clinical establishment to supply those medical supplies upon receiving such instruction from the Clinical establishment along with the prescription from the Primary Medical Attendant or DMO.

(4) The clinical establishment shall generate and maintain a complete inventory of drugs, medical devices and consumables in a stock-book as a part of mandatory record keeping containing such appropriate particulars like (i) batch No, (ii) expiry date etc. and any other particulars as may be notified in such a manner which may enable anyone to verify the actual consumption of drugs, medical devices and medical supplies by a particular patient.

(5) The clinical establishment shall generate and maintain a complete inventory of all major equipment furniture and machineries in a 'Dead stock register' and a separate 'logbook' for each of such as a part of mandatory record keeping containing such appropriate particulars as may be notified.

12. User charge Standards.

(1) Subject to declaration of a rate-chart of user-charges, the clinical establishment shall have a right to impose different rates of charges in consideration of the provision of different kind of services to be rendered by it:

Provided that, such rate-chart describing item-wise charges for all services along with concession under rule 13, if any, shall be published in the Information brochure under rule 25; and shall be displayed as a part of mandatory display;

Provided further, that, the clinical establishment shall have no right to impose differential rates for a particular service, including differentials based on such factors as the setting in which the service is rendered; the paying capacity of the patient; the mode of payment; the opportunities of cashless payment; or the incidence of demand for the service or any other factor:

Provided furthermore, that, clinical establishment may impose differential rates for a particular service, procedure or test including differentials based on only the factors which can influence the outcome of the treatment.

Provided finally, that, the clinical establishment shall have no right to impose any fine or penalty from the Patient or party for any reason whatsoever.

Illustration: the rate of charge for 'laparoscopic appendectomy' and 'laparoscopic cholecystectomy' may be different or the rate for 'cholecystectomy by open method' may be different from 'cholecystectomy by laparoscopic method' but the specific rate, not package-rate, of 'laparoscopic cholecystectomy' for a patient admitted in general ward shall not be different from that of a patient admitted in a cabin.

Explanation: the rate is the maximum payable amount and shall include any tax, duty, surcharges levied by the government from time to time

(2) Subject to the provisions of the rule 12, the Clinical establishment shall have the right to recover or collect, on issuance of a proper receipt, the amount payable as user-charges as per the payment option and schedule mutually agreed upon beforehand between the establishment and the patient/patient party:

Provided that, before collecting the user-charges, the Clinical establishment shall have to produce a claim in the form of a proper itemized bill(s) prepared by that clinical establishment which is reasonably accurate.

Provided that, such claim of bill shall not contain any amount of user charges in excess of the rate of charges declared beforehand or any amount of user charges payable against any services, which were not actually rendered by that clinical Establishment;

Provided furthermore, that, the clinical establishment may collect as deposit or any form of advance the part or whole amount likely to be payable which is to be adjusted before settlement of final payment.

Provided finally, that, the patient/patient party shall be given the opportunity to choose from such different payment options as may be declared by the Clinical establishment beforehand.

Explanation 1: user charges are charges for service(s) rendered by the clinical establishment which is the maximum payable amount and may include the any charges towards the recovery of cost of any damaged

property from the patient or any subscription for any sort of membership to avail any benefit offered by that clinical establishment but does not include any tax, surcharges levied by the government.

Explanation 2: Proper receipt shall bear unique number and the name of the clinical establishment along with the License number showing the exact amount paid against the bill.

Explanation 3. – "collect" includes demand, charge or accept or try to demand, charge or accept any consideration in the form of cash, kind or service.

(3) Beside declaring the rates for separate item wise services as per sub-rule (1), the clinical establishment is entitled to determine and declare the rate for a whole package of service combining together such different services likely to be provided to the patient during the course of his treatment and care:

Provided that, while offering any such package rate, the Clinical establishment shall –

(a) clearly mention the inclusion, exclusion or add-on components of services which can be dovetailed with the package;

(b) declare that the rate is the lump sum, maximum payable amount.

Explanation 1. – "package" or "package of service" means a collection of related healthcare services and non-healthcare services that are usually paid separately under a fee-for-service system, but which may be combined by a provider in delivering a full diagnostic or treatment procedure to a patient

Explanation 2. – 'package rate' is a rate contract where a basket of services are being offered by the CE in exchange for a lump sum payment of an assured sum by the service recipient;

(4) The Clinical Establishment shall ensure that prior to the initiation of care or treatment, and at any point of time, on demand, the patient and party has been informed and explained without any ambiguity about-

(a) the estimated user-charges likely to be payable at the rate either for the whole Package of service or separate item wise service;

(b) other anticipated user-charges for services that is routine, usual and customary including any kind of tax payable to the Government;

(c) the billing and payment procedures including options for payment;

(d) any concession or free treatment facilities available

(5) The patient or party shall have the right –

(a) to obtain a written statement of such estimate under sub-rule (4) on demand without any delay.

(b) to be informed of the extent to which payment may be expected from any Insurance Company or third party and any charges for which the patient may be personally liable.

(c) to obtain and examine, on demand, an itemized common bill for all the services charged by the clinical establishment, including the cost of medical supplies consumed for the patient along with a thorough explanation of such bill, at no extra cost, regardless of the manner and source of payment.

Provided that, such estimate may contain the approximate expenditure due to medical supplies likely to be consumed for the patient as per rule 11.

(6) All debit and credit vouchers including the duplicate copy of bill and payment shall be retained by the clinical establishment for a period not less than five years which shall be liable for inspection by the Licensing Authority.

13. Free Treatment & concession.

(1) Notwithstanding anything contained in rule (12), the clinical establishment may provide for such concession or free treatment facilities to any such deserving person as it deems appropriate:

Provided that, the clinical establishment, who has availed any privilege from any agreed party, shall provide for such concession or free treatment facilities to any such deserving person including indigent person as mentioned in the agreement.

Provided further, that, the mechanism to avail such concession or free treatment facilities shall be published in the mandatory display and information brochure for the benefit of all service-recipients.

Explanation 1: 'privilege' shall include but not limited to (a) full or partial exemption of any tax, duty or fees levied by the Government; (b) procurement of any land, property, equipment or medical supply at a concession rate or free of cost or (c) any kind of gift or donation

Explanation 2: 'Agreed party' means any person who has entered into the agreement with a clinical establishment where the terms and conditions of the privilege offered by that person and the concession or free

treatment facilities offered by that clinical establishment are mentioned and such person shall include any individual, or any private sector agency or any public sector agency.

(2) If not otherwise mentioned specifically in the agreement, the term 'concession or free treatment facilities' shall include full or partial exemption of all service charges including bed charges; free medical supplies or diet; free screening or medical checkup; reservation of certain percentage of beds or any such benefits for such patient.

(3) In the interest of public service, the agreed party, may time to time refer such indigent person to avail the free treatment facilities at those clinical establishments and it shall be the duty and obligation of the clinical establishment to honor such referral as per the agreement.

(4) In the interest of public service, the licensing authority shall have the power to supervise the availability of such concession or free treatment facilities mentioned in the agreement and the clinical establishment shall submit a copy of such agreement to the licensing authority along with the application.

(5) The clinical establishment shall be generated and maintain the records of such patients and shall submit an Annual report thereof in Statutory CE Form XIV to the Licensing Authority as a part of mandatory reporting.

CHAPTER III
Process Standards

14. Dignity, Privacy & Confidentiality.

(1) The service recipient shall have the right that he may be subjected to any healthcare related intervention in such a manner that proper respect is shown for his privacy and dignity.

Explanation: The term 'healthcare related intervention' or 'healthcare intervention' shall include examination and procedures, invasive or non-invasive, whether diagnostic, preventive, curative, rehabilitative or therapeutic.

(2) The service recipient shall have the right that a particular healthcare intervention may be carried out only in the presence of those persons who are necessary for the intervention, unless the service recipient consents or requests otherwise; and for women service recipient, that intervention may be carried out only in the presence of a female service provider, unless the service recipient herself waives this right or unless it is not feasible at all in given circumstances:

Provided that, in case of Medical clinic, such intervention may be carried out in presence of any female member of the family or friend.

(3) In order to maintain the dignity of the patient, the clinical establishment shall take all necessary steps to minimize the use of restraints or use of a monitoring device on patients, whenever possible.

Provided that the clinical establishment may restrain a patient or use a monitoring device on him or her under the following terms and conditions, subject to the consent obtained from the patient or patient party and authorization of the primary Medical Attendant

(4) The patient shall have the right to be free from unwarranted public exposure, except in the following cases:

(a) when his mental or physical condition is in controversy and the appropriate court, in its discretion, order him to submit to a physical or mental examination by a registered medical practitioner; or

(b) when the public health and safety so demand; or

(c) when the patient waives this right in writing.

(5) The patient shall have the right to demand that all information, communication and records pertaining to his care be treated as confidential.

(6) The information regarding patient's condition including specific medical information may be disclosed to the spouse or the family to the first degree or near relative of the patient's:

Provided that, the patient of legal age shall have the right to choose on whom to inform; further, in case the patient is not of legal age or is mentally incapacitated, such information shall be given to the parents, legal guardian or his next of kin.

(7) Any healthcare provider involved in the treatment and care of a patient or any person who has legitimate access to the patient's record is not authorized to disclose any information to a third party who has no concern with the care and welfare of the patient without his written consent:

Provided that such disclosure may be allowed when such disclosure is needed:

(a) for the benefit public health and safety; or

(b) in the interest of justice or upon the order or a competent court; or

(c) for continued medical treatment or advancement of medical science subject to de-identification of patient and shared medical confidentiality for those who have access to the information; or

(d) for the purpose of Licensing Authority or Medical Council of any state of India.

(8) Based on a doctor's best judgment of that patient's condition, the information regarding such condition in general terms may be disclosed to anybody using such terms limited to 'Undetermined', 'Good', 'Fair', 'Serious' or 'Critical' to describe such condition

(9) The service recipient, including an indigent person, once registered by the Clinical establishment, shall have the right to be treated by health care providers with patience, empathy, respect, and humanness; further, this shall mean that no one shall be subjected to any coercive healthcare intervention or subjected to discriminations and denials.

15. Counseling & Consent.

(1) The patient shall have the right to a clear, truthful and substantial explanation, in the form of a counselling in a manner and language understandable to the patient, of all proposed healthcare intervention, wherein the person who will perform the said procedure shall provide the following information as a part of such counselling: (a) his name and credentials to the patient; (b) possibilities of any risk of mortality or serious side effects; (c) problems related to recuperation; (d) probability of success and reasonable risks involved; (e) alternative healthcare intervention available; and (f) medical consequence of refusal etc:

(2) No patient shall be subjected to any healthcare intervention without his written informed consent, except in the following cases:

(a) in emergency cases, when the patient is at imminent risk of physical injury, decline or death if treatment is withheld or postponed. In such cases, the physician can perform any healthcare intervention as good practice of medicine dictates without such consent;

(b) when the health of the population is dependent on the adoption of a public health program;

(c) when the law makes it compulsory for everyone to submit to a healthcare intervention;

(d) when the patient is incapable of giving consent because he is of under-age, or is unconscious or is in a state of mind constituting a mental impairment;

(e) when disclosure of material information to patient may jeopardize the success of treatment, in which case, third party disclosure and consent shall be in order;

(f) when the patient waives his right in writing.

(3) Informed consent shall ordinarily be obtained from a patient concerned if he is of legal age, conscious and of sound mind in a consent form printed or written in a language understandable by all the signatories containing such particulars as may be notified with the Clinical establishment's name and License number boldly indicated.

(4) If the patient is incapable of giving consent because he is of under-age, or is unconscious or is in a state of mind constituting a mental impairment a third party consent shall be required wherein the following member of the patient party, in the order of priority stated hereunder, may give such consent: (a) spouse; (b) son or daughter of legal age; (c) either parent; (d) brother or sister of legal age, (e) guardian, or (f) Any near relative or any one of the patient party.

16. System of medicine

(1) The service-recipient shall have the right to choose between different system of medicine and such system of Medicine shall be classified into mutually exclusive groups: (a) Allopathy:, (b) Ayurveda, (c) Unani, (d) Siddha, (e) Homeopathy, (f) Naturopathy, (g) Yoga, or (h) Any other recognized system of Medicine (to be specified by the applicant)

(2) The Allopathy System of Medicine shall be further classified into mutually exclusive sub-groups: (i) General; (ii) Specialty e.g. Medicine, Surgery, Pediatrics etc.; (iii) Super-specialty e.g. Plastic Surgery, Pediatric Surgery etc.; (iv) Dental; or (v) Any other Allopathy (to be specified by the applicant).

Provided that All other system of Medicine shall be further sub-classified in such a manner as may prescribed.

Explanation: The term 'specialty' and 'superspecialty' shall have the same meaning as defined by the medical Council of India.

(3) The clinical establishment shall ensure that the patient registered under a Primary Medical Attendant practicing a particular system of medicine is not administered treatment by any Registered medical practitioner practicing another system of medicine.

Explanation. 'treatment" means administration of any one or combination of therapies under any recognized system of medicine by a Registered Medical practitioner to a person for restoring or maintaining his health;

Illustration: 'Acupuncture' as defined in the West Bengal Acupuncture system of therapy Act, 1996 [WB Act VIII of 1996] is a 'therapy' not a system of Medicine;

17. Professional care.

(1) The clinical establishment shall ensure that the patient received or accommodated shall be attended without any undue delay by either a duty medical officer or a consultant who is well oriented to the working arrangement of that clinical establishment.

Explanation 1: Duty Medical Officer means registered medical practitioner on duty having adequate knowledge, skill, expertise or experience who shall to be available within the premises of that clinical establishment at all time during his duty hours for providing different kind of assured services to the patients especially attending emergency call of the indoor patients, till the services of a consultant is available.

Explanation 2: 'Consultants' means Registered medical practitioner in different fields of medicine having specialized knowledge, skill, expertise or experience who can act as specialists to provide expert medical care and services to the patients.

Explanation: 3: 'working arrangement' include both healthcare and non-health care related services; arrangement for sanitation, hygiene, safety and security.

(2) The clinical establishment shall provide for a 'patient registration system' to register all the service-recipient as a patient of that clinical establishment and generate and maintain an out-patient register thereof containing such particulars as may be notified as a part of mandatory record keeping.

(3) A patient receiving health care services at a clinical establishment shall be registered under the professional care of a particular registered medical practitioner during the entire course of his care and such registered medical practitioner shall be recorded as 'Primary Medical Attendant' of that patient.

(4) The Primary Medical Attendant shall, after examining the patient; make a provisional diagnosis; and draw up a written treatment plan, which is medically necessary, record the salient clinical findings and advice in the case-sheet containing such particulars as may be notified as a part of mandatory record keeping.

(5) The treatment plan under sub-rule (4) shall include but not limited to (a) Details of investigation service; (b) Details of Professional care services including services from Visiting Consultant; (c) Details of Nursing services; (d) Details of Rehabilitative services; and (e) Detail of nutritional or dietary service

(6) In the course of his treatment and hospital care, the patient or patient party shall have the right to be informed of the result of the evaluation of the nature and extent of his disease, any other additional or further contemplated healthcare intervention, including the possible complications and other pertinent facts, statistics or studies, regarding his illness, any change in the treatment plan before the change is made.

(7) For any treatment plan, requiring multiple patient encounters, an Explanation and instruction shall be provided to the patient by the Primary Medical Attendant the at the beginning of such treatment plan and shall be in accordance with the requirements of these rules.

(8) The patient or party shall have the right to select a Primary Medical Attendant before commencement of care & treatment and the clinical establishment shall display the name, qualification and availability of medical staff as a part of mandatory display.

18. Admission & Inpatient Care.

(1) To ensure their round-the-clock availability, the clinical establishment with inpatient facilities shall engage such Duty Medical Officer as per requirement as specified in the schedule II and shall generate and maintain a roster of all such DMOs.

(2) Any service recipient shall be allowed to get admitted and kept as an in-patient by any clinical establishment having in-patient facility only if it is medically necessary only after being properly registered as an in-patient under a Primary medical Attendant:

Provided, that, the clinical establishment may deny to admit or to keep the patient if it is satisfied that –

(a) it is not or no longer medically necessary;

(b) the prevailing services or infrastructure facilities including isolation facilities are not sufficient enough to provide treatment and care for such type of patient;

(d) the patient is unwilling or unable to follow the direction or advice of the consultant or DMO;

(e) the patient or patient party is unwilling or unable to accept or follow the regulations of that clinical establishment as mentioned under rule 24;

(f) the patient or patient party is unwilling or unable to accept or fulfill the obligation including financial obligation as mentioned under rule 41

Provided further, that during the period of confinement the clinical establishment may take necessary action to ensure the safety of the patient, other patient and service-provider including imposition of restriction on movement of such admitted patient and may formulate appropriate regulations thereof.

Explanation: 'confinement' is a state of being placed in a clinical establishment with some restriction of movement either due to physical/mental incapacitation or the restriction being imposed to prevent further incapacitation

(3) The clinical establishment shall ensure that the admission is restricted to the number of beds as mentioned in the registration and license and shall display the current bed occupancy status and availability of beds as apart of mandatory display:

Provided that such restriction may be relaxed if the admission of the patient is medically necessary to provide emergency medical care.

(4) The clinical establishment shall generate and maintain an admission/In-patient register containing particulars and unique identification number of every patient accommodated as in-patient and such other particulars as may be notified along with a bed-head ticket or case sheet for recording his care & treatment particulars as a part of mandatory record keeping.

Provided that, the patients accommodated in the observation beds of the emergency department have to be registered in such admission register.

(5) The clinical establishment shall ensure that a newborn whose birth has taken place in the Clinical establishment shall have to be registered in the admission register as mentioned under sub-rule (4) and be provided with a separate bed-head ticket or case-sheet.

(6) The clinical establishment shall ensure that all cases of birth and still birth, which have taken place there, are being recorded in the birth and still birth register respectively as a part of mandatory record keeping.

(8) The patient shall have the right to receive personal care from such a non-medical attendant engaged by the clinical establishment who is not a Medical, Nursing or Paramedical professional or from a family member subject to the permission from the Primary Medical Attendant

Explanation: 'personal care' means care which can be provided by a non-professional and shall include but not limited to-

(a) assistance with one or more of the following activities namely bathing, showering or personal hygiene; toileting; dressing or undressing; eating meals; or

(b) assistance for persons with mobility problems; or

(c) assistance for persons who are mobile but require some form of supervision or assistance; or

(d) the provision of substantial emotional support; or

(e) assistance for summoning up on-duty nurse or medical officer; or

(f) any such reasonable assistance expected of him subject to his skill, competency and experience;

19. Diagnostic procedure, surgical procedure, medication or treatment.

(1) The clinical establishment shall ensure that the diagnostic procedure, medication, diet or treatment is being provided only on the duly authenticated written order of a registered medical practitioner and the requisition forms for all pathology laboratory or diagnostic imaging laboratory tests is containing all relevant particulars including such particulars like as may be notified;

(2) The clinical establishment shall ensure that—

(a) the generic names of drugs shall be written in full before the usage of any abbreviation in the patient's medical record;

(b) all medication administered to the patient shall be recorded with date and time and signed by the concerned nursing staff;

(c) self administration of medications by patient shall be permitted only when specifically ordered in writing by a registered medical practitioner;

(d) any medication errors and adverse drug reactions shall be informed immediately to the prescribing Primary Medical Attendant or RMO;

(e) any medication errors and adverse drug reactions shall be recorded in the patient's medical record; and

(f) all medications shall be kept in properly labeled containers in storage conditions as recommended by the manufacturer.

(3) As the tests are not being performed there but only samples or specimens are collected, every collection centre' shall have such arrangement or affiliation with any reference laboratory to perform those tests and shall display the certificate of such affiliation as a part of mandatory display and shall submit a copy of such certificate along with the application.

Explanation 4. "Reference laboratory" means a pathology laboratory, other than a collection centre, registered under the Act or similar Act of other state, Union territory, Government of India or accredited by 'National Accreditation Board for Testing and Calibration Laboratories or NABL' or organization of similar repute, which accepts sample or specimens from other clinical establishments for testing and examination.

(4) The clinical establishment using computerized medical record shall ensure that all orders for diagnostic procedure, medication or treatment are signed by a registered medical practitioner submitting them and entered in the patient's medical record by technologically appropriate medium as may be determined by the clinical establishment.

(5) Authentication of orders under this rule may be in a written signature, or digital signature with identifiable initials or computer key along with date and time

Explanation: registered medical practitioner means a person as defined in the Act and shall include registered Dental Practitioner.

(6) The clinical establishment shall ensure that all the pathology lab reports diagnostic imaging lab reports are prepared clearly; duly authenticated duly authenticated mentioning date and time; without any errors, specifying measurement procedure where appropriate; containing such particulars as may be notified.

(7) The clinical establishment shall ensure that relevant particulars of all cases of surgical procedure along with classification of such cases into major or minor surgery are recorded in the standard OT register (Logbook) as a part of mandatory record keeping.

Explanation 1. 'major surgery' means all surgical cases done under general anaesthesia or spinal anaesthesia or cases where body cavity were entered and include cases of eye surgeries.

Explanation 2. Minor surgery means such surgical cases other than major surgery.

(8) Any clinical establishment may offer different special care/therapy/treatment services in tune with the advance of modern medicine provided that such special care/therapy units are attached to a maternity home or nursing home.

(9) Such special care/therapy units as mentioned in sub-rule (8) shall be classified into following mutually exclusive categories: (i) Intensive Care/Therapy unit; (ii) Intensive Coronary care Unit; (iii) Intensive Neonatal care Unit; (iv) High Dependency Unit; (v) Nuclear Medicine therapy Unit; (vi) Radiotherapy unit or (vii) any other care/therapy unit (to be specified by the applicant).

Explanation 1: The special care/therapy units are mainly in-patient department of a clinical establishment which is specifically designed, staffed by specialized personnel, located, furnished and equipped with sophisticated equipment and medical supplies to offer more specified and sophisticated service for the patient in need of those which cannot be provided in general department.

Explanation 2: The High Dependency Unit (HDU), also called step-down, progressive or intermediate care unit, is a special care unit of in-patient department to offer more specified and sophisticated service for critically ill patients in the form of more intensive observation, monitoring, treatment, nursing care and management than that is possible in a general ward but slightly less than that given in intensive care.

Explanation 3: The Intensive Care Units (ICU) is a special care unit of in-patient department to offer more specified and sophisticated service for critically ill patients than that is possible in a general ward or High Dependency Unit. For the current purpose it shall include but not limited to ICCU, ITU, NICU, PIKU, SNCU etc.

20. Emergency Care.

(1) All clinical establishment, wherever a Registered Medical Practitioner(s) is engaged, shall have the provision of emergency medical treatment to administer necessary first aid to stabilize the emergency medical condition of any person who comes or is brought to such clinical establishment.

Explanation 1 "Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in (i) death of the person or; (ii) serious jeopardy in the health of the person (or in case of pregnant woman, in her health or health of the unborn child); (iii) serious impairment to bodily functions; or (iv) serious dysfunction of any organ or part of a body;

(2) The clinical establishment with more than 30 (thirty) beds shall have separate emergency department or facility with requisite manpower, infrastructure, equipment and medical supplies to render emergency medical service round the clock.

Explanation: 'emergency medical service' means the organization responding to a perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury;

(3) Failure to have the requisite equipment in working order and non-availability of competent staff within reasonable time while providing the emergency medical treatment as mentioned in sub-rule (2) by such Clinical establishment that declare, or profess, in writing that it provide emergency services for 24 hours, shall be treated as major deficiency under section 29 of the Act.

(4) The clinical establishments shall provide emergency medical treatment to the individual in all cases, whether medico-legal or not, immediately without any delay or waiting for the arrival of the police or completing legal formalities.

Explanation 1: 'emergency medical treatment means' the action that is required to be taken after screening a person who is in an emergency medical condition, as to the stabilization of the person and rendering of such further treatment as may be necessary for the purpose of preventing aggravation of the medical condition of the person or his death

(5) The Emergency medical treatment as mentioned in sub-rule (4) shall be provided to any person including any indigent person under any circumstances, as per provision of the clause (k) of sub-section (3) of section 7 of the Act.

(6) A part or whole of the amount likely to be payable may be collected as deposit or any form of advance for rendering such services as mentioned in sub-rule (4) which shall be adjusted before settlement of final payment:

Provided that the clinical establishment shall not demand any deposit or any other form of advance payment as a prerequisite for providing such Emergency medical treatment as mentioned in sub-rule (4) of rule 18 and such request, solicitation or demand shall be treated as a major deficiency under section 29 of the Act.

(7) the Primary Medical Attendant or the RMO or any Registered Medical Practitioner may refer the patient to effect an appropriate transfer under rule 21 to another appropriate Healthcare establishment or Registered Medical Practitioner for further medical treatment if in its or his opinion further treatment is medically necessary

(8) The transferring Clinical Establishment shall inform, by telephone or otherwise, the Healthcare Establishment to which the person is being transferred that a patient in an emergent medical condition is being transferred and furnish the details of the person's condition.

21. Referral & Transfer.

(1) If it is medically necessary, the Primary Medical Attendant or the DMO or any Registered Medical Practitioner may refer the patient to another Consultant for a second opinion or advice or execution of a particular healthcare intervention in his capacity of being a Consultant having specialized knowledge, skill, expertise or experience:

Provided that, the Primary Medical Attendant may or may not agree to change or modify his treatment plan according to the advice of the second Consultant or allow him to carry out any healthcare intervention.

(2) The patient shall have the right to seek for a second opinion and subsequent opinions, if appropriate, from another consultant and the Primary Medical Attendant shall explain his reason for non-agreement, if any, if he feels that such consultation is not medically necessary for the treatment plan.

(3) If it is medically necessary, the clinical establishment may permit the consultation service including telemedicine to be provided by a Visiting Consultant who is not an employee or empanelled, on the request of the Primary Medical Attendant or the patient or the patient party:

Provided that he shall be qualified enough and such request is recorded in the case-sheet;

Provided further that his name particulars are entered in the staff register under rule 9 before rendering his service.

(4) If it is medically necessary, the Primary Medical Attendant or the RMO or any Registered Medical Practitioner may refer the patient to effect an 'appropriate transfer' to any appropriate Healthcare establishment for receiving and/or accommodating the patient.

(5) A transfer to another Health care establishment shall be treated as an appropriate transfer if –

(a) before transfer, the patient has been provided with highest possible medical treatment by the clinical establishment within its capacity to minimize the risks to the health of the patient.

(b) before transfer, the patient and the party has been provided with adequate consultation and counseling regarding the necessity of such transfer; and

(d) The transferring Clinical Establishment sends to the receiving Health care establishment or receiving Registered Medical Practitioner –

(i) all medical records (or copies thereof), relating to the screening and the emergency medical condition of the person, which are available at the time of such transfer, including records relating to the patient's medical condition, observation of signs or symptoms, preliminary diagnosis, treatment provided, results of any investigation and the informed written consent, if any, and

(ii) a Discharge Certificate or

(iii) a certificate of transfer that, based upon the information available at the time of transfer that the medical benefits reasonably expected from the provision of appropriate medical treatment at the receiving Health care establishment outweigh the increased risks, on account of the transfer, to the patient so far as the treatment of patients are concerned,

(d) The transferring Clinical Establishment provides necessary medical facilities including life support systems and qualified personnel within the capacity of the transferring Clinical Establishment or medical practitioner, to accompany the patient during the period covered by transport to the receiving Health care Establishment or receiving medical practitioner.

(e) all such referral cases are being registered in a referral register as a part of mandatory record keeping containing such particulars as may be notified.

(6) The clinical establishment having more than 300 beds, shall provide and maintain ambulance van or any such suitable conveyances, with such sufficient attendants and other such requisites to transfer patients as may be notified by the Government from time to time.

(7) Where an entry made in the Admission register referred to in rule 18 relates to a woman who has been admitted for delivery, and a child born to such woman is transferred with the consent of the clinical establishment and of the parents, or near relative, such clinical establishment shall in addition to the particulars specified in rule 18 also record in the Admission register the name and address of the person to whose custody and the date on which and the reasons for which the child was so transferred.

22. Discharge & Death.

(1) Any patient admitted in the clinical establishment shall ordinarily be discharged, on issuance of a Discharge Certificate containing such particulars as may be notified by the consultant or RMO as when further stay is not medically necessary as determined by the Primary Medical Attendant of that patient:

Provided that, the patient may be discharged, on issuance of a Discharge Certificate or transfer certificate for the sake of transfer to another Clinical establishment or Healthcare establishment following the procedure of appropriate transfer as per Rule 21.

(2) The patient may be discharged regardless of his physical condition on a request made by him or the patient party on issuance of a 'Discharge against Medical advice Certificate' by the consultant or RMO subject to the following terms and conditions:

a) before such discharge, the patient and the patient party is informed adequately by his Primary Medical Attendant of the medical consequences of his decision;

b) before such discharge, the patient releases those involved in his treatment & care from any obligation relative to the consequences of his decision by signing a written declaration or bond in that regard by the patient or the patient party if the patient is unable to do so;

c) such discharge will not prejudice public health and safety.

Provided that the patient may be discharged so, if he fails to comply the advice given by the Primary Medical Attendant.

(3) The patient or patient party shall have the right to be informed by the Primary Medical Attendant or his delegate of his continuing health care requirements following any kind of discharge, including instruction about home medications, diet, physical activity and all other pertinent information to promote health and well-being.

(4) The clinical establishment shall make suitable arrangement for discharge of a patient at such a convenient time on the day of discharge so that the patient is not compelled for paying the bed-charge for the next day.

(5) The clinical establishment shall ensure that all cases of death, which have taken place there, are being declared as soon as possible and are issued with a proper death certificate and all such cases are recorded in a death register generated and maintained thereof as a part of mandatory record keeping

(6) Until it is released, the Clinical establishment shall preserve the corpse in an appropriate manner without showing any disregard for it and shall release and hand over it to the patient party or near relative forthwith subject to observation of all the legal formalities.

23. Sanitation, Hygiene, Safety & Security.

(1) In order to ensure adequate sanitary and hygienic condition, the clinical establishment shall exercise reasonable care and take all necessary measures including disinfection, sterilization and such measures as specified in schedule IV.

(2) No application for new license or renewal shall be granted unless the applicant has obtained a valid trade license or certificate of enlistment issued by the local authority and submitted a copy of such along with the application.

(3) In order to ensure the sanitation, hygiene, safety & security, the clinical establishment shall either obtain the authorization/license / No Objection Certificate under the following Acts/Rules and shall submit a copy of such along with the application or shall submit a self-declaration in the form of an affidavit as a part of statuary CE Form III along with the application that he shall abide by the provisions of such Acts/Rules

(i) the West Bengal Fire Service Act, 1950,

(ii) the Bio-Medical Waste (Management and handling) Rules, 1998,

(iii) the Atomic Energy Act (33 of 1962) and the Atomic Energy (Radiation Protection) Rules, 2004, if applicable; and

(iv) any other acts/rules as may be notified

(4) In order to minimize the undue risk for the service provider, the clinical establishment shall exercise reasonable care and take all necessary measures which include but not limited to 'Universal work precautions', chemoprophylaxis, vaccination, post-exposure prophylaxis and adequate capacity building.

Explanation: 'Universal work precautions' means infection control measures that prevent occupational and nosocomial exposure to or reduce the risk of transmission of pathogenic agents including Hepatitis B, Hepatitis C and HIV and includes the provision for education, training, personal protective equipment such as gloves, gown and masks, hand washing, cough hygiene and employing safe work practices.

(5) The Clinical establishment, as soon as it comes to its notice that any person, who has been received or accommodated in the clinical establishment, is suffering from or has been attacked with any infectious diseases, the Clinical establishment shall take appropriate precautionary measures for the protection of other patients, service providers and public at large.

Explanation 1: 'appropriate precautionary measures' includes but not limited to (a) Universal work precautions; (b) Barrier Nursing; (c) Isolation; (d) disinfection; and (f) any other scientific measures

Explanation 2: "Infectious disease" means a clinically manifest disease of man or animal resulting from an infection. Infection means the entry and development or multiplication of an infectious agent in the body of a man or animal.

(6) The clinical establishment shall take such necessary measure for handling and disposal of general waste as per the provision of relevant acts and rules of the local self government and obtain permission as such.

(7) In order to ensure the safety, security and physical comfort of the service-provider as well as service-recipient, the clinical establishment shall exercise reasonable care and take all necessary measures including installation of such safety measures and physical amenities as may be specified in schedule IV.

(8) To ensure safety and utilization of space by disabled and elderly people, the clinical establishment shall provide Barrier free access environment for easy access to non-ambulant(wheel- chair, stretcher), semi-ambulant, visually disabled and elderly persons as per "Guidelines and Space Standards for barrier-free built environment for Disabled and Elderly Persons" of CPWD/ Ministry of Social Welfare, GOI.

(9) Notwithstanding anything contained in the rule 22, the patient, his personal belongings including his corpse shall remain in the safe custody of the Clinical establishment in an appropriate manner unless he or it is being released or handed over to the patient party and the clinical establishment shall take appropriate safety and security measures thereof.

Provided that, No clinical establishment shall release or handover or dispose the of the same in any manner or try to do so without the consent of the patient party

Provided further, that, no CE shall detain or try to detain the patient or the corpse against the will of the patient or patient party due to any reason including the failure of the patient or patient party to fully settle his financial obligations and such detention may be amounting to an offence under sections 339 to 344 of the IPC and the Competent Authority may take appropriate action under section 97 of the Cr.PC.

Explanation: Personal belongings shall include specimen, x-ray film, USG film and such other images, photographs etc.

(10) In order to ensure safety, security and a conducive atmosphere, the clinical establishment shall exercise reasonable care and take all necessary measures to prevent the occurrence of any events of patient abuse or

misappropriation of patient property and any failure to take such measures shall be treated as major deficiency under section 29 of the Act.

(11) The patient has the right to communicate with the patient party and to receive visitors subject to such reasonable restriction:

Provided that, in order to ensure the safety and security, the Clinical establishment shall have the right to impose reasonable restriction regarding entry and movement of the patient, patient party, escorts of the patient and visitors in the premises of the clinical establishment and formulate regulation thereof.

24. Standard Operating Procedures & Practices

(1) In order to ensure the quality of service, the clinical establishment shall exercise reasonable care and take all necessary measures including measures to comply the standard operating procedures and practices as mentioned in schedule V.

(2) The clinical establishment shall ensure that any service provider or any person associated with the Clinical establishment shall not

(a) directly or indirectly request, receive or participate in the division, transference, assignment, or splitting of a fee; or

(b) directly or indirectly request, receive or profit by means of a credit or other valuable consideration as a commission, discount or gratuity

in connection with (i) the furnishing of healthcare or non-health care related service; or (ii) the sale, rental, supplying or furnishing of drug, equipment, medical supplies and medical devices

(3) The clinical establishment shall ensure that no service provider or person associated with the Clinical establishment shall practice fee-splitting.

Explanation: "fee-splitting" means any form of arrangements made between practitioners, healthcare facilities, organizations or individuals as an inducement to refer or to receive a patient to or from another practitioner, healthcare facility, organization or individual for the sole purpose of financial gain.

(4) The clinical establishment shall ensure that no service provider or person associated with the Clinical establishment shall –

(a) carry out multiple consultation or encounter with the patient when it is not medically necessary; or

(b) refer the patient to a Visiting Consultant when it is not medically necessary; or

(c) keep a patient in the Clinical Establishment as an in-patient when it is not medically necessary or longer than is medically necessary; or

(d) carryout or undertake to carry out any form of investigation and healthcare intervention which is not medically necessary.

(e) insist upon the patient or party to get admission in a particular clinical establishment due to any reasons other than scientific

(f) insist upon the patient or party to get the investigation done from a particular clinical establishment due to any reasons other than scientific.

(g) engage in any other unethical or unfair trade practice as may be notified

(5) The clinical establishment shall ensure that no service-provider of that clinical establishment shall be engaged in cross-practice.

Explanation: ‘cross-practice’ or cross system practice is the practice of a particular system of medicine by a registered medical practitioner of another system who is not qualified enough to practice that system of medicine.

(6) The clinical establishment shall ensure that no person associated with that establishment shall insist upon procurement or purchase of particular brand of drug, medical device or medical supplies; or procurement or purchase of drug, medical device or medical supplies from a particular shop, establishment, manufactures or vendor due to any reason other than the scientific reason.

(7) Any act of violation mentioned under sub-rule (2) to (6) by any service provider or any person associated with the Clinical establishment shall be considered as unethical or unfair trade practice by the clinical establishment under section 7 (3) (c) of the Act and such clinical establishment shall be liable of contravention.

(8) The clinical establishment may make its own set of Regulation, and standard operating procedures concerning the organization and operation of that establishment subject to the following terms and conditions:-

(a) Those regulation, and standard operating procedures are not contrary to the provision of any law of the land particularly those acts and rules mentioned in schedule IX including the Clinical Establishment Act, rules and regulation;

(b) Those regulation, and standard operating procedures are not violating the fundamental rights or human rights; and

(c) any other terms and conditions as may be notified.

Provided that the clinical establishment shall have to submit a copy, if any, of those regulation, and standard operating procedure along with the application.

Explanation. – "Regulation" contains set of instruction for patients and patient party and "SOP" contains set of instructions for the service providers

(9) In order to provide assured quality service, the clinical establishment shall formulate and implement its Internal Quality Assurance programme including Medical audit and other necessary measures and exercise reasonable care to prevent the occurrence of events of patient neglect.

Explanation. – "Patient neglect" means a failure, through inattentiveness, carelessness, or other omission, to provide to a patient goods and services necessary to avoid physical harm, mental anguish, or mental illness when an omission is not caused by factors beyond the person's control or by good faith errors in judgment.

(10) The Licensee of the clinical establishment shall read and understand and make all the staff to read and understand the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 (West Ben. Act XXVI of 2010) and the rules made thereunder as amended from time to time.

(11) It shall be the duty of the licensee of the clinical establishment to make all service recipients and service providers aware of the relevant section(s) of such regulation, and standard operating procedures developed or adopted by them.

(12) The clinical establishment conducting or intending to conduct any kind of training or biomedical research shall take reasonable care not to cause any deficiency of the assured service there.

(13) Any clinical establishment conducting or intending to conduct any biomedical research shall obtain a prior approval from the State Prescribing Authority in respect thereof and shall comply with the terms and conditions of that approval.

(14) The State Government may, by notification, designate an officer not below the rank of Joint Secretary, Medical Education as the State Prescribing Authority for Bio-medical research; and lay down the principles and procedure of approval under sub-rule (13).

(15) The clinical establishment shall actively take part in such External Quality Programme as may be notified.

CHAPTER IV
Reporting Standards

25. Mandatory record keeping.

(1) In order to ensure proper patient care, legal formalities including medico-legal formalities, the clinical establishment shall exercise reasonable care and take all necessary measures including generation and maintenance of such standards of registers and records in such a manner as specified in schedule VI.

(3) No service recipients shall be provided with any kind of service by the clinical establishment unless he is registered by the 'patient registration system' of that clinical establishment:

Provided that, a service recipient whose identity could not be determined shall be registered as such with immediate information to the nearest Police Station.

Provided further, that, any person may be provided for and administered with the Emergency medical treatment without waiting for registration.

(4) The clinical establishment shall generate and maintain all the mandatory registers and records mentioned under this Act or rules in hard copy having machined-pressed page number and duly authenticated:

Provided that, the Licensing Authority may consider generation and maintenance of such registers and records in electronic form affixing digital signature if he is satisfied with such manner.

(5) The clinical establishment shall ensure that –

(a) all the Registered Medical Practitioners of the Clinical establishment are following the guideline of Medical record keeping issued by the Medical Council of India or WB Medical council or such guidelines as may be notified from time to time;

(b) The records, registers and documents generated and maintained by it is being entered fully, chronologically and legibly and is not being tampered with;

(c) The records, registers and documents are being updated and authenticated periodically at least 6 monthly interval.

26. Mandatory Display.

(1) At reception area and other suitable places, the clinical establishment shall make available Information Display Boards in such a conspicuous manner as to be visible to everyone visiting such establishment and shall affix the Duplicate copy of Clinical establishment license(s);

(2) In such display boards under sub-rule (1), the clinical establishment shall make available such appropriate, adequate and comprehensive information useful for public prepared in both the local and English language in a manner understood by a non technical person of the concerned area as mentioned under different provisions of the Act and rules or any such information as may be notified.

(3) At reception area and other suitable place(s) including public domain, the clinical establishment, for the benefit of the service recipient, shall make available an Information Brochure prepared in both the local and English language in a manner understood by a non technical person of the concerned area and containing appropriate, adequate and comprehensive information prepared including information mentioned under sub-rule (1) particular such information which are too lengthily to display in the board:

(4) For the purpose of this rule 'other suitable place including public domain' shall include the website maintained by the clinical establishment and the department.

(5) The clinical establishment shall submit a copy of Information Brochure mentioned under sub-rule (3) to the Licensing Authority along with the application for grant or renewal of license under rule 30.

(6) Besides having information display boards, the clinical establishment shall have adequate sinage system including a prominent board displaying the name of the establishment in the local language; Colour coded guidelines and signages indicating access to various facilities; at strategic points in the establishment; sinages of bio-safety symbles etc. at strategic points in the establishment for guidance of the public.

(7) The Licensing Authority may consider any of the relevant information, contained in the mandatory display mentioned under this rule as a public record and may make those records available in the public domain or to any public servant in public interest.

(8) While displaying or causing display of any information or advertisement, the Clinical Establishment, shall take reasonable care that the information are factually accurate and capable of substantiation, and are not exaggerated, false, misleading or be reasonably capable of being misinterpreted.

27. Mandatory Reporting.

(1) In order to ensure proper patient care, legal formalities including medico-legal formalities, the clinical establishment shall exercise reasonable care and take all necessary measures including generation, maintenance and submission of mandatory reports and returns mentioned under different provisions of the Act and rules or any such reports as may be notified in such a manner as specified in schedule VI.

Provided that, the clinical establishment shall, as soon as possible, generate and submit to the Licensing Authority such other reports, as may be demanded by the Licensing Authority pertaining to the discharge of his duties.

(2) The clinical establishment shall submit all the reports mentioned in sub-rule (3 and 4) in any effective manner to the Licensing authority or to the Designated Officer as may be notified and obtain an acknowledgement of the same and shall submit a copy of such acknowledgement along with the application for renewal of license.

(3) The clinical establishment shall submit a report regarding any of the sentinel events in such a manner as may be notified that has occurred at the clinical establishment to the appropriate authority with a copy to the Licensing Authority as a part of mandatory reporting immediately after the clinical establishment has reasonable cause to believe that the incident occurred:

Explanation: A sentinel event is an unexpected, unforeseeable or unanticipated occurrence which result in or may result in death or serious physical or psychological injury, or any serious adverse outcome heath including disruption of service or the risk thereof needing immediate intervention.

(4) The clinical establishment shall generated and maintain a Police intimation register as specified in schedule V. as a part of mandatory record keeping and shall submit reports regarding medico-legal cases though that register.

28. Access to Medical Records.

(1) As soon as possible, after the purpose for which the patient had visited or had been admitted is over the patient is entitled to a brief, written summary of medical record related to observation, treatment, test, investigation, advice and diagnostic opinion pertaining to the patient free of cost:

Provided that, the patient is entitled to such Summary Medical Report even if he was discharged against medical Advice.

Explanation. The Summary Medical Report is a report under sub-rule (1) to be provided by the Primary Medical Attendant containing such particulars which includes but not limited to –

(a) The reasons for admission, significant clinical findings, provisional diagnosis and results of investigations, treatment and the nature of the health service rendered; and

(b) The final diagnosis and condition of the patient at the time of discharge

(b) Follow-up advice, medication and other instructions and when and how to obtain urgent care when needed in an easily understandable manner; and

(c) Any other particulars which shall be useful for future health care of the patient.

(2) The summary of Medical Records under sub-rule (1) made available to the patient party at the time of Death to be known as Summary Medical Report (Death) shall contain the following additional particulars:

(a) The terminal care given; and

(b) a copy of death certificate issued as per Medical certification of Cause of Death guideline provided under the Birth & Death Registration Act, 1969 [Act No. 18 of 1969]

(3) Notwithstanding that he may not be able to fulfill his other financial obligation, the patient or patient party is entitled to reproduction, at his expense, the pertinent part or parts of the medical record and reports pertaining to his healthcare' the purpose(s) of which he shall indicate in his written demand for reproduction.

(4) On such demand under sub-rule (3), the clinical establishment shall, as soon as possible, make available such hard copy to the patient or patient party either at free of cost or after receiving payment of such charges at a reasonable rate not exceeding the rate of Rs.5 per A4 size pg or Rs.50 per Compact Disc.

(5) All records, registers, reports, or any such instruments, either medical, medico-legal, mandatory or of any kind including the confidential medical records shall be open to inspection, in due discharge of his duties, by the Licensing Authority or Supervisory Authority and shall, as soon as possible, be made available to them in the form of duly authenticated hard copy or soft copy on demand under Rule 36 free of cost by the clinical establishment.

29. Statement & Representation

(1) The clinical establishment shall have an obligation to exercise reasonable care to ensure the truthfulness, completeness, accuracy, timeliness and other aspects of quality of all such applications, claims, reports, documents, and other information and of all statements and representations as per instruction of the Government under this Act or rules which are made or submitted, or to be made or submitted by the clinical establishment

(2) The clinical establishment may authorize a representative competent enough to make, execute or submit such instruments as mentioned in sub-rule(1), on its behalf subject to provisions of this Act or rules:

Provided that such representative shall sign those instruments in the form of the signature showing unambiguously that the signature is made on behalf of the clinical establishment which is identified in that instrument.

(3) Such person under sub-rule (2) shall be considered to represent to the Government, to the best of the clinical establishment's knowledge and belief, that the items containing in the instrument is genuine and that its contents, including all statements, claims, and representations contained in the document, are true, complete, accurate, and not misleading.

Explanation. – 'to make includes 'to generate, maintain, or display'

(4) The Clinical establishment is liable if on any instrument so executed by its representative –

(a) the form of signature does not show unambiguously that the signature is made in a representative capacity or

(b) the represented person is not identified in the instrument; or

(c) the signature is an unauthorized signature

Explanation. – Unauthorized signature means one made without actual, implied or apparent authority and includes a forgery under section 464 of the IPC.

(5) Any person is considered to have known that a claim, statement, or representation related to the Act or rules was false, incomplete, inaccurate or misleading, if the person knew, or by virtue of the person's position, authority, or responsibility shall have known, of the falsity, incompleteness, or inaccuracy of the claim, statement, or representation.

(6) The clinical establishment shall provide such capacity building program of instruction and assistance to person or persons authorized by it to generate, maintain, display, or submit any applications, claims, reports, documents, and other information as per instruction of the Government under this Act or rules, which shall include –

(a) clear directions for the completion of applications, claims, reports, documents, and other information;

(b) examples of properly completed applications, claims, reports, documents, and other information;

(c) a method by which persons submitting applications, claims, reports, documents, and other information may, on a case-by-case basis, receive accurate, complete, specific, and timely advice and directions from the Authority before the completed applications, claims, reports, documents, and other information shall be submitted to the Authority;

(d) any other components of instruction and assistance as may be notified

(7) All records, registers, and reports, either medical, medico-legal, mandatory or of any kind shall be considered as properly maintained if –

(a) those instruments are generated and maintained in such manner and retained for such period as may be specified in schedule VI;

(b) those instruments are authenticated by affixing signature and properly dated or by any other effective manner as may be directed by the Licensing authority

(c) those instruments including bills, vouchers and correspondence letter-heads are bearing the name of the clinical establishment along with the License number with period of vailidy, if any.

(8) For the purpose of these rules, unless mentioned otherwise, signature is the personal name written in one's hand accompanied with appropriate a mark, seal, stamp denoting the designation of that person.

(9) The clinical establishment may generate, maintain and retain such instruments in the form of electronic records as per provisions of the Information Technology Act, 2000 [No. 21 of 2000].

(10) Unitil further notification, the clinical establishment may submit the all the mandatory reports mentioned in this Act or rules made thereunder in any one of the following effective manners:

(a) submission in hard copy form personally, or by messenger, or by registered post;

(b) submission in soft copy form or electronic form affixing digital signature if permitted by the govt though notification;

(c) submission in any other effective manner as may be notified

CHAPTER V
Registration & Licensing

30. Application and Accompanied evidence.

(1) To obtain the registration and license, any person, who intends to commence, keep or carry on a clinical establishment, has to submit an application in statutory CE Form I to the licensing authority along with the required supporting documents mentioned under different provisions of the Act and rules or any such document as may be notified.

(2) Unless mentioned otherwise, the following documents are to be submitted as evidence of having met the requirements of minimum standards along with the application made under sub-rule (1):

(a) copy of plan for construction or modification approved by the Local Authority;

(b) Sketch map showing detailed position and floor measurement of the different facilities.

(c) copy of The tax receipt [property tax] form the Local body;

(d) copy of the current rent receipt or rent agreement or 'No objection certificate' from the Owner of the premises or any such document if the applicant is a tenant or the current lease-deed if the applicant is a lessee or the current consent letter from the owner if the applicant is granted rent free accommodation by the owner of the premises or any such document;

(e) any such documents as may be notified

(3) To obtain an amended license as mentioned in rule 7, the applicant has to submit an application in statutory CE Form I along with the required supporting documents and the stipulated License fee to the respective Licensing Authority.

(4) To obtain a duplicate copy of license under section 12 of the act, the applicant has to submit an application in statutory CE Form I along with the evidence of loss, destruction mutilation or damage and any other documents as may be required by the Licensing Authority to such Authority.

(5) The applicant shall submit a self-declaration as per statutory CE Form III in the form of an Affidavit on requisite stamp paper sworn by him to the licensing authority

(6) All the supporting documents along with the application form properly filled in respect of all particulars under a cover letter/forwarding letter to the Licensing Authority shall be submitted in any effective manner and the clinical establishment shall ensure that the Licensing Authority always has up-to-date information on their establishments and it shall convey any changes in the particulars already submitted in the application form forthwith.

(7) Copy of documents mentioned in this rule means self-attested photocopy/digital copy of such original documents.

31. The Applicant.

(1) Depending upon the nature of ownership, the clinical establishment shall be classified into following mutually exclusive groups: (A) Individual Proprietorship; or (B) Collective proprietorship or company or organization and in case of company, a copy of Memorandum/Articles of Association or Partnership deed or similar document has to be submitted along with the application

Explanation: Collective proprietorship or company or organization shall be further classified into: (B1) Registered Partnership; (B2) Registered Company; (B3) Corporation registered under a Central, Provincial or State Act (to be specified); (B4) Trust (including Charitable) registered under a Central, Provincial or State Act (to be specified by the applicant); (B5) Organization registered under society registration Act or (B6) Any other (Private Sector enterprise (to be specified by the applicant)

(2) In case of clinical establishment having ownership in the nature of Collective proprietorship or company or organization as mentioned under sub-rule (1), the following additional documents are to be submitted along with the application form:

(3) In case of Collective proprietorship or company or organization the applicant has to mention whether such organization is a branch of a Foreign Service provider or not;

(4) Notwithstanding anything contained in section 6 of the Act, in order to fix up the responsibility, the application made under Rule 30 shall be filled in with the name of a particular individual as an applicant and not with the name of a Company or organization who shall be considered as the licensee of that clinical establishment.

Provided that, in case of a Collective proprietorship or company or organization**,** the applicant shall be a representative of such Company or organization after being nominated through resolution by that Company or organization to act as such.

Provided further, that, such arrangement shall not absolve the company or any one of its director, manager, secretary or any other officer of that company from being responsible for the compliance of the provision of the Act or rules.

(5) Along with the application, the company shall inform the Licensing authority in statutory CE Form II, the particulars of applicant concerned, with due certification that such applicant has been so nominated for the purposes of sub-rule (2).

(6) The Company shall also intimate to the Licensing Authority, as and when any change occurs in the nomination given in sub-rule (4) above forthwith, in statutory CE Form I.

(7) Only the applicant under sub-rule (4) after being granted a license under the Act shall be registered as the Licensee of that Clinical Establishment.

32. Fees and Fines.

(1) Unless exempted under section 25 of the Act, for new license or renewal, the clinical establishment shall submit the whole amount of fee mentioned under in the schedule VII as license fee and shall submit a copy of Treasury challan along with the application.

(2) Any fee or fines under the Act and rules shall be paid in cash to Reserve Bank of India in Kolkata and to the Treasury elsewhere under the appropriate receipt Head either directly or through any such agency or agencies in a manner as may be notified.

Provided that, the government may notify the mode of payment of fees and fines vide pay order or demand draft or any online/offline mode of payment

(3) The Licensing authority shall have the power to consider any claim for refund of license fee deposited and fund the same under appropriate refund head but in case of application being rejected or withdrawn, the Licensing authority shall refund the license fee after deducting ten percent of the amount deposited as application processing fee.

(4) The licensing authority shall keep a record of accounts of the fees so debited and credited, on receipt of the Treasury Challan and submit such records to the State Register annually.

33. Validity & Renewal of license.

(1) Unless suspended or cancelled or otherwise specified, a Registration or license granted under these Regulations shall ordinarily be valid and subsisting, for a period of 1 (one) to 3 (three) years as chosen by the applicant in his application, from the date of issue of license subject to advance remittance of stipulated License fee applicable for the period and compliance with all conditions of license:

Provided that, if not mentioned by the applicant, the license shall ordinarily be valid for 1 (one) year.

Provided further that, the license being non-transferable as per section 18 of the Act, in case of sudden death of the licensee, which shall be conveyed to the Licensing Authority immediately, the license shall subsist until the expiry of –

(a) the period of three months beginning with his death; or

(b) such longer period as the Licensing Authority may allow.

Provided furthermore that, the amended license issued in favour of the applicant under rule 7 shall be valid for the remaining period of validity as mentioned in the existing License

Explanation: 'Stipulated License fee' shall be computed by adding the Whole amount for the first year and the 50% of the whole amount for the subsequent year(s) of License fee as mentioned in rule 32.

(2) Any application for the renewal of a registration or license granted under these rules shall be made statutory CE Form I along with the existing duplicate license, not later than 30 days prior to the expiry date indicated in the license:

Provided that, in case of the last date of submitting an application is a gazetted holiday, the application shall be submitted on the immediate next working day.

(3) The Registration or License shall continue to be in force till such time that the orders are passed on the renewal application which in no case shall be beyond 90 (ninety) days from the date of expiry of registration or license.

(4) Any application for renewal submitted beyond the period mentioned under sub-rule (2) above but before the expiry date, shall be accompanied by a late fee of twenty five percent of the License fee.

(5) Any Registration or license for which renewal has not been applied for within the period mentioned in sub-rule (2) or sub-rule (4) above shall expire and the clinical establishment shall stop all healthcare service related activities at the premises:

Provided that, the applicant shall have the right to apply for fresh Registration or license as mentioned in rule 30, if it wants to restart the healthcare service related activities.

(6) In case the application for renewal is made after expiry of the validity of the registration and license, the licensing authority shall treat it as a application to obtain new license as per rule 30:

Provided that the applicant made an additional payment of One hundred rupees for each day of delay of submission of application from the date of expiry of the validity of the license.

34. Processing of Application.

(1) On the receipt of an application, the Licensing Authority, or any person in his office authorized in this behalf, shall, acknowledge such receipt of the application for registration, in the acknowledgment slip in statutory CE Form V either issued by him or generated automatically by the web-based system.

(2) Such acknowledgment slip shall bear a unique Application ID number to each application that can be referred to for all future correspondence between the Licensing Authority and the applicant or for any other official purposes.

(3) The licensing authority may generate and maintain an Application register in such form as may be notified to record the relevant information regarding application submitted to him.

(4) Within a period of 15 days after issuance of acknowledgement, the Licensing Authority may assign the task of further processing the application including inspection and/or inquiry to the Supervisory Authority constituted under rule 35.

(5) If, upon scrutiny of the application within 15 days from the date of receipt of the application, the concerned Supervisory Authority requires any additional information, explanation or supporting document in respect with the application, the Supervisory Authority shall issue an order in writing on the applicant to furnish such additional information, explanation, or supporting document within 30 days from such order.

(6) In case the applicant fails to furnish the required information within the stipulated time of 30 days, the application for license shall stand rejected under section 14 of the Act.

(7) Within a period of 30 days from receipt of a complete application, the Supervisory Authority shall conduct necessary inspection and/or inquiry in a manner under rule 35 and may issue an improvement notice on behalf of the Licensing Authority to the applicant, if it deems fit, guiding him on necessary steps to be taken or changes or alteration to be made in order to ensure the fulfillment of terms and conditions of licensing.

(8) The applicant shall carryout the required steps, changes or alterations and intimate the Licensing Authority within 30 days or such period as may be allowed by the Licensing Authority.

(9) In case the applicant fails to carry out such steps and intimate the Supervisory Authority within the stipulated time, the application for license shall stand rejected under section 14 of the Act.

(10) Within a period of 30 days from receipt of an inspection report in Statutory CE form V, the Licensing Authority shall consider the application and pass an order for grant of license in Statutory CE form VIII or refusal of license in Statutory CE form IX under section 13 of the Act:

Provided that, before refusing license an applicant shall be given an opportunity of being heard by the Licensing Authority and the reasons for such refusal shall be recorded in writing.

(11) The Licensing Authority shall send the copy of order of grant or refusal to the applicant in any effective manner as he deems fit for the purpose.

35. Inspection & Inquiry.

(1) The Licensing Authority shall order a scheduled inspection and/or inquiry as soon as possible and as often as may be necessary to verify the material facts and statement made in the application under rule 30; and to ascertain the quality of standard of service under rule 8 to 29.

Provided that, it shall be the duty and responsibility of the Licensing Authority to cause periodic inspection or inquiry of clinical establishments as often as may be necessary to satisfy himself that the clinical establishment is being kept or carried on in accordance with terms and conditions of the license and that its directions are complied with.

(2) The Licensing Authority, as soon as possible, shall order an unscheduled inspection or inquiry to verify the material facts and statement made in the complaint upon receiving such a written specific complaint of serious nature from a patient or a representative body of patients/citizens alleging non-compliance of the provision of the act:

(3) The Licensing Authority, as soon as possible, shall order an unscheduled inspection and/or inquiry if he has reasonable ground for believing that

(a) the clinical establishment has got no valid license or

(b) the conditions mentioned under sub-section (1) of section 21 exists including imminent danger to the safety and security of service-user, service-provider or public at large; or

(c) the clinical establishment has failed to comply with any provision of this act.

(4) The reason(s) for such inspection shall be recorded in writing in such order

(5) For the purpose of inspection and inquiry as per sub-rule (1), (2) and (3) the Licensing Authority, in exercise of the power under section 22 of the Act by issuing a general or specific Authorization Notice, shall constitute a Supervisory Authority of no less than 1 member of Govt. servant headed by a govt. medical officer.

Provided that, govt. medical officer(s) of different specialties or systems of medicine shall be included as member(s) depending upon the circumstances.

(6) Any person who obstructs, hinders or impedes the Supervisory Authority in the performance of its function or execution of its duty shall be guilty of a contravention under sub-section (1) of section 28 of the Act

(7) Any person who refuses or fails, without reasonable cause, to furnish any information to the Supervisory Authority, or gives any false or misleading information to the Supervisory Authority shall be guilty of a contravention under sub-section (2) of section 28 of the Act.

36. Entry Search Seal Seizer.

(1) The Supervisory Authority, or any officer of the State Government authorized by the State Government under Section 28 or the Supervisory Authority, preferably in the presence of two or more independent and respectable persons, shall enter any premises specified in the Authorization Notice, including a private dwelling, and-

(a) inspect, photograph, copy, test and examine any material object, or cause it to be inspected, photographed, copied, tested and examined;

(b) observe and examine any activity, operation process or procedure carried out on the premises; and

(c) seize any material object if he has reason to suspect that it might be used as evidence in a trial

Explanation 2. – "Material object" means any equipment, sample, article, document, record, register, book, pamphlet, advertisement or any other material object for the purpose.

Explanation 3. – 'premises' shall not include the area for residential accommodation of a registered clinical establishment

(2) Such Authority or officer shall conduct the search and seizer as per the Cr.PC.

37. Inquiry Report & Improvement Notice Suspension, Cancellation, Prohibition orders.

(1) The Supervisory Authority shall record the salient points of their observation or inspection in the inspection book (register) to be kept by the CE specified in the schedule as a part of mandatory record keeping with reference to the availability of minimum standards and also detail the specific deficiencies to be corrected, if any.

(2) The Supervisory Authority shall record his observation of inspection and recommendation(s) to the Licensing Authority in the inspection/inquiry report as specified in statutory CE Form V and submit such report to the Licensing Authority.

(3) In the event that any Licensing Authority is of opinion that there is reasonable ground to believe, on a review of the report mentioned under sub-rule (2), or any such report of any scheduled or unscheduled inspection made under Rule 35, that such conditions exists warranting the issuance of an improvement notice under section 23 of the Act, such authority may forthwith issue such improvement notice or may take any necessary action according to the procedure notified by the Government from time to time.

(4) Under the provision of section 20 and section 21, The licensing authority, if he is reasonably satisfied, may issue an order of suspension or cancellation or prohibition and may consider publication of such order in the public domain or to any public servant in public interest.

(5) Whenever any order or notice is required to be served under any provision of the Act or rules, such order or notice shall be served in accordance with the Civil Procedure Code.

(6) Whoever, without lawful authority, destroy or damage or cause to destroy or damage any order, notice or document given or prepared or kept in accordance with this Act and rules shall be guilty of contravention .

(7) The Licensing Authority may consider such enquiry report or improvement notice or any of the relevant information, contained therein as a public record and may make those records available in the public domain or to any public servant in public interest.

38. District & State Register.

(1) In exercise of power under section 9 of the Act, the licensing authority, to be known as District Registrar, shall generate and maintain a register in statutory CE Form VI to be known as the District register of Clinical establishments for recording the details in respect of clinical establishments of that district.

Explanation: 'district' means such administrative district or the health district as may be notified.

(2) The names of the clinical establishments shall be entered in the Register in the order in which the license are granted and sufficient space shall be left for future additions and alterations in respect of the entries made about the establishment(s).

(3) Each License shall bear a 12 digit registration/License Number consisting of three parts: (a) a 4 digit district code as may be directed; (b) a 4 digit serial number of the entry in the district register and (c) Year of registration

(4) The entries in the District Register shall be made serially and a fresh serial shall be started at the commencement of each calendar year and the serial number of the particular year shall be distinguished from the serial number of other years by mentioning the year against the serial number,

Illustration.- serial number 5 of 2012 and serial number 5 of 1973 shall be mentioned as WMDP-0005-2012 and WMDP-0005-2013 respectively.

(5) Within the 31st January, each year each District registrar shall supply in digital or in such other prescribed format to the State Registrar of clinical establishments of all the additions and alterations in the district register as stood on 31st December of the previous year to ensure that the state register is up-to-date

(6) In accordance with the provisions of section 4 of the Act, the State Registrar shall generate and maintain a register in statutory CE Form VII to be known as the State Register of clinical establishments that shall be an amalgam of the District Register of clinical establishments maintained by the District Registrar & Licensing Authority.

(7) In accordance with the provisions of section 9 of the Act, the State Registrar shall compile and update the state register immediately upon receiving information from the District Registrar regarding all additions, alteration to and other amendments in district register.

(8) By 31st March of every year, the State Registrar shall publish a list in the website of the department containing the name, address, and period of validity of license of such clinical establishments which were registered or renewed during the preceding calendar year.

(9) The state registrar shall supply such relevant information pertaining to the state register to other department of the state government, local bodies, other state government, the central government or other such statutory/constitutional bodies in such manner at such interval as may be notified.

(10) While discharging his duties mentioned in this rule, he State Registrar shall ac as the State Prescribing authority for Registration & Licensing and issue suitable instructions, co-ordinate, and supervise the work of registration in the State for securing an efficient system of registration.

(11) The state Government may consider any of the information contained in the state register or district register or license or any application made thereof as a public record and may make those records available in the public domain or to any public servant in public interest in such a manner as it deems fit.

39. Correction or cancellation of entry in the register.

(1) As soon as it is brought to the notice of the District Registrar that any entry of a clinical establishment in the register kept by him under this Act is erroneous in form or substance, or has been fraudulently or improperly made, he shall cause to correct the error or cancel the entry if he is satisfied after making any suitable enquiry.

(2) The District registrar shall correct the error or cancel the entry under sub-rule (1) by suitable entry in the margin or remarks column, without any alteration of the original entry, and shall sign the marginal entry and add thereto the date of the correction or cancellation.

(3) Immediately after making the correction or cancellation under sub-rule (1), the District Registrar shall send a report to the State Registrar containing an extract of the entry showing the error and how it has been corrected.

(4) After receiving such report under sub-rule (3), and after making any suitable enquiry, if the State Registrar is satisfied, he shall cause to correct the error or cancel the entry in manner specified under sub-rule (2).

(5) The Government may notify the terms and conditions for correction and cancellation of any entry of District of State Register from time to time

40. The Appeal.

(1) Under clause (i) of Sub-section (1) of Section 26 of the Act, in case of the failure of the licensing authority in communicating the allowing or rejection of application, any appellant may prefer an appeal in the Statutory CE Form XIII to the Appellate Authority within 120 days from the date but not before 90 days of submission of such application.

(2) Under clause (ii), (iii), (iv) or (v) of Sub-section (1) of Section 26 of the Act, any appellant, aggrieved by the order of the Licensing Authority may prefer an appeal in the Statutory CE Form X to the Appellate Authority within thirty (30) days from the date of receipt of such order.

(3) Any appeal preferred under Sub-rule (1) or (2) shall be accompanied with a non-refundable appeal fee to be deposited in the appropriate receipt head, amount of which shall be ten percent of the license fee.

(4) After receipt of such appeal, the Appellate Authority shall fix the time and date for hearing and inform the same to the appellant and others concerned by a registered letter giving at least 15 days time for hearing of the case.

(5) The appellant may represent by himself or authorized person or a Legal practitioner and submit the relevant documentary material if any in support of the appeal

(6) The Appellate Authority, shall hear all the concerned, receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its decision preferably within 30 days from the date of filing the Appeal.

(7) If the Appellate Authority considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal.

(8) The Special Secretary (General Administration Branch) of the department or any such officer as may be notified by the Government from time to time shall be the Appellate Authority under sub-rule (1).

(9) The Government may either on its own motion or on the application of any party, call for the records of any proceedings before the Licensing Authority or the Appellate Authority for the purpose of satisfying itself as to the legality or the propriety of any order passed by the such Authorities and may pass such order in reference thereto as it thinks fit:

Provided that the Government shall not vary or reverse any order affecting any right of the party without giving notice of being heard;

Provided further that no revision shall lie after the expiry of ninety days from the date of issuance of such order.

CHAPTER VI
Grievance Redressal

41. Responsibilities, Obligation & Rights.

(1) The Patient shall at all times accept and fulfill his obligations and responsibilities regarding healthcare and his personal behavior enumerated below:

(a) He shall ensure that he knows and understands what the patients' rights are and shall exercise those rights responsibly and reasonably;

(b) He shall provide, to the best of his knowledge, accurate and complete information about all matters pertaining to his health, including medications and past or present medical problems to his service provider;

(c) He shall report unexpected changes to his condition or symptoms to his service provider;

(d) He shall ensure that he understands the purpose and estimated cost of any proposed healthcare intervention before deciding to accept the service;

(e) He shall notify the service provider if he does not understand any information about his treatment, investigation or care;

(f) He shall accept all the consequences of his own informed consent. If he refuses treatment or do not follow the instructions or advice of the service provider, he shall accept the consequences of his decision and thus relieve the service provider of any liability;

(g) He shall so conduct himself or herself so as not to interfere with the well-being or rights of other patient or service providers;

(h) He shall act in a considerate and cooperative manner, respect the rights and responsibilities of others and follow the policies and procedures of the health care establishment;

(i) He shall use the property of the Clinical establishment with due care and diligence not to cause any damage or deterioration;

(j) Subject to the right to submit complaints, he shall without prejudice to the complainants, observe such regulation concerning the organization and operation of the clinical establishment establishments as mentioned under rule 24; and

(k) He shall ensure that financial obligations of his health care are fulfilled as promptly as possible, otherwise, he shall make a appropriate arrangements to settle unpaid bills through any mechanism agreeable to the Clinical establishment;

(l) He shall fulfill any other obligation mentioned elsewhere in the Act or the rule.

(2) The clinical establishment shall adopt, display and observe A Standard Charter of patient rights based upon various rights provided under this act and rules and shall orient the staff, patient and patient party thereof.

(3) If he refuses treatment or do not follow the instructions or advice of the service provider, he shall accept the consequences of his decision and thus relieve the clinical establishment of any liability;

(4) Any patient, who has failed to fulfill his obligations and responsibilities, shall forfeit any rights conferred upon him.

(5) Appropriate action may be taken against any patient or patient party who has contravened the provisions under the West Bengal Medical service persons and Medicare Service Institution (Prevention of Violence and damage to Property Act, 2009 [WB Act XI of 2009].

(6) For the purpose of this rule the term 'patient' shall include 'patient party' also wherever and whenever applicable.

Explanation: "patient party" means a person willing to enjoy all the rights, responsibilities and Obligation conferred upon a patient and is recognized as such by the clinical establishment or the service provider and includes

(a) An adult member of the family or near relatives; or

(b) Guardian of the service recipient, in case of service recipient being a minor; or

(c) One of the Friends, colleagues or any person authorized by the service recipient as his Representative; or

(d) Guardian, legal heir or natural successor or near relatives of the service recipient in event of the death of the service recipient or his being incapacitated due to existing physical/mental/emotional state rendering him incapable to authorize a person as his Representative, or any.

42. Vicarious Liability.

(1) The service recipient shall have the right to health care services corresponding to his state of health, assured by the clinical establishment within its limits of the resources, manpower and competence available for services at the relevant time.

(2) It is the responsibility of not only the service provider but also the licensee of the Clinical Establishment (a) to provide the service recipient with the assured service without any undue denial, delay or harassment and (b) to provide the service recipient appropriate healthcare and non-healthcare services of good quality.

(3) If any service recipient cannot immediately be given care and treatment that is medically necessary he shall, depending on his state of health, either be directed to wait for care, or be referred or sent for care & treatment elsewhere, where the appropriate care & treatment can be provided:

Provided that, the service recipient shall be informed of the reason for such delay if he has to wait for care.

(4) The Licensee of the clinical establishment shall be responsible for the misconduct of the service provider engaged by the clinical establishment as an employee or consultant unless it can be proved beyond reasonable doubt that such acts of misconduct was beyond the Licensee's supervisory control.

(5) The clinical establishment shall be responsible for any test report provided by it in cases where the sample or specimen is collected by them and sent for examination but the actual tests are being performed by a reference laboratory.

43. Grievance redressal System.

(1) The Clinical establishments, with more than one service provider, shall have an internal grievance redressal system and the aggrieved party shall have to first exhaust the grievance mechanism provided under this Act before filing any administrative or legal action.

(2) Anyone aggrieved by the denial of assured service shall have to first exhaust the grievance mechanism provided in this Act before filing any administrative or legal action whereas the "Denial of assured services" means and includes

(a) non-provision of any of the assured services including non-provision of emergency treatment; or

(b) defective or sub-standard quality of assured services; or

(c) any unethical or unfair trade practice, including but not restricted to recovery of money in excess of standard charges; or

(d) violation of patient rights specified in the Act and rule; or

(e) any other deficiency of service.

Provided that if the clinical establishment does not have the requisite human resource equipments and medical supplies which it professes to have possessed it shall be amounting to non-provision of any of the assured services.

(3) As per section 40 of the Act, any complaint of medical negligence against any medical, nursing or paramedical professional shall be addressed to the respective state medical council, nursing council, paramedical council or other council of similar nature.

(4) The clinical establishment shall designate a specific member of the staff preferably having experience in public relations to be designated as Grievance Officer as the person in charge of internal Grievance redressal mechanism who, upon receiving a complaint, oral or written, from the aggrieved party for redressal of grievance, shall

(a) register the complaint without any delay in a complaint book (register) mentioning details as may be notified as a part of mandatory record keeping, and provide the aggrieved party an acknowledgement number which may be used as reference by the aggrieved party; and

(b) provide the aggrieved party, within a reasonable period, with a written response for his application, along with the action taken/proposed to be taken; and

(c) contact the concerned health service provider and remedy the situation, when possible; and

(d) provide to the aggrieved party, printed information in English and local language on all the remedies available to him, including the right to approach the tribunal under section 40 of the Act.

Explanation: "Aggrieved party" means any person who has submitted a complaint as per sub-rule (4) and includes: (a) Any service recipient including Patient or Patient Party whose individual rights are alleged to be violated; or (b) Any person(s), as a potential service recipient whose collective community rights are alleged to be violated; or (c) any organization acting in public interest.

(5) The Grievance Officer shall submit such report out of extracts from the register of grievance on grievances made, action taken or not taken, as may be notified, to the respective Licensing Authority at the end of each month/year.

(6) The clinical establishment shall display the procedure of laying complaints, Full contact details of the Grievance Officer mentioned with clear mention of the time of availability of the same as a part of mandatory display and shall communicate the procedure to the service recipient on a regular basis.

(7) If the aggrieved party feels that the grievance is not properly redressed, he has the right to approach the Tribunal under section 41 of the Act:

Provided that, till such Tribunal is constituted under section 40 of the Act, the aggrieved party, may approach the High Court under section 42.

44. Adjudication.

(1) Under Sub-section (1) of section 34 of the Act, the adjudicating authority shall, on receipt of a complaint and accompanied documents, if any from the accuser, refer a copy of such complaint along with accompanied documents, if any, to the accused party directing him to submit his version of the case within a period of 15 days or such extended period not exceeding 15 days more as may be granted by the adjudicating authority.

Explanation 1: 'Accuser' means the 'Licensing Authority' or any person who has given notice of not, less than sixty days, to the Licensing Authority concerned, of the alleged contravention and of his intention to make a complaint to the Adjudicating Authority.

Explanation 2: 'Accused Party' means the person against whom the complaint is made by the Accuser under sub-section (2) of Section 34 of the Act.

(2) If after receiving the complaint referred to him under sub-rule (1) the accused party does not appear or omits or fails to take any action to represent his case within the time given by the Adjudicating Authority, the Adjudicating Authority shall proceed to settle the complaint on the basis of evidence brought to its notice by the Accuser.

(3) If after receiving the complaint, the accused party appears before the adjudicating authority, the particulars of the contravention of which his accused shall be stated to him and the accused party shall be asked whether he pleads guilty or has any defense to make.

(4) If the accused party pleads guilty, the adjudicating authority shall record the plea as nearly as possible in the words used by the accused party, if possible verbatim or by way of transliteration and may in his discretion convict him thereon.

(5) If the accused party does not admit or pleads guilty, the adjudicating authority shall proceed to hear the accuser and take all such evidence as may be produced in support of the complaint and also to hear the accused party and take all such evidence as he produces in his defense.

(6) The adjudicating authority may, if he thinks fit, on the application of the complainant or the accuser may issue a summon to any witness directing him to attend or to produce document or other thing.

(7) The adjudicating authority may before summoning any witness on such application, require that the reasonable expenses of the witness to be incurred in attending for the purposes of this trial be deposited before the adjudicating authority. If the accused party wants to summon any witness the adjudicating authority may allow the same and in case of rejection a reasoned order has to be passed.

(8) After taking evidence of both sides and documents if any, filed by the parties, the adjudicating authority shall fix up a date for argument and after conclusion of such argument the adjudicating authority shall pass a judgment within a fortnight , copy of which has to be given to the both parties either by post or by otherwise on the application of the parties opted for copy of the judgment.

(9) If the accuser, at any time before a final order is passed, in any case satisfies the adjudicating authority that there are sufficient grounds for permitting him to withdraw his complaints against the accused party, or if there be more than one accused party against all or any of them, the adjudicating authority may permit him to withdraw the same, and shall there upon acquit the accused party against whom the complaint is so withdrawn.

(10) The Adjudicating authority may for reasons to be recorded by him stop the proceeding at any stage without pronouncing any judgment but it shall not be more than 3 months. Every such record and judgment shall be written in any official language prevalent in the locality and if it is other than in English language, in that case a translated version in English has to be attached also.

CHAPTER VII
Miscellaneous

45. Role in Public Health.

(1) The clinical establishment shall actively participate in the implementation of all National and State public Health programmes including Intensified pulse polio immunization NPCB, NVBDCP, RCH etc. and implementation of various public health laws in such manner as may be notified by the State Government from time to time and shall follow such mandatory diagnostic/therapeutic guidelines as per those programmes.

(2) The clinical establishment shall generate and maintain mandatory reports related to the public Health programmes mentioned under sub-rule (2) containing such particular and submit such reports to appropriate authority in any effective manner as may be notified and obtain an acknowledgement thereof.

(3) The clinical establishment shall generate and maintain reports related to the performance containing such particular and submit such reports to State Bureau of Health Intelligence or any such authority in any effective manner as may be notified and obtain an acknowledgement thereof.

(4) The clinical establishment, shall encourage and motivate all the service-provider for active participation in such public health programmes and organize such capacity building programme for them with or without reasonable assistance provided by the department from time to time, about the recent development in public health programme including recent changes of Standard treatment protocol.

(5)) The clinical establishment shall actively participate in management of any disaster, man-made or natural, and or any public health exigency, and shall co-operate and provide such reasonable assistance and Medical aid as may be considered essential in course of disaster management by the Licensing authority at the time of natural calamity of disastrous situation.

(6) Within shortest possible time period from the occurrence of such infection or dangerous diseases or other condition known as Notifiable Diseases mentioned in schedule VIII, if any, of any service recipient received or accommodated or both in any clinical establishment, that clinical establishment shall give information of such occurrence to the appropriate authority over telephone, fax or email. followed by submission of a written report as a part of mandatory reporting in any effective manner as may be directed by the appropriate authority.

(7) In case of emergence of any infection or dangerous disease, the Clinical establishment shall perform such other mandatory duties as may be notified in respect of such diseases to prevent the spread and further occurrence of the disease.

(8) For the purpose of this rule 'appropriate authority' means such authority as may be notified.

46. Public Disclosure.

(1) Subject to the provisions of these rules, the Government may cause to be published in the Official Gazette, print media, electronic media or by any other means; the names and particulars of the clinical establishment or the persons attached with establishment who have been found guilty after the adjudication.

Explanation. - For removal of doubts, it is hereby declared that in case the person is a firm, company or other association of persons, the names of the partners of the firm, directors, managing agents, secretaries, treasurers or manager of the company, or any member of association, as the case may be, may also be published if, in the opinion of the Government, circumstances of the case justify it.

(2) If the Licensing Authority, having jurisdiction over such clinical establishment, is satisfied that it is necessary or expedient in the public interest to publish the names and any other particulars as he deems fit, he shall after due verification of the facts, and the circumstances of the case, forward a proposal for such publication to the State Register.

(3) The State Register, on receipt of proposal referred to in sub-rule (1), shall within fifteen days from the receipt of such proposal, examine it and if he is satisfied that circumstance of the case justify such publication, may make a recommendation to the Government accordingly.

(4) On receipt of the recommendation by the State Register, or on its own, the Government may cause publication of the name and other particulars in a manner as specified in sub-rule (3).

SCHEDULE I
Standards for Building & Accommodation

[Refer Rule 8]

Part I: General

1. Introduction

1.1. The clinical establishment should maintain the Building & Accommodation standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

1.2. The premises of the clinical establishment should be separated from rooms for private uses i.e. there should be no free access. The use of the premises should conform to the land use prescribed under relevant law(s) relevant Acts, rules and bye-laws of the concerned local authorities as in force and other relevant acts and rules.

1.3. No person, other than on-duty service providers should be allowed to reside in the premises except with the special permission of the Licensee. No person should be allowed to sleep on the floor where the patients are accommodated. The Entrance of the premises should bear an inscription in front describing the Name of the Clinical Establishment.

1.4. The plan of the building should be duly certified by the local Authority on the body of the plan. If the construction is approved for residential purpose, it should be converted accordingly with due approval of the Local Authority concerned. It should conform to the Building Engineering Environmental Standards mentioned in Annexure 1 of this schedule.

1.5. The clinical establishment may be accommodated in buildings ordinarily (a) owned by the proprietor; (b) rented; or (c) leased. If the proprietor is a tenant, the documentary proof in form of (a) copy of the current rent receipt or (b) rent agreement or (c) any such document is required. If the proprietor is a lessee; the documentary proof in form of lease-deed is required. If the licensee is granted rent free accommodation by the owner of the premises; the documentary proof in form of a current consent letter from the owner is required.

1.6. All the rooms, wards operation theatres, labour room, special care areas, out-patient department and diagnostic departments should be easily approachable by stretcher and a wheel chair. As much privacy should be provided to the patients as possible. A telephone is a must for every hospital. There should be adequate provision for adequate parking facilities for staffs and visitors in case of clinical establishment with more than 100 beds.

1.7. All clinical establishment should be well ventilated, illuminated with Uninterrupted power supply arrangement. All clinical establishment should follow the minimum space requirement mentioned in the table annexed with. The space requirement of Diagnostic Imaging should be as per AERB guideline

1.8. The basement, if any, should be used with caution as per Fire safety Act and No patient should be received or accommodated there.

1.8. If not mentioned otherwise, the clinical establishment should follow the IPHS regarding equipment and medical supplies for that category of establishment and Guidelines for Good Clinical Laboratory Practices by Indian Council of Medical Research.

Part II: Specific

1. Outpatient based Facilities

1.1. Outpatient based Facilities should be provided with (a) The Reception & Information area for providing information to the patients and their attendants; (b) Waiting area with adequate and comfortable seating arrangements for the patients and their attendants. It should be provided with (i) drinking water facilities adjoining to waiting area and (ii) toilet and wash rooms (separate for male & female)

1.2. Depending upon the type and number of specialties being offered, the clinical establishment should be provided with consultation-cum-examination room /cubicles for to run OPD clinics of different types like Medicine, surgery, obstetrics & Gynaecology etc.

2. Inpatient based Facilities

2.1. Space requirements Inpatient based Facilities have been divided into following categories: (a) Entrance area; (b) Ambulatory area; (c) Diagnostic area; (d) Intermediate area; (e) Critical area; and (f) Service area.

2.2. Entrance area: It should have the Separate public areas earmarked for (a) reception and information, (b) registration and record keeping; (c) Waiting area; (d) Water & Toilet facilities area. Registration area should be located near the entrance provided with a counter with facility of drawers etc. The area and the number of desks will depend upon patient load. Record keeping room/area should be suitably located with adequate space.

2.3. The nursing home should have adequate space devoted to stairs, ramps, corridors for internal transportation of the patients on wheel chairs, trolleys etc. In case of nursing home with more than 30 beds,

2.4. Ambulatory area: It The outpatient department should be located such that patients visiting the outpatient department need not pass through inpatient areas. Depending upon the type and number of specialties being offered, the Nursing Home should have consultation-cum-examination room /cubicles to run OPD clinics of different types like Medicine, surgery, obstetrics & Gynaecology etc. The ambulatory zone should have the following rooms in addition to the consultation room: (a) Treatment and dressing room (b) Nursing station for OPD block with clean and dirty utility room;

2.5. Diagnostic area: Facility like Pathology Lab, if any, should ideally be interposed between OPD and IPD and should follow the standards as described in Part IV of this schedule. Facility like X-Ray and ultrasound, if any, should be so located to serve both indoor and outdoor patients and should follow the standards as described in Part V of this schedule. The room housing diagnostic X-Ray units and related equipment should be located as far away as feasible from areas of high occupancy and general traffic, such as maternity and pediatrics wards and other departments of the hospital that are not directly related to radiation and its use.

2.6. Intermediate area: It should be consisting mainly of Inpatients nursing units and wards, toilet rooms, closet, lockers, ward robes, etc. The Indoor blocks should be located away from the main roads and OPD area to avoid disturbances and the cross infection. The beds should be laid out in such a way as to make the patient accessible for treatment from either side. In wards, visual privacy should be provided for each patient according to the need. Separate ward units should be provided for male and female patients. Admission should be restricted to the number of beds to be maintained.

2.7. Separate wards should be provided for male and female patients. Patients with infectious diseases should not be admitted into general wards. Every patient should have access to a toilet area without having to enter the general corridor area. The ward should have the facilities for (a) Nursing station (including work area, space for cabinets, medicine trolley, refrigerator etc.) (b) Treatment room (c) Ward store (d) Emergency Trolley (e) Patients' toilet (f) Space for pantry for collection and distribution of meals.

A Sluice Room (one per ward) meant for emptying and cleaning bed pans, urine bottles and sputum mugs, disposing of used dressing and similar material, storage of stool and urine specimens, cleaning mackintoshes/rubber sheets should be provided (preferable).

2.8. Service area: All nursing homes providing dietary services should have: (a) Cooking area (b) Washing area; (c) Garbage collection; (d) Dry ration storage area.The Nursing home should have (a) General store/linen store; (b) Medical records room (c) Administrator and nursing-in-charge office; (d) Nurses changing/duty room with toilet (e) Doctors' duty room with toilet 100 sq.ft

2.9. The Nursing home should have a Medicine store 90 sq.ft. The drug storage cabinets, shelves, refrigeration facilities for keeping the vaccines and other drugs in controlled temperature should be provided). If it has a Pharmacy, it should be so located that it serves both inpatient and outpatients and all the provisions according to the Drug & Cosmetic Act has to be followed.

2.10. The nursing home should have generator/back-up power source so that in case of a power failure, all equipment, instruments and electrical points of the nursing home (including those for refrigerator, fans, lights) can be able to work as normal. The capacity of generator required should be accordingly calculated. It should be installed in a place where it will not disturb patients and traffic.

2.11. Additionally, the Nursing home should have (a) Space for storage of oxygen cylinders; (b) Nitrous oxide cylinders. Enough reserve cylinders should be stored to complete at least one day's procedures.

2.12. Critical Area: This area is required in surgical and maternity homes. This area consists of the Operating Suite and Delivery Suite. This is technically a therapeutic aid in which a team of surgeons, anaesthetists, nurses, gynecologists and sometimes pathologist/s and radiologist/s operate upon or care for the patient. The critical area should be located and arranged to prevent general traffic through the suites. When delivery and operating rooms are in the same suite, access and service arrangements should be such that neither staff nor patients need to travel through one area to reach the other.

2.13. If outpatient surgery (i.e. surgery which is performed without anticipation of overnight patient care) is to be integrated with hospital inpatient surgery, at least one room should be specifically designated for outpatients to change from street clothing to hospital gowns and to prepare for surgery. Room for post anaesthesia recovery of outpatient surgical patients should be provided.

2.14. Depending on the patient load, this room may also serve the purpose of a supervised 'recovery lounge' for patients who do not require post anaesthesia recovery but need additional time for their vital signs to stabilize before safely leaving the facility. Such a room should have an area of at least 180 sq.ft. It should be provided with two cots, have convenient access to toilets large enough to accommodate a patient and an assistant, space for one to two family members, provisions for privacy and a small space which can serve as a nurses counter.

2.15. Operating suite is divided into: (a) Protective Zone, (b) Clean Zone (c) Aseptic or sterile zone (d) Disposal zone

2.15.1. Protective Zone: (i) Nursing Station with storage facility (sterile); (ii) changing rooms for with toilet. staff arrive through this zone and proceed via changing areas dressed for their task

2.15.2. Clean Zone: This includes the recovery room. It is principally the corridor linking the transfer bay to the theatre suite. Patients are brought from the ward and should not cross this zone in their ward- clothing which is a great source of infection. Changeover of trolley should be affected just before the clean zone. All staff should enter from a separate route and through a set of change rooms and through an air lock. They should communicate with the sterile corridor. A shoe change and gowning space near the air lock should be provided.

2.15.3. Aseptic or sterile zone: It consists of (i) operation theatres, (ii) Instrument sterilization, (iii) theatre pack preparation and sterile storage, (iv) scrub up and gowning rooms. In the theatres to ensure the minimum risk of infection to the patients, fortnightly bacteriological sampling should be carried out from registered Lab. and reports maintained for inspection on demand.

2.15.4. Disposal zone: Also erroneously called the dirty zone. Soiled instruments and dressings are transacted through this area for washing and resterilisation or disposal.

2.16. Casualty and emergency care area It should be as per norms as may be notified

2.17. Nursing Homes: Provisions for OPDs, Indoor, Theatres, ICUs, Labour room etc. should be provided depending upon the type of facilities being offered. Working arrangements with Labs, Blood Bank and other diagnostic centres for investigation of the patients can be made or can have their own Lab and Diagnostic (x-ray, Ultrasound etc.) facilities which should be established as per the norms indicated against such facilities. In case of Hospital or Nursing homes having more that 30 beds, It should have provision for emergency lab. tests and mobile x-ray machine for emergency x- ray.

2.18. Maternity Homes: All Nursing/Maternity Homes taking care of Obstetrics patients should be able to carry out procedures like suction and evacuation, dilatation and curettage, Lower Segment Cesarean Section and Hysterectomy on an emergency basis. It should provide proper arrangement for Blood transfusion facilities. Such Nursing/ Maternity Homes should have facilities for new born care corner and Neonatal Stabilization Unit as per IPHS norm. Where obstetric services are given, rooming-in of new born be provided. It should have Operating suite and Delivery suite as per norm. In maternity homes an arrangement should be provided to isolate a patient of ecclampsia.

3. Special Care Units

3.1. The beds should be laid out in such a way as to permit observation of every patient from the nursing station. When patients are provided with privacy and are kept in different enclosures a central monitoring station is a must. There should be adequate moving and working space around the beds.

3.2. These units should be declared as restricted area and access to such units should be regulated. It should be on the same floor as the OTs and recovery ward Adequate attention should be paid towards asepsis. The noise level should not be above 50 db.

3.3. In a room divided for each patient with curtains to provide privacy to the patients of three sides with a screen up to an acceptable height of 8 ft. In the specialized/ superspeciality/ Intensive Care, the minimum carpet area should be 120 sq. ft. per bed beds should be provided.

3.4. The Heating, Ventilation and Air-conditioning (HVAC) system of ICU should be:

3.4.1. The ICU should be fully air-conditioned which allows control of temperature, humidity and air change. Suitable and safe air quality should be maintained at all times. Air movement should always be from clean to dirty areas. It is recommended to have a minimum of six total air changes per room per hour, with two air changes per hour composed of outside air.

3.4.2. The dirty utility, sluice and laboratory need five changes per hour, but two per hour are sufficient for other staff areas. Central air-conditioning systems and re-circulated air should pass through appropriate filters.

3.4.3. It is recommended that all air should be filtered to 99% efficiency down to 5 microns. Smoking should not be allowed in the ICU complex. Heating should be provided with an emphasis on the comfort of the patients and the ICU personnel.

3.4.4. For critical care units having enclosed patient modules, the temperature should be adjustable within each module to allow a choice of temperatures from 16 to 25 degrees Celsius. Temp. should be 21 deg C (for adult), 24 deg C (for child) and humidity 50-60%.

3.4.5. A few cubicles may have a choice of positive or negative operating pressures (relative to the open area). Cubicles usually act as isolation facilities, and their lobby areas should be appropriately ventilated in line with the function of an isolation area (i.e. pressure should lie between that in the multi-bed area and the side ward).

3.5. The ICU should have its own power back, which should start automatically in the event of a power failure. This power should be sufficient to maintain temperature and run the ICU equipment (even though most of the essential ICU equipment has a battery backup). Voltage stabilization is also mandatory. An Uninterrupted Power Supply (UPS) system is preferred for the ICU.

4. Pathology Laboratory Facilities

4.1. The basic infrastructure facilities include 4 areas: (a) Reception/waiting room/area where requisition forms are received and reports disbursed along with toilets, , facilities for disabled persons, toilet for staff; (b) Specimen collection room/area, with privacy for special purposes eg. semen collection

4.2. In case a specialized Lab, following room/space should be provided: (a) Histopathology : (i) Gross room and specimen preservation room/space; (ii) Processing and block making to sectioning and staining room/space (b) Immunohistochemistry: FNAC room with bed.

4.3. It should have (a) Uninterrupted power supply; (b) Specimen/Sample/slide storage facility including cold storage where applicable; (c) Facility for cleaning of glassware, sterilization / disinfection and (d) Separate facilities/area for staff for hand washing, eating and storing food, drinks etc.

4.4. Equipment should be suitably located in the laboratory so as to allow accessibility and sequential utilization thus minimizing the need for frequent movement of specimens or reagents. Additional infrastructure facilities may be added for special tasks as and when needed.

4.5. The collection center should have an adequate waiting space and a room having at least 100 sq.ft. floor area. No collection center should be operated by any pathological laboratory in any medicine shop. If any laboratory is found to operate through a medicine shop the authority may cancel the license of such laboratory.

5. Standard measurements for clinical establishments

	Item	Measurements (minimum floor area)
(1)	Additional Reception/waiting area for clinic/lab	60 sq.ft.
(2)	General consultation-cum-examination room /cubicles	100 sq.ft.
(3)	Eye / ENT /Ortho/Other consultation-cum-examination room / cubicles with equipments	140 sq.ft.
(4)	Audiometery Room	120 sq ft
(5)	Refraction perimetry/ Tonography/ slit lamp Room	160 sq ft
(6)	Physiotherapy clinic	180 sq.ft.
(7)	Wellness/Fitness clinic	180 sq.ft.
(8)	Dental clinic area per dental chair	140 sq.ft
(9)	Space / bed in ward	30 sq.ft.
(10)	Distance between centre of 2 beds	6 ft.
(11)	Distance between bed & wall	1 ft
(12)	Width of a door in a ward	3 ft.
(13)	Toilet	36 sq.ft.
(14)	General operation theatre area per table	160 sq ft (with additional 100 sq ft per additional table).
(15)	CTVS and Neurosurgery operation theatre area per table	500 sq ft.
(16)	Area for instrument sterilization	50 sq.ft.
(17)	Area for scrub up	25 sq.ft.
(18)	Area for dirty wash	25 sq.ft.
(19)	Area for pantry	80 sq.ft.
(20)	Area for Observation room with 1 bed	As above for 1 bed in ward
(21)	Area for nursing station	120 sq.ft.
(22)	Area for DMO's room	100 sq.ft.
(23)	Delivery room	120 sq.ft.
(24)	Small laboratory	120 sq.ft.
(25)	Medium laboratory	160 sq.ft.
(26)	Large Laboratory	210 sq.ft.
(27)	X Ray lab with dark room facility	270 sq.ft.
(28)	USG lab	120 sq.ft.
(29)	TMT Lab	120 sq.ft
(30)	ECG Lab	80 sq.ft

SCHEDULE II
Standards for Service Provider

[Refer Rule 9]

Part I: General

1. Introduction

1.1. The clinical establishment should maintain the Service Provider standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

1.2. The staff can be classified into the following categories: (a) Medical Staff; (b) Nursing staff; (c) Paramedical-Technical Staff; (d) General Duty attendant and other Gr-D staff; (e) Administrative-Managerial staff; (e) Non-medical technical staff; (f) Other staff,

1.3. Unless mentioned otherwise by the applicant, all staff requirement should be calculated on the basis of a routine 3 shift arrangement along with adequate number of reserve staff.

1.4. All the medical and nursing staff of the clinical establishment registered with councils of other state should be registered with the respective councils of West Bengal within 90 days of commencement of this rule. They should have adequate communication skill and should be able to speak in Bengali (and Nepali in GTA area).

1.5. Any kind of trainee Medical/Nursing/paramedical staff should not be included while considering the manpower number norms under this schedule.

2. Medical Staff

2.1. In case of specialized service, it should have at least registered medical practitioner of modern medicine having minimum qualification of a post-graduate diploma/degree in relevant discipline supervise/perform/conduct the test/procedure, to interpret and give the result or to examine and advice.

Illustration. (a) One opththalmologist in case of eye clinic; (b) One dental surgeon in case of Dental clinic; (c) One doctor with Diploma in physical medicine in case of physiotherapy clinic (d) one Radiologist in case of X-Ray lab; (e) One sologolist in case of utrasonography lab etc.

2.2. There should be one registered medical practitioners available on duty at each consultation room of the OPD clinic during the OPD hours to ensure the availability of services as described in the mandatory display by the clinical establishment.

2.3. IPD facilities should have two kinds of Medical staff or doctors: (a) Consultants and (b) Duty medical officers. As soon as a patient arrives at a clinical establishment he or she should immediately be attended by a Duty Medical Officer. A consultant should see the patient as soon as possible.

2.4. If it is medically necessary, the Primary Consultant may refer the patient to another Registered medical Practitioner who should be asked to render his opinion or advice or to perform a particular procedure in his capacity of being a Consultant having specialized knowledge, skill, expertise or experience. Any kind of trainee Doctor should not be considered as the service-provider for the purpose of the Act or rules.

2.5. There should be at least one Duty medical officer to act as RMO, in case of a Maternity/nursing home, available on duty round the clock for every 15 Patients or 15 beds or a fraction thereof. To ensure such availability, the Clinical establishment should engage adequate number of reserve staff also.

Illustration. A twenty bedded Nursing home without any special care units with a 3-shifts arrangement should have at least 2 into 3 that is 6 DMO plus reserve.

2.6. In case of inpatient based facilities with more than 30 beds, there should be (a) Two duty medical officers to function as O.T. assistants during routine O.T. hours (8 hrs) and one each for the next two shifts in those facilities providing emergency surgical care (b) one duty medical officer available on duty round the clock for the labour ward in every eight hour shift; (c)

2.7. In addition to the duty Medical officer, the number of consultant required in the Inpatient based Facilities should depend upon type of the services being provided (general /specialty/super-speciality etc) there.

Illustration. A nursing home providing medical facilities should have a physician available on call round the clock. A nursing home providing surgical facilities should have a surgeon and anesthetist available on call. In case Emergency Surgical Facilities are also provided then a surgeon and anesthetist should be available on call round the clock.

Illustration. The resuscitation of new born should be under the supervision of a trained Registered Medical Practitioner preferably a pediatrician. Maternity home should have gynecologist /surgeon, anesthetist, and pediatrician.

3. Nursing staff

3.1. There should be one qualified Nursing Staff, in case of a Nursing Home, or one qualified Nursing staff/Midwife in case of a Maternity Home available on duty round the clock for every 5 patients or 5 beds if on same floor or a fraction thereof in every eight hour shift and if on different floors then in same proportion on different floors.

3.2. There should be at least one qualified nurse on duty round the clock for labor room. There should be two trained operation theatre nurses for routine surgery. In case of inpatient based facilities with more than 30 beds offering maternity facilities and emergency surgical facilities, two more operation theatre nurses will be required on shifts. (In practice the number of nurses posted specifically for this area would depend on the patient load there).

3.3. The nurses for operation theatres and special care units need additional training/experience/expertise and care should be taken not to engage untrained staff into these critical areas.

4. Paramedical-Technical Staff

4.1. Depending upon the nature of service offered by the clinical establishment and the expected workload, at least one on-duty qualified paramedical technical staff should be engaged.

Illustration. (a): Minimum One pharmacist, One OT technician, One Anaesthesia Technician in case of inpatient based facilities with more than 30 beds; (b) Minimum One Dental Hygienist, Dental Mechanic In case of Dental clinic etc; (c) physiotherapist in case of physiotherapy clinic; (d) Medical Technician (Lab) in case of Pathology lab; (e) Medical Technician (X-Ray) in case X-Ray lab etc.

4.2. In case of old establishment, the technical personnel who are found to be underqualified may continue to work in the same capacity but for further recruitment, properly qualified personnel are to be engaged. No paramedic should run the establishment without the supervision of a registered medical/dental practitioner.

5. General Duty Attendant & Other Gr-D staff

5.1. Each OPD clinic or lab should have at least one helping hand preferably female.

5.2. In case of all inpatient based facilities, there should be (a) at least one General Duty Attendant, available round the clock for every 10 Patients or 10 beds or a fraction thereof, in every eight hour shift; (b) at least one sweeper 10 Patients or 10 beds or a fraction thereof, in every 8 hour shift and One sweeper for operation theatre and Labour ward

5.3. In case of inpatient based facilities with more than 30 beds, there should be at least one GDA (Female) for obstetrics and gynaecology OPD; one GDA for surgical and medical OPD; one GDA (Female) for labour room; one GDA for O.T. suite.

6. Administrative-Managerial staff

6.1. This category of staff includes – Managers, receptionists, supervisors, security personnel etc. The requirement of this category of staff depends solely on the type of a hospital and its size. As the size of a hospital increases the need for this category of staff also increases proportionately. Such staff should be provided in such number as per advise of the Licensing Authority.

6.2. Administrative-Managerial staff should be available at the Inpatient based Facilities as per following norms: (a) One Manager/Administrator/Chief executive Officer; (b) One Receptionist (shift duty); (c) One Cashier (More than 100 beds); (d) One Medical Record Keeper (more than 100 beds), (e) One Storekeeper (more than 100 beds).

7. Non-Medical technical staff

Depending upon the type of facilities being offered, extent of outsourcing etc, support staff like Dietician, Cook, Plumber, Electrician, Telephone operator, Central heating/AC operators etc. should be at the disposal of the clinical establishment.

Part II. Specific

1. ICU

1.1. In case of nursing homes providing special care unit facilities, there should at least two Duty medical officer exclusively for intensive care having post graduate diploma or degree or adequate working experience at a recognized hospital in the concerned discipline.

1.2. In case of nursing homes providing special care unit facilities, there should be adequate number of nursing staff exclusively for critical care having certificate, diploma or degree or adequate working experience at a recognized hospital in the concerned discipline.

1.3. There should be one trained nurse available round the clock for every 3 beds in such special care units including post-operative wards. There should be one qualified critical care Technician available round the clock in such special care units.

2. Eye Clinic with operating facility

Eye Clinic with operating facility should have (a) Doctors with post graduation in ophthalmology, (b) minimum of two nurses for 10 beds and supportive staff preferably qualified O.T Technician. Service of Anesthetist should be available as and when required.

3. Pathology Laboratory Facilities

3.1. Every Small Laboratory should have at least one registered medical practitioner of modern medicine having minimum qualification of a DCP or DTM&H or equivalent post-graduate diploma or a MBBS degree with at least five years experience in laboratory medicine to supervise the Laboratory work, to interpret and give the result. It should have one on-duty qualified medical technician on duty having minimum qualification in Medical Laboratory technology or equivalent

3.2. Every Medium Laboratory should have (a) at least one registered medical practitioner as mentioned under the small laboratory and in addition to that, (b) one qualified person having a minimum qualification of a MSc (Biochemistry / Medical Micro-biology) or MD (Biochemistry) or equivalent post-graduate degree who can supervise those tests. It should have two on-duty qualified medical technicians.

3.3. Every large Laboratory should have (a) at least one registered medical practitioner having minimum qualification of a MD (Pathology) or equivalent post-graduate degree; and (b) at least one registered medical practitioner having minimum qualification of a MD (Microbiology) or equivalent post-graduate degree; and (c) at least one registered medical practitioner having minimum qualification of a MD (Biochemistry) or equivalent post-graduate degree to supervise the Laboratory work, to interpret and give the result. It should have three on-duty qualified medical technicians.

3.4. The histopathological, cytopahological and special hematological tests should be carried out personally by a MD (Pathology) or equivalent. Multi-disciplinary laboratories should identify a group leader, with specific qualification for each.

Explanation. A qualified person having Ph.D. in the respective discipline should be considered as equivalent.

3.5. A collection center should be under supervision of a registered Medical Practitioner of modern medicine. The collection centre should have one on-duty qualified medical technician or support staff having Higher secondary (with bioscience) certificate with a minimum five year experience in an established medium sized laboratory.

SCHEDULE III
Standards for Equipment, Medical Devices, Medical Supplies

[Refer Rule 11]

Part I: General

1. Introduction

1.1. The clinical establishment should maintain the Equipment, Medical Devices, Medical Supplies standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

1.2. If not mentioned otherwise, the clinical establishment should follow the IPHS regarding equipment and medical supplies for that category of establishment and Guidelines for Good Clinical Laboratory Practices by Indian Council of Medical Research.

1.3. The clinical establishment should provide adequate numbers of Equipment of good quality depending upon the service offered by that clinical establishment. The clinical establishment should be reasonably satisfied about the quality of the Equipment, Medical Devices, Medical Supplies before procurement of the same. It should procure Equipment, Medical Devices, Medical Supplies with BIS standard as far as possible. While commissioning or decommissioning such equipment, the clinical establishment should follow the manufacturer's guideline.

1.4. All equipment should be in good working condition at all times to meet workload requirement. Periodic inspection, cleaning, maintenance of equipment should be done as per manufacturer's guideline.

1.6. New equipment should be checked, calibrated and validated before routine use. Periodic performance check/calibration check for all equipment should be done using reference standard/reference material.

1.7. Under no circumstances should the completion of necessary equipment servicing or calibration be delayed or cancelled in order to accommodate further service provision.

2. Medical Gas

2.1. If central medical gas supply system is not available then (a) Oxygen cylinders should be provided as per the following norms: (i) Three cylinders for each Operating theatre; (ii) Two cylinders/8 beds for Wards; (iii) Two cylinders for each Delivery room; (iv) Two cylinders for Emergency area/ward. Stock for one week should be maintained. In each of these areas flowmeters and trolleys should be provided and (b) Suction apparatus should be provided as per the following norms: (i) One suction apparatus for operating theatre; (ii) One suction apparatus for delivery room; (iii) One suction apparatus for every eight beds; (iv) One suction apparatus for emergency and casualty patients. At least two of these should be foot operated.

2.2. If central medical gas supply system is available then (a) Oxygen outlet should be provided as per the following norms: (a) Two outlets per table for each Operating theatre; (b) Separate outlet per table/bed each Delivery room/ Recovery room/ Emergency area/ward; (b)vacuum outlet should be provided as per the following norms: (a) Two outlets per table for each Operating theatre; (b) Separate outlet per table/bed each Delivery room/ Recovery room/ Emergency area/ward.

2.3. Nitrous oxide um outlet should be provided as per the following norms: One outlets per table for each Operating theatre.

2.4. In all these areas one O2 cylinder should be kept as spare. These three pipelines have to be of different colours conforming to a laid down standard and mounted on wall or ceiling surface. Precautions should be taken regarding the storage of oxygen and nitrous oxide.

Part II: Specific

1. Examination Treatment Dressing room

1.1. Each Examination Room should be provided with equipment like: Chair for consultants (One for each consulting room); Chairs for patient and persons accompanying patient (Two or three per consulting room and casualty); Revolving stool (metallic - One for each consulting room); Doctor's table (One for each consulting room); Examination table with safe footsteps, mattress and pillow (One for each consulting rooms); Examination table for OBG clinic (with appropriate light fixture and stool for doctor); X-ray viewing box; Bowls; Wash basin with liquid soap dispenser and towel rail (One in each consulting room and in casualty), Weighing machine; Screens for every examination table.

1.2. Each Examination Room should be provided with instruments and medical supplies for patient examination like (torch, tongue depressor, stethoscope, Blood Pressure Apparatus, Thermometer, Kidney trays, Proctoscope, (small medium and large for surgical OPD), Hammer (for eliciting tendon jerks), Tuning fork, Ant. vag wall retractor For OBG/OPD; Bivalved speculum, Sims speculum sterilizer (preferable); Gloves; Disposable Syringes, Gloves and Masks; Towels, Bedsheets post exposure Prophylactic kit, First Aid equipments, emergency Drugs.

1.3. Treatment/Dressing room and Injection room should be provided with Equipment & Furniture like: (1) IV stands; (2) Examination table with mattress to carry out dressings (3) Dressing trolley; (4) Ambus bag; (5) Suction apparatus; (6) Oxygen cylinder with flowmeter; (7) One trolley for oxygen cylinder; (8) Laryngoscope with blades; (9) Dustbins with lids etc.

1.4. Treatment/Dressing room and Injection room should be provided with medical supplies like Hydrogen peroxide solution, Cetrimide solution, solvent ether spirit, Povidone iodine solution, Freshly prepared Eusol, Freshly prepared 1% Na Hypochlorite solution, Cheatles forceps, Drums with sterile gauze and bandages, Sterile packets of catgut, ethylon, prolene, silk, etc., autoclaved linen, sticking plaster, 2% Xylocaine without adrenaline, suture cutting scissors, Disposable syringes 5,10.20 ccs needles curved, cutting and round bodied small and medium sizes etc.

1.5. Emergency trolley tray should be provided with: Inj adrenaline,; Inj. soda bicarb; Inj aminophylline; chlorpheniramine; Inj calcium gluconate; Inj Frusemide; Inj vesopressor; Inj. 25% glucose I.V. fluids etc.

1.6. Catheters tray should be provided with: Endotraceal tubes tray (all sizes of cuffed tubes) with connectors; Oropharyngeal airway (all sizes); Spirit bottle. Syringes and needles; Foleys Catheters

1.7. Venesection tray should be provided with: Small plain forceps and small toothed forceps; Venesection scissors; Curved cutting needles medium sizes; Small mosquito forceps; Towels; One bowl; Lubricating jelly;

2. IPD facilities

2.1. The number and type of such equipments should vary with the services being provided and work load in the Nursing Home, but to provide the optimal services and to maintain the sterility of the equipment/ instruments, each nursing Home should be provided with adequate quantity & quality of equipment and medical supplies like (a) equipment for emergency (b) equipment for ward (c) Trolley & Stretcher; (d) Hospital furniture; (e) Linen etc.

2.2. Each nursing Home should be provided with such equipments for emergency like suction machine with generator connection & standby foot suction machine; all instruments /equipments required for emergency & Basic life support (CPR); Emergency Tray; ECG Machine; Dressing trolly; Resuscitation tray.

2.3. In case of nursing home with more than 30 beds, each nursing station should be provided such equipment and medical supplies like: (1) Desk/counter; (2) Wall clock; (3) Wash basin with liquid soap dispenser and towel rail; (4) Sink unit; (5) Notice boards; (6) Fire fighting equipment; (7) Enema can-set (One per ten beds); (8) Vohler-Braun splint (for limb elevation); (9) Ophthalmoscope; (10) Torch (One large size -3 batteries & one small size -pin-point source); (11) Percussion hammer; (12) Laryngoscope with blades of all sizes; (13) Medicine trolley; (14) X-ray viewing box for one X-ray plate; (15) Refrigerator 300 litres; (16) Weighing machine; (17) Speculum & retractors; (18) Height scale (19) Stethoscope; (20) Glucometer; (21) Suture removal sets; (22) Dressing sets; (23) Cutdown sets etc

2.4. Each nursing Home should be provided with such Trolley & Stretcher for each ward: Minimum of two stretchers/ trolleys and two wheel chairs should be provided. These stretchers/ trolleys/ wheel chairs (should always be functional in noiseless condition).

2.5. Each nursing Home should be provided with Hospital furniture (per bed one of each) like Bedside lockers with table top; Chair/Stool; urinal; bed-pan; sputum cup, kidney tray, Bedsteads (If provided with facility for IV sets, separate IV stands need not be provided); drip stand; One dustbin with lid; Indoor papers stand/holder

2.6. Each IPD facilities should be provided with Linen adequate scale. Sheet and cover should be changed on daily basis. Fresh blankets and linen-set should be supplied at the time of admission..

2.7. Each Ward store should be provided such equipment and medical supplies like (1) Storage racks; (2) Oxygen cylinders; (3) IV stands; (4) Suction apparatus; (5) IV fluids and IV sets; (6) Foley's catheters with urine bags; (7) Naso-gastric tubes

2.8. Each nursing having Operation theatre should be provided with OT equipments (1) Anaesthesia machine with complete accessories; (2) Multi Channel Monitor; (3) Pulse Oximeter; (4) Suction apparatus – Electric/ Battery/ Foot operated; (5) Fix Operating Room lights with operation; (6) Bipolar Electro –Surgical Cautery; (7) Resuscitation Trolley; (8) Facilities for Blood Transfusion; (9) Surgical operating instruments for type of surgery which is being conducted in the Nursing Home; (10) High pressure autoclave with modern system of quick sterilization of surgical sterilization instruments and operating linen and other items; etc. In case of nursing home with more than 30 beds, each OT should be provided with Defibrillator with automatic external defibrillator and Ventilator.

2.9. Nursing station should be provided with Equipment & Furniture like: (1) Desk/counter; (2) Chairs; (3) Notice boards; (4) Communicating system; (5) Storage space; cupboards, etc.

3. Maternity Home

3.1. All Maternity home should have the following instruments & equipment required for Emergency obstetric care: LSCS, Low mid cavity foreceps/ kielland forecep, Vacuum extractor and suction machine); D&C sets; MTP set; Cervical exploration set; Uterine packing forceps; Post partum ligation set; Abdominal and Vaginal Hysterectomy set; Tuboplasty set; Electrocautery diathermy set. Anaesthetic equipments

3.2. All Maternity home should have the following instruments & equipment Labour Room & Newborn corner: Delivery sets; Labor table; Doppler Foetal monitor; suction machine with generator connection & standby foot suction machine; Neonatal Resuscitation kit; oxygen cylinder; one infant warmer; weighing machine for the babies.

4. ICU

4.1. The beds should have a firm base to permit cardio-pulmonary resuscitation and should be movable easily. Provision should be there to alter height of the head and foot of the patient and the plank at the head end should be detachable to facilitate endotracheal intubation when required.

4.2. It should be provided with adequate quantity & quality of equipments and oxygen (preferably central oxygen or one oxygen cylinder per bed with two standby cylinders) etc. An indicative List of Equipment (12 Bedded ICU and 8 Bedded HDU) is given below:

(1) Bedside Monitors (at the rate of one per bed of ICU) with Modular -2 Invasive BP, SPO2, NIBP, ECG, RR, Temp Probes with trays;
(2) 6-12 Ventilators with paediatric and adult provisions, graphics and Non-Invasive Modes (Two Ventilators should be with inbuilt compressor. Each should have a heated Humidifier.
(3) 3 Non invasive Ventilators with Provision for CPAP and IPAP;
(4) Infusion Pumps (at least 2 per bed in ICU or 1 per Bed in HDU) with Volumetric with all recent upgraded drug calculations;
(5) Syringe Pumps (at least 2 per bed in ICU) with recent up gradation;
(6) Head End Panel (at the rate 1 per bed) with two O2 Outlets, two vacuum, one compressed air and twelve electric outlets , provision for Alarm, trays for two monitors, Two Drip stands, one Procedure light;
(7) Defibrillator (2 with TCP facility - 1 standby) with Adult and paediatric pads with Trascutaneous pacing facility;
(8) ICU Beds (Shock Proof) (Fibre) Electronically Manoeuvred with all positions possible with mattress.
(9) Over Bed Tables (1 for each Bed) with all SS with 6 to 8 cupboards in each to store Drugs, side tray for x-rays, BHT, on wheels;
(10) ABG Machine (1 plus 1 standby) with facility for ABG and Electrolytes.
(11) Crash/ Resuscitation trolley to hold all resuscitation equipment and Medicines (at the rate of 2 for ICU and 1 for HDU;
(12) Pulse Oxymeter (Small Units 2 as stand-by units;
(13) Refrigerator (1 per ICU) with freezer compartment;
(14) HD Machines (2 per ICU) with user friendly so that even a Nurse can operate;
(15) CRRT (1 per ICU) with high flow /Speed Model;
(16) CO, SVR, ScvO2 Monitor (1 per ICU)
(17) Intermittent Leg Compressing Machine to prevent DVT (2 per ICU);
(18) Airbeds to prevent Bed sores (1 per 2 beds);
(19) Intubating Video scope to make difficult intubations easy (1 per 1CU);
(20) Glucometer (2 for ICU, 1 for HDU);
(21) ICU Dedicated Ultrasound and Echo machine (1 per ICU) with recent advances to look instantly even at odd hours. Vascular filling, central lines, etc,;
(22) Bedside X ray (1 per ICU);
(23) ETO sterilization to sterilize ICU disposables regularly (1 per ICU);
(24) Spinal Board for spine trauma patients (2 per ICU);
(25) Rigid Cervical Spine collars for stabilizing cervical spine (2 per ICU);
(26) Ambu Mask different sizes Silicon, ETO sterilisable (10 sets including 2 for Pediatric use);
(27) Pollution control buckets (1 set for each Bed);
(28) Trays for Procedures For putting central lines, ICD, catheters etc
(29) I A Balloon Pump (1 per ICU);
(30) Fibroptic Bronchoscope (1 per ICU)
(31) Computers with LAN, Internet facility and printer to be connected with all departments

5. Nuclear Medicine Therapy Unit

5.1. There should be installation of "Type approved" PET-CT, SPECT-CT and GAMMA CAMERA for medical diagnostic purposes (Certificate of "Type Approval" to be obtained from AERB). Other equipments like Gamma Probe, Thyroid uptake system etc need to be purchased from approved vendor and to be AERB

approved. For the supplied isotopes, radiopharmaceuticals and blood products used in nuclear medicine from external suppliers.

5.2. Equipment for sedation and monitoring of sedated patient should be available on site. If intravenous sedation is performed there should be equipment for continuous pulseoximetry. Equipments and drugs for the management of potential complication should be immediately available. For paediatric patient, sedation monitoring equipment should be capable of measuringsaturating end tidal CO2 and non invasive blood pressure. There should be equipment for endotracheal intubation of children in case of complication. If clinical exercise stress testing is performed, there should be equipment available for it

5.3. Where appropriate to the patient population and procedure performed, equipment for general anaesthesia and monitoring of the patients should be available on site. Where warranted there should be appropriate resuscitation equipment available. Facilities should be available for cardio pulmonary resuscitation and basic life support appropriate to the level of cardiac stress testing performed.

5.4. In addition all the equipment should be checked and calibrated specifically for the following: (a) Dose calibration and constancy check; (b) Reproducibility and linearity checks of the dose calibrator; (c) Geometric correction factor check; (d) Calibration of energy window setting; (e) Check of signal uniformity, linearity, sensitivity and resolution; (f) Check of geometric distortion and spatial resolution; (g) Check of collimator absolute and relative sensitivity; (h) Centre of rotation check; (i) Pixel calibration; (j) SPECT phantom reconstruction check; (k) Crystal energy resolution check; (l) Molybdenum breakthrough check; (m) Ambient radiation dose management; (n) Radiopharmaceuticals sterility checks; (o) Film processor checks

6. Pathology Laboratory

6.1. Equipment performance should be verified from Internal Quality Control results and External Quality Assessment results. Outlier parameter trend analysis record should be maintained in respect of its effect on the equipment. The frequency of performance check should be based on the day-to-day performance of the equipment

6.2. In case of large laboratory, all analytical equipment should be calibrated and calibration certificate provided by equipment company. Non-analytical equipment such as pipette, thermometer, weighing balance and centrifuge should be calibrated by accredited calibration laboratory or done in-house with traceability to National Physical Laboratory (NPL).

6.3. The pathology laboratory should be provided with the Furniture & Fixtures as per following norms: (a) 600mm wide and 900mm high bench of length about 2 meters per technician and to full width of the room for pathologist in charge of the laboratory. Top of the laboratory bench should be of acid alkali proof. (b) laboratory sink with swan neck fittings, reagent shelving, gas and power point and under counter cabinet.

6.4. Standard reagents of certified quality should be used for the purpose of analysis. The batch number of reagents should be recorded. The quality of the reagent viz. Analar grade, HPLC grade, etc. to be used for in-house procedures should be defined in SOP. Those reagents are to be recorded in stock register.

6.5. Quality of newly purchased reagents should be validated against suitable control/reference material prior to use. Validation data should be properly documented. In-house prepared reagents should also be checked periodically for stability and a record of the same should be maintained.

6.6. Reagent label should contain name of reagent, concentration, date of preparation/opening, date of expiry, storage conditions and warnings eg. 'do not use if solution is turbid' where applicable. When individual bottles are small, this information can be recorded in a goods received ledger.

6.7. Microbiology laboratories should check activity/potency of each lot of antibiotic sensitivity discs before using and at least weekly thereafter with reference strains. Other microbiological consumables such as strips etc. used for identification should be checked against reference strains. Laboratories testing microbiology specimens should check the quality of media by using appropriate reference strain and pH of the media.

6.8. All batches of culture containers should be checked for sterility before issuing to patients for collection of specimen.

6.9. Water quality should be checked for its grade and presence of interference elements. Reagent grade water according to IS1070 : 1992 of Bureau of Indian Standards (BIS) should be used for testing.

6.10. Depending upon the services available, the small, medium or large laboratory should be provided with (a) General equipments for lab; (b) Equipments for Clinical Pathology; (c) Equipments for Histopathology; (d) Equipments for Microbiology; (e) Equipments for Haematology; (f) Equipments for Biochemistry; (g) Equipments for Serology

6.11. General equipment for lab: Autoclave; Infection control coded bags and buckets; Equipment for collection and thereby transport of various specimens from outside the lab; Other miscellaneous necessary equipment depending upon the function of the lab, needle destroyer stopwatch, slid trays, test tube stands, stop watch etc

6.12. Equipment for Clinical Pathology: Binocular Microscopes; Auto-analyzer/multi-functional for hematology and biochemistry; Coagulometer; Colorimeter; Centrifuge; Water bath; Refrigerator; ESR tubes; Counting chambers; Micro pipettes; Preservative vials preferably vacutainers; Glass slides; Disposal methods for collections of specimen.

6.13. Equipment for Histopathology: Automatic tissue processor or standard methods of hand processing; Hot air oven; Hot Plate; Microtome (rotatory); Automatic knife sharpener or standard method; Water bath with thermostat; Glass specimen containers (small & large); Tissue cassettes with lids (steel made); L molds (large and small); Spirit lamps; Wax (paraffin with ceresin) melting point 58 -600 c.; Slides and cover slips; Diamond pencils; Surgical grossing instruments e,g knife, scissors, foreceps, blades etc; weighing machine (electronic preferred); Disposables gloves, masks and white coats; Kits for immunohistochemistry and other necessary equipment; Stains and other reagents.

6.14. Equipment for Microbiology: Various media for culture and sensitivity; Swab sticks, transport media, universal containers, blood culture bottles; Antibiotics disks; Biological safety cabin II; Discard jars and disinfectants; Loops, wires, spirit lamps etc.

6.15. Equipment for Haematology: Microscope; Cell Chamber; Cell Counter (Preferable); Haemocytometer; Haemometer etc.

6.16 Equipment for Biochemistry: Centrifuge; Colorimeter/Semi-autoanalyzer; Refrigerator; Micropipettes; Water bath etc.

6.17. Equipments for Serology: Centrifuge; Refrigerator; Water bath; Incubator etc.

7. X-Ray lab

7.1. X-ray equipment for medical diagnostic purposes need to be purchased from approved vendor. There should be installation of “Type approved” X-ray equipment for medical diagnostic (Certificate of “Type Approval” to be obtained from AERB). Any radiation equipment/radiation installation should be commissioned only after all aspects including design, planning construction and operation have been duly approved by the AERB

7.2. X ray machines should be of 100-1000 MA (as per scope of services), dental X-ray of 6MA and OPG X-ray of 4.5 to 10 MA. Each X-ray lab should be provided with the following protective accessories: Protection Screen; Lead apron 1-1.5 mm thickness upto 75 kV; Protective gloves; Protective goggles; Lead blocker for protection of generative organ or patients; Cones; film-badge etc.

7.3. The lab should be provided with: (1) Cassettes with intensifying screens; (2) Chair, (3) Dark room with safe light; (4) Dark room timer; (5) Film clips; (6) Film hanger and wall brackets; (8) Hanger for X-ray film; (9) Lead numbers for marking X-ray film; (10) Magnifying glass; (11) Step stools; (12) Revolving stool; (13) Tank thermometer; (14) Patients' trolley; (15) Wash basins with towel rail/liquid soap dispensers; (16) X-ray view box; (17) X-ray protection screen; (18) X-ray film processing tank; (19) X-ray film corner etc. An automatic film processor is desirable

7.4. X-ray equipment’s and protective clothing’s should be checked from time to time. For this purpose, fluorescent screen should be used. Safe light provision and Developer tanks/tray is a should for Dark room. There should be appropriate resuscitation equipment and drugs available on site for management of contrast reactions.

7.5. All the equipments should be checked and calibrated for at least the following: (a) Calibration of signal to noise ratio(wherever applicable); (b) Calibration of mA; (c) Calibration of kV; (d) Calibration of timer; (e) Check geometric distortion; (f) Check of Phantom image quality; (g) Check of functioning of film processing units etc.

7.6. In addition all the equipment should be checked and calibrated specifically for the following: (a) All X-ray machines should be calibrated as per AERB guidelines; (b) Calibration of mA; (c) Calibration of Kv; (d) Calibration of timer; (e) Check of collimeter/diaphragm/lead curtains; (f) Check of table movement and tilt; (g) Check phantom image quality; (h) Check of positioning accuracy; (i) Check of film processing unit etc.

8. Mamography Lab

7.1. There should be dedicated mammographic equipment with a grid and appropriate compression device. Mammographic biopsy attachment is desirable.

7.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Collimation alignment check; (b) Focal spot size measurement; (c) Beam quality half layer value HLV assessment; (d) Automatic exposure control(AEC) check; (e) Artefact evaluation; (f) Breast compression deice check; (g) Screen cleanliness check

8. Ultrasongraphy

8.1. The equipment should be registered under the PC-PNDT act as per rules and the certificate should be displayed. Registration of clinic is mandatory along with details of machine and radiologist/sonologist. The equipment should have convex, sector and linear probe with frequencies ranging from 3.5 MHz to 12MHz. Equipment for vascular studies should have colour Doppler imaging capability. There should be a trans-vaginal probe where pelvic imaging and obstetric imaging is offered and other endo-cavitory probes as per scope of services. Each USG Clinics should be provided with USG scanner, printer, CTV, table and couch for patient..

8.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Calibration of calipers; (b) Calibration of power output

9. Bone mineral densitometry

9.1. There should be a phantom/other calibration standards to evaluate the accuracy of Bone mineral density measurement. There should be software to compare with standards (specific to the equipment) which are age and gender related normal.

9.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Maintenance of QCT software, phantom and associated accessories; (b) Recalculation of LSC (least significant changes) in case of replacement of a CT scanner, CT X-ray tube, recalibration of CT scanner or modification to the QCT accessory components.

10. MRI

10.1. MRI equipment should meet the requirements for safety in medical diagnosis. MRI equipment should also meet safety requirements for machinery, electronic and medical devices associated with the unit. An automatic film processing unit should be linked to the MRI for documentation purposes.

10.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Calibration centre of frequency; (b) Check of shimming; (c) Check of gradient linearity; (d) Check of spikes; (e) Check of auditory noise level; (f) Check of ghost intensity; (g) Quench pipe of MR should be safely positioned; (h) Equipment in the unit should be MR compatible including trolleys; (i) Certificate of fitness for use my manufacturer for units more than 10yrs old.

10.3. The equipment should be registered under the PC-PNDT act as per rules and the certificate should be displayed. Registration of clinic is mandatory along with details of machine and radiologist/sonologist. Signages in local & English language should be displayed, indicating that “Sex determination is not done here. It is a punishable offence”.

11. CT scan

11.1. Whole body CT Scan with scan cycle less than I sec (sub second). Installation of all equipments should be approved by AERB. Basic life support and resuscitation equipment and drugs should be available on site.

11.2. The tube housing, Beam limiting devices, Beam filtration, scan plane accuracy couch position accuracy, Beam –ON indicators, scan increment accuracy, gantry aperture clearance, Image receptors, visual indicators, timer and warming conditions should be as per AERB Safety Code No.AERB/MED -20(Rev.1).

11.3. In addition all the equipment should be checked and calibrated specifically for the following: (a) Calibration of signal to noise ratio; (b) Calibration of mA; (c) Calibration of Kv; (d) Check of phantom image quality; (e) Check for radiation leakage wherever lead glass is installed; (f) Calculation of dose for each case and a log/ record of the same should be maintained; (g) Certificate of fitness for use by the manufacturer for machines more than 10yrs old.

12. Interventional radiology

12.1. There should be fixed high resolution image intensification system with a minimum field of 25cms. Sites performing angiography should have digital acquisition and subtraction facilities. The angiographic injector should be capable of injecting varying rates and volumes and it should have appropriate safety mechanism to prevent over-injection .

12.2. Mobile intensifiers are not recommended for diagnostic angiography on a routine basis due to their limitation and image quality and data handling and also increased requirement of contrast and increased radiation dose and produces suboptimal images of thick body parts.

12.3. There should be facilities for patient monitoring by ECG/BP monitoring/pulse oximetry / monitoring of direct pressure gradients as required by the scope of services listed.

12.4. The supply of diagnostic and therapeutic devices should be sufficient to support the range of services offered and for treatment of possible complications arising therein (e.g. transcutaneous ultrasound, intra arterial ultrasound , thrombectomy and arthrectomy devices, with associated catheters, tissue ablation devices).

12.5. There should be adequate protective measures as per AERB guideline.

SCHEDULE IV
Standards for Water, Sanitation, Hygiene, Safety & Security

[Refer Rule 23]

Part I General.

Introduction

The clinical establishment should maintain the Water, Sanitation, Hygiene Safety & Security standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

1. Location and surroundings

1.1. The clinical establishment should be situated in a site having clean & hygienic surroundings free from nuisance and should not be adjacent to an open sewer drain, filth, garbage bins or public lavatory or to a factory emitting smoke or obnoxious odor or public conveniences and any surrounding in unsanitary condition.

1.2. The clinical establishment should not be located in a dingy, damp or otherwise unsuitable building and premises in unsanitary condition. The site should be compatible with other considerations such as accessibility and availability of services and should be approved by the the appropriate authority.

1.3. The surrounding should be quite. The government should declare the surroundings of the clinical establishment as a 'noise-free zone' and should impose restriction in exercise of power as per Envionmental Protection Act and other relevant Acts and rules.

(4) No clinical establishment shall be allowed to function from an unsafe building.

2. Health, Clothing and Sanitary Requirements of staff

The staff employed should be free from contagious disease and should be provided with clean uniforms suitable to the nature of their duties. The workers should be medically examined at the time of employment and periodically so examined thereafter. There should be facilities for medical check up of hospital staff of all categories particularly cooks and staffs of the dietary department.

3. Sanitation & Hygiene

The clinical establishment should apply the "Precautionary Principle" wherever and whenever necessary. The interior should be clean and hygienic. All the rooms/ wards should be properly ventilated and have adequate lighting facilities. The minimum floor area for toilet should be 36 sq.ft. Arrangement should be made for sanitary fitments as per Annexure 1 of this schedule. There should be adequate Sewage Disposal arrangement.

4. General Water Supply:

4.1. Arrangement should be made to supply adequate quantity and quality of water. The inpatient facilities with more than 30 beds should have supply of alteast 350 litres of potable, wholesome water per day, per bed to meet all requirements (including laundry), except fire fighting.

4.2. The term "Wholesome water" means water that is: (a) free from pathogenic agents; and (b) free from harmful chemical substances; and (c) pleasant to the taste, i.e. free from colour and odour and (d) usable for domestic purposes.

4.3. Storage capacity for minimum 48 hours requirement should be made on the basis of above consumption. Systems should be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand. Arrangement should be provided to ensure uninterrupted water supply for operation theatre.

4.4. In case of inpatient facilities with more than 30 beds, hot water supply to wards and departments of the general hospital should be provided by means of electric storage type water heaters or centralized hot water system of capacity depending upon the need of hot water consumption.

5. Signage

The clinical establishment should have: (a) properly displayed safety signs, for example, (a) signs of identification of safety equipments such as fire extinguishers, showers, eyewash facilities, (b) signs to identify hazards and hazardous activities, (c) signs to delineate public areas from area of restricted access.; etc;

6. Standard Fire safety measures

6.1. It should be provided as per West Bengal Fire safety Act/Rules and guidelines issued by that department.

7. Standard Biosafety Measures

7.1. Entry into Laboratory/work area should be restricted. Staff should be attired with aprons or suitable clothing for working in the laboratory. Work surfaces should be disinfected when procedures are completed and at the end of each working day.

7.3. Gloves should be worn for all handling of infectious material. Examination gloves of vinyl or latex should be used in laboratory, ward, operation theatre. General purpose utility gloves (i.e. rubber gloves or household gloves, reusable) should be used while cleaning instruments, decontamination procedures and other activities where manual dexterity is not required.

7.4. In operation theatres and delivery rooms, cleaning should be carried out every day. Cleaning with suitable disinfectant has to be carried out and swabs should be sent to laboratory for cultures regularly. Fumigation should be done as and when necessary. Records for the same should be maintained so that they can be scrutinized periodically. All horizontal surfaces including floor should be mopped between cases.

7.5. All medical instruments should be properly sterilized. Hepatitis vaccine should be provided for all personnel. Adequate arrangements for pest and rodent control should be provided by the clinical establishment.

8. Safety measures against Disaster

It should be provided as per IPHS guideline

Part II. Specific

1. Radiation safety

Rooms housing diagnostic X-ray units and related equipment should be located preferably on ground floor as far away as feasible from areas of high occupancy and general traffic, such as maternity and paediatric wards and other departments of the hospital. The machine should be placed at the end of the lab so as to have less lead shielding of the walls. The X-Ray lab should take due safeguards against the radiation protection and should adhere to prescribed regulations of AERB which are amended from time to time.

2. Water supply

Filtered and soft water supply should be arranged in pathology laboratories. Cold water supply should be arranged for processing tanks in film developing room, Water For Dialysis unit should be de-ionized using reverse osmosis process and disinfected by ultraviolet radiation.

3. Sanitary Fitments

3.1. The pathology lab should maintain a separate toilet. The radiology lab should have following special toilet facilities in case it carries out procedures like IVP.

3.2. Sanitary Fitments for IPD & OPD should be: (a) Water closets for males at the rate of 1 for every 40 persons or 8 beds or part thereof; (b) Water closets for females at the rate of 1 for every 25 persons or 6 beds or part thereof; (c) Ablution taps for males at the rate of 1 for each water closet plus one water tap with draining arrangement in the vicinity of water closets; (d) Ablution taps for females at the rate of 1 for each water closet plus one water tap with draining arrangement in the vicinity of water closets (e) Urinals (males only) at the rate of 1 for every 25 persons or 12 beds or part thereof; (f) Wash basins and drinking water fountains for males at the rate of 1 for every 50 persons or 12 beds or part thereof; (g) Wash basins and drinking water fountains for females at the rate of 1 for every 50 persons or 12 beds or part thereof

3.3. Sanitary Fitments for IPD only should be: (a) Baths at the rate of 1 bath with shower for every 12 beds or part thereof; (b) Bed pan washing sinks at the rate of 1 for each ward In dirty utility and sluice room; (c) Cleaner's sinks and sink/slab for cleaning mackintosh at the rate of 1 for each ward; (d) Kitchen sinks and dishwashers at the rate of 1 for each pantry for ward or cubicles

4. Biosafety Measures in clinical lab

4.1. The lab should ensure Safety in laboratories therefore includes protection of both the staff and the environment from hazardous materials because (a) the Personnel working in laboratories is at risk from various chemicals, infectious materials, fire hazard, gas leak etc. and (b) The environment is also at risk of being contaminated by hazardous materials used and wastes generated in the laboratory.

4.2. Regarding biosafety, the labs should follow the Four levels of biosafety laboratories (BSL) developed by World Health Organization (WHO).

SCHEDULE V
Standard for Operating Procedures

[Refer Rule 24]

Part I: Introduction

1. General

1.1. The clinical establishment should maintain the Operating Procedure standards as specified in this schedule or any such standards as may be notified from time to time.

1.2. If the clinical establishment comes across any such medico-legal cases as may be notified, it should report promptly such cases to the police station, within the jurisdiction of which such clinical establishment is located though a Police intimation register maintained and generated by the clinical establishment in such a manner and should contain such particulars as may be notified.

Part II: Patient care

1.1. Proper arrangements for attending the patients and prompt answering to their calls should be made available round the clock. All emergency diagnostic procedures should be done immediately.

1.2. Adequate and wholesome diet should be provided to the patients as per advice of the attending Doctor and cleanliness is to be maintained in preparation of diet and it's service to the patients. The diet should be prepared and served in hygienic conditions.

Part IV: Pahology Laboratory Facilities

1. Collection

1.1. Appropriate counselling should be done before specimen collection and consent taken whenever needed. Attention should be paid to patient's sensibilities during the entire process. Any error in specimen collection should be avoided as it can lead to erroneous results. Stand-alone collection center should not conduct any invasive procedure to collect any specimen.

1.2. All pathology Laboratories including Collection centers should have a "primary specimen collection manual", containing information on patient preparation before specimen collection (if any), exact methodology of specimen collection, labeling, handling, transportation and storage of the specimens. In addition, the laboratory should provide adequate and appropriate information/instructions to patients wherever necessary. The manual should include guidelines on specimen collection including preservation for histopathological examination. These manuals should be available for reference and should be used for training of staff engaged in specimen collection.

1.3. Specimen should be secured properly so that there is no leakage, spillage or contamination. A Biohazard symbol should be used on the containers during transportation. Appropriate specimen transportation kit (such as use of dry ice, etc.) to be used wherever required. Specimen should be sent to the laboratory along with the requisition form.

2. Analytical work or Test

2.1. Accession list is a record of all the specimens received by the laboratory for analysis and is prepared by the laboratory at the time of specimen receipt.

2.2. It records the patient's identity including name, age, sex, location in the hospital/ medical facility, name of referring physician, investigations requested, date and time of receipt of specimen and condition of the specimen at receipt. The laboratory assigns a unique laboratory number to register each specimen received, which can be used to trace the specimen in the laboratory. The test results and remarks if any are also entered in the accession list.

2.3. In laboratories handling a very large number of specimens, the accession list may be computer generated and the condition of specimen at receipt may not be recorded unless it has been rejected.

2.4. Worksheet is essentially a form provided to the analyst along with the specimen. The following details should be recorded on the worksheet: (a) Date of analysis; (b) Condition of the specimen before starting analysis (should be entered in the laboratory notes); (c) Findings and result; (d) Name and signature of the analyst (In case of electronically generated and maintained worksheets, appropriate control, validation and access procedures should be built in the system)

2.5. Laboratory number assigned to the specimen should be mentioned in the worksheet before sending the specimen to the analyst.

2.6. The specimen should be analyzed according to the plan mentioned in the SOP. Any deviations from the analysis plan should be mentioned giving reasons. Wherever applicable the laboratories can use requisition form cum worksheet instead of two separate forms.

3. Reporting Test Results

3.1. Test results approved and signed by the pathologist should be made available in a sealed cover to authorized person(s) like Patient/Patient party/Medical attendant only. For the disposal of Lab material every Lab should have needle destroying unit, sodiumhypochlorite solution, lab wash and formalin solution for fumigation of the Lab and other appropriate provisons as per Environmental Protection Act.

3.2. The proper maintenance of the record of the tests undertaken should be maintained in serial number w.e.f 1st January to 31st December every years.

4. Quality Control

Medium/large labs should adopt the external and internal quality control measure To have accuracy and precision. Preferably, at least two samples/ month should be sent to the other registered Labs with in the State and two samples outside the State and the results should be compared and recorded properly in the Quality Control Register, which should be produced on demand for inspection.

5. General Safety measures in Laboratory

5.1. All laboratory personnel should be aware about the laboratory safety policies and procedures and follow these at all times. List of hazardous materials used in the laboratory should be prepared. All hazardous materials should be accounted for on a continuous basis.

5.2. Laboratory personnel should follow safe hygienic practices which include hand washing, wearing protective clothing, gloves, eye protection devices etc. Eye wash facility should be available as "stand-alone" facility or attached to sink. Portable, sealed, refillable bottles should also be available.

5.3. Biohazard symbol should be used on all container/equipment containing biohazardous material. Laboratories should ensure proper preservation and security of specimens. Destruction/disposal of hazardous material should be authorized, supervised and handled according to standard procedures.

5.4. Laboratory personnel should be thoroughly trained in managing fire, and non-fire emergencies such as large spillage, gas leakage etc. Adequate fire extinguishers should be readily available in the laboratory

5.5. Periodic checking of all safety equipment and accessories should be ensured.

5.6. Accident/incident/injuries record of laboratory personnel should be maintained and reported to the designated authority. The report should include description of the event, factors contributing to the event and information on first aid or other health care provided. This information can be analyzed periodically towards effectively controlling and preventing future events. The records should be checked periodically by the Doctor in-charge even in the absence of fresh entries.

Part V: Diagnotic & Imaging Laboratory Facilities

1.1. Sitting room for the patients and attendants should be away from X-ray room and at the time of X-raying patients, attendants should not be normally allowed inside the X-ray room. In case of children being x-rayed, the attendants should, however, be allowed to stay.

1.2. While taking X-ray of teeth, films should be held by the patients themselves and not by the X-ray Technicians. In clinics where Radiographic contrast is administered, adequate resuscitation drugs should be available and these investigations should be performed under the supervision of Radiologist. The safe guard of the patients and staff members against the radiation problems should be ensured as per the guidelines of AERB.

1.3. The X-ray machines should be operated only by qualified X-ray Technicians. The technicians should wear lead aprons while giving exposures. The MAS exposures given by the X-Ray technician should be displayed so that the higher radiation does is not given to the patient. Monitoring (Film badge service) should be used.

1.4. Intensifying screens and x-ray cassettes should be changed after two years or earlier in case they are not giving proper results and the Radiologist should certify it. All records relating to X-ray should be properly maintained. Complete record of the x-ray done along with duplicate report duly signed by the radiologist should be mandatory.

1.5. Pregnant women should be exposed to radio wave only after due consideration by the radiologist of the relative risks and benefits of such exposure. A warning that “x-ray’s are potentially harmful and should be done only when advised by the a doctor” should be displayed in Hindi, English and Urdu with warning that “pregnant ladies and small children and infants should not stand near the x-ray machine as a spectator/attendant with the patient when he/she is x-rayed”.

SCHEDULE VI
Standards for Records, Reports & Registers

[Refer Rule 25]

Part I. Introduction

1. General

The clinical establishment should maintain the Records, Reports & Registers standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

1. Maintenance

1.1. For maintaining various ledgers / registers, the guidelines and protocol as may be notified should be followed strictly.

1.2. Medico legal documents should be prepared and maintained then and there properly and promptly. Care should be taken to leave none of them incomplete. Statutory Format should be used for preparing them.

1.3. A 'Record keeping Register' should be maintained in all section / wards of the hospital with the following minimum title columns: (a) Sl No., (b) Date, (c) Nature of record / register, (d) Date of originating / receiving the document in the section, (e) From whom received, (f) Condition of the document at the time of receiving, (g) Date of issue / disposal, (h) To whom issued, (i) Order for disposal and (10) Remarks.

1.4. Responsibility of maintaining / safeguarding the document should be vested with the in-charge of the section but all the staff in the section should have the responsibility of safeguarding every document in that section and with all the staff involved in preparing the registers at various periods till the register is handed over to the Medical Record Department on completion.

2. Preservation

2.1. All records should ordinarily be preserved for a minimum period as mentioned below: (a) all OPD records for 5 years; (b) all IPD records for 10 years; (c) all Medico-legal records for 15 years; (d) all accounting records for 5 years.

2.2. On completion of the register it should be kept under lock and key in the section and/or handed over to the concerned officers to be kept in the Medical Record Section. Other documents are to be kept at the place of origin and disposed after the preservation period.

3. Disposal

3.1. When preservation period of a document is over, it should be treated as inactive and should be disposed. The custodian of that document in the section should report the fact to the head of the institution. With permission of the head of the institution those documents should be removed from the Record keeping Register. Head of the institution should issue a proceedings to this effect and copy served to all sections and concerned officials.

3.2. The disposed items are to be destroyed by burning or giving to the waste paper contractors authorized by the institution. The procedures of disposal and destruction should be transparent and the file regarding this should be kept safely as this could be asked by appropriate authority.

4. Medico-Legal documents

4.1. Medico-Legal documents should be kept safely and separately. Case records involving Medico-Legal aspects should be kept separately. They should be identified by marking "MLC" at the right hand top corner of the cover page or identified by any colour code.

Part II: Statutory Forms

Statutory CE FORM I: Application for Registration

[Refer Rule 30]

Part –A

(Common for all establishment)

01. Application Acknowledgement: (For office use only)

01A. Acknowledgement No. …… 01B. Acknowledgement Date …….

02. Purpose of Application:

02A. New License □, Renewal □, Applied for other purposes like Change or modification of particulars □, Composite License □, Issuance of Duplicate Copy □, Amendment of old license □

02B. Accompanied separate sheet mentioning other purposes enclosed as enclosure □□

03. Name of the Clinical Establishment:

03A. Proposed Name:……

03B. Existing Name: ……

04. Existing Clinical Establishment License:

04A. Not applicable □, Applicable □ 04B. If applicable, License:

04B1. License 1: ……., 04B2. License 2: ……..,

03C. Copy/ copies of existing license enclosed as enclosure □□

Particulars for any additional license is enclosed as separate sheet in enclosure □□

05. Address of the Clinical Establishment: ……..

06. Local Body:

06A. Name of the local body:……

06B. Nature of local body: Corporation □, Municipality □, Notified area □; Panchayat Area □

06C. The copy of Property Tax [from local body] enclosed as enclosure No. □□

06D. Location: Metropolitan □, or Urban □, or Rural □

07. Name of the Applicant:

07A. Full Name ……..

07E. Son/Daughter/wife of: ……

08. Address of the Applicant: ……

09. System of Medicine Offered: (Multiple options possible)

Allopathy □, Ayurveda □, Unani □, Siddha □, Homeo □, Naturopathy □, Yoga □, Any other □ (Please specify .....)

10. Subsystem of Medicine Offered: (Multiple options possible)

10A. Allopathy: General □, Specialty □, Super-specialty □, Dental □; or other Allopathy □ (Please specify ……..)

10B. Ayurveda: AYR01 □, AYR02 □, AYR03 □, AYR04 □, AYR05 □; AYR06 □ (Please specify …….)

10C. Unani: UNN01 □, UNN02 □, UNN03 □, UNN03 □, UNN04 □, UNN05 □ (Please specify ……..)

10D. Siddha: SDD01 □, SDD02 □, SDD03 □, SDD04 □ (Please specify ……..)

10E. Homeopathy: HOM01□, HOM02 □ (Please specify ……..)

10F. Naturopathy: NTR01 □, NTR02 □ NTR03 □ (Please specify ……..…..)

10G.Yoga: YOG01 □, YOG02 □ (Please specify ……)

10H. Any other recognized system of Medicine □ Please specify ……)

11. Service Facilities offered: (Multiple options possible)

11A. Outpatient based Service □, 11B. Inpatient based service □, 11C. Diagnostic laboratory service □, 11D. Diagnostic Imaging service □, 11E. Any other type □ (Please specify _____)

11F. This is a single doctor establishment: Yes □, No □

12. Sanitation & Hygiene Part I:

12A.Drinking water supply as per standard norm provided: Yes □, No □

12B. Toilet is adequate Yes □, No □

12C. Whether the Lighting is adequate: Yes □, No □

12E. Whether the Ventilation is adequate: Yes □, No □

13. Mandatory Reporting Part I:

13A. Reports of Notifiable disease: generated/maintained □ not generated/maintained □ not applicable □

13B. Reports of Health Program: generated/maintained □ not generated/maintained □ not applicable □

13C. Reports related to medico-legal cases: generated/maintained □ not generated/maintained □ not applicable □

13D. Copy of Acknowledgement receipt (only in case of renewal) enclosed as enclosure □□

14. Mandatory Display Part I:

14A. Copy of Clinical establishment license(s): Displayed □, Not displayed □, Not applicable □

14B. The name of the Establishment with names of the Licensee: Displayed □, Not displayed □

14C. Clinical establishment license Number: Displayed □, Not displayed □, Not applicable □

14D. The system(s) of Medicine practiced: Displayed □, Not displayed □

14E. Types and availability of health care and other services: Displayed □, Not displayed □

15. Mandatory Register Part I:

15A. Out-patient register: generated/maintained □ not generated/maintained □ not applicable □

15B. Inspection book (register) generated/maintained □ not generated/maintained □ not applicable □

15C. Police intimation register generated/maintained □ not generated/maintained □ not applicable □

Part B

(Only for Single Doctor Establishment)

16. Mandatory Particulars:

16A. Name …… 16B. Qualification (Highest): ……

16C. Name of the University: …… 16D. Copy Certificate of qualification enclosed as enclosure □□

16E. Registration No. …… 16F. Name of the Council registered with: ……..

16G. Copy Certificate of registration enclosed as enclosure □□

Part-C

(Only for establishments other than Single Doctor Establishments)

17. Nature of ownership:

17A. Individual Proprietorship □, Collective proprietorship or company or organization □

17B. If Collective proprietorship or company or organization, the nature of organization: Registered Partnership □; Registered Company □; Corporation □; Trust (including Charitable) □; Organization registered under society registration Act □; Any other organization

17B. In case of Collective proprietorship or company or organization, such organization is registered under a Central, Provincial or State Act …….. (Please specify)

17C. Name of such organization: ……..

17D. Supporting document for above statement enclosed as enclosure No. □□

17E. In case of Collective proprietorship or company or organization, such organization is a branch of a Foreign Service provider or not: Yes □, No □

18. Name & Address of the Company:

18A. Name: ……

18B. Address: ……..

19. Service sub-Facilities offered:

19A. In case of Outpatient based Service:

19A1. Solo clinic □, 19A2. Polyclinic □, 19A3. Dental Clinic □, 19A4. Physiotherapy Clinic □, 19A5. Occupational therapy Clinic □, 19A6. Infertility Clinic □, 19A7. Dialysis Centre □, 19A7. MTP clinic □, 19A9. Day care centre □, 19A10. Wellness/Fitness centre/clinic □, 19A11. Integrated Counseling & Testing Centre □, 19A12. any other clinic or OPD based service centre without beds □ (Please specify ……..); 19A13. any other clinic or OPD based service centre with beds □ (Please specify ……)

19B. In case of Inpatient based Service:

19B1. Types: Maternity Home □, 19B2. Nursing Home/Hospital □, 19B3 Any other IPD based service centre □ (Please specify …….)

19C. In case of Diagnostic laboratory service:

19C1. Collection centre □, 19C1. Small Laboratory □, 19C3. Medium Laboratory □, 19C4. Large Laboratory □

19D. In case of Diagnostic Imaging service:

19D1. X-Ray lab (Conventional or Digital) □, 19D2. Mamography lab □, 19D3. Bone Densitometry lab □, 19D4. Ultrasonography lab □, 19D5. Colour Doppler Imaging lab □, 19D6. CT Scan lab □, 19D7. Magnetic Resonance Imaging (MRI) lab □, 19D8. Positron Emission Tomography (PET) Scan lab □, 19D9. Echo lab □, 19D10. Any other Imaging Centre □ (Please specify ……..)

20. OPD based Service:

20A. Not applicable □, Applicable □

20B. Practice: General Practice □, Specialty Practice □, Maternity Practice □

20C. Specialty Services: Single □, Multispecialty □, Superspecialty □

20D. No. of Consultation Room: 20D1. Existing: □□□□; 20D2. Proposed: □□□□;

20E. Name of the Specialty:

20E1. Specialty 1: …… 20E2. Specialty 2: ……

Particulars for any additional Specialty is enclosed as separate sheet in enclosure □□

21. IPD based Service:

21A. Not applicable □, Applicable □

21B. Practice: General Practice □, Specialty Practice □, Maternity Practice □

21C. Specialty Services: Single □, multispecialty □, Superspecialty □

21D. Service: Operation Theatre □, Maternity □, Emergency Casualty □, Special care Unit □

21E. Name of the Specialty:

21E1. Specialty 1: …… 21E2. Specialty 2: ……

Particulars for any additional Specialty is enclosed as separate sheet in enclosure □□

21F. Total Bed strength: 21F1. Existing bed strength: □□□□, 21F2. Proposed Total bed strength: □□□□

21G. Special care/therapy facilities beds: 21G1.Existing bed strength: □□□□, 21G2. Proposed bed strength: □□□□
21H. Special care/therapy facilities beds breakup:
21H1. Intensive Care/Therapy unit: 21H1A. Existing bed strength: □□□□; 21H1B. Proposed bed strength: □□□□
21H2. Intensive Coronary care Unit: 21H2A. Existing bed strength: □□□□; 21H2B. Proposed bed strength: □□□□
21H3. Intensive Neonatal care Unit: 21H3A. Existing bed strength: □□□□; 21H3B. Proposed bed strength: □□□□
21H4. High Dependency Unit: 21H4A. Existing bed strength: □□□□; 21H4B. Proposed bed strength: □□□□;
21H5. Nuclear Medicine therapy Unit: 21H5A. Existing bed strength: □□□□; 21H5B. Proposed bed strength: □□□□
21H6. Any other care/therapy unit…….. (to be specified by the applicant):
21H6A. Current bed strength: □□□□; 21H6B. Proposed bed strength: □□□□
21I. Categories as per total bed-strength for which registration is to be issued: Nil □, Up to 30 beds □, 30-50 beds □, 51-100 beds □, 101-300 beds □, 301-500 beds □, More than 500 beds □

21. License Application Fee:

21A. Amount Rs. ……. deposited in head of accounts–"0210-01-800-001- 14" vide
21B. Challan No …….. and 21C.Date ……. And 21D. The copy of Treasury Chalan enclosed as enclosure No. □□

22. Any other fees & Fines:

22A. Amount Rs. ……. deposited in head of accounts–"0210-01-800-001- 14" vide
22B. Challan No ……. and 22C.Date …… and 22D. The copy of Treasury Chalan enclosed as enclosure No. □□

23. Layout & design:

23A. Separate Reception Counter: Yes □, No □ 23B. Separate Waiting room/space/area: Yes □, No □
23C. Separate Record room: Yes □, No □ 23D. Sketch map enclosed as enclosure No. □□

24. Sanitation & Hygiene Part II:

24A. Provided □, Not Provided □ 24B: Supporting documents enclosed as enclosure □□

25. Safety & Security:

25A. Provided □, Not Provided □ 25B: Supporting documents enclosed as enclosure □□

26. Mandatory Reporting Part II:

26A. generated/maintained □ not generated/maintained □ 26B. Supporting documents enclosed as enclosure □□

27. Mandatory Display Part II:

27A. Provided □, Not Provided □ 27B: Supporting documents enclosed as enclosure □□

28. Mandatory Register Part II:

28A. Provided □, Not Provided □ 28B: Supporting documents enclosed as enclosure □□

29. Accommodation:

29A. Premises ownership: Rented □, Leased □, Granted rent free by the owner of the premises □ and Copy of Rent receipt, agreement or any such supporting document enclosed as enclosure □□ or Owned □
29B. NOC from owner of premises (in case of New license only): Not applicable □, applicable □ and a copy enclosed as enclosure □□; applicable but copy not available □

30. Premises:

30A. a Copy of approved Plan enclosed as enclosure No. □□;
30B. The tax receipt [property tax] form the Local body: a copy enclosed as enclosure No. □□;

31. Space:

31A. Provided □, Not Provided □ 31B: Supporting documents enclosed as enclosure □□

32. Equipment & Medical supplies:

32A. Provided □, Not Provided □ 32B: Supporting documents enclosed as enclosure □□

33. Trade License or certificate of enlishment from Local body

33B. Trade License Number: …….. 33D. Date of issue: ……
33C. Name of the Issuing Authority: ……..……. 33D. the copy enclosed as enclosure No. □□

34. Education & Research:

34A. Intend to conduct research: Yes □, No □; 34B. If yes whether NOC obtained: Yes □, No □;
34C. if yes, the copy of NOC enclosed as enclosure □□
34D. Intend to conduct training/education: Yes □, No □; 34E. if yes, details of course enclosed as enclosure □□

35. Manpower: Medical Staff:

35A. Number: 35A1. No. of Full-time Medical staff □□□, 35A2 No. of Part-time Medical Staff □□□ 35A3. Total □□□
35B. Particulars of individual medical staff to be enclosed with the following particulars

---

01A. Name ……. 01B. Qualification (Highest): ……..
01C. Name of the University: ……..... 01D. Copy Certificate of qualification enclosed as enclosure □□
01E. Registration No. …….. 01F. Name of the Council registered with: ……
01G. Copy Certificate of registration enclosed as enclosure □□
01F. Copy of Offer letter enclosed as enclosure □□ 01G. Copy of Acceptance letter enclosed as enclosure □□
35B 01H. Designation as per offer letter: ……
35B 01J. Type: Full-time □, Part-time □, only empaneled □
35B 01K. Already engaged by any Public sector agency: Yes □, No □; If yes NOC enclosed as enclosure No. □□
35B 01L. Already engaged by any other Private sector agency: Yes □, No □; If yes Number of such agencies □□

36. Manpower: Nursing Staff:

36A. Number: 36A1. No. of Full-time Nursing staff □□□, 36A2. No. of Part-time Nursing Staff □□□ 36A3. Total □□□

36B. Particulars of individual Nursing staff to be enclosed with the particulars mentioned above

37. Manpower: Paramedical Staff:

37A. Number: 37A1. No. of Full-time Paramedical staff □□□, 37A2. No. of Part-time Paramedical Staff □□□ 37A2. Total □□□

37B. Particulars of individual Paramedical staff to be enclosed with the particulars mentioned above

38. Manpower: General Duty Attendant:

38A. Number: 38A1. No. of Full-time General Duty Attendant staff □□□, 38A2. No. of Part-time General Duty Attendant Staff □□□ 38A3. Total □□□;

38B. Outsourced: Yes □, No □, If yes agreement copy enclosed as enclosure No. □□

38C. Particulars of individual General Duty Attendant staff need not be enclosed

39. Manpower: Administrative-Managerial staff

39A. Chief Executive Officer designated: 39A1. Proprietor himself □ , 39A2. Any other staff □, if other staff

39B1. Name ……

39B2. Ph (Office) …….. 39B3. Mobile …… 39B4. E.mail ID: ……..

39C. Grievance Redressal Officer designated: 39C1. Proprietor himself □ , 39C2. Any other staff □, if other staff

39D1. Name ……

39D2. Ph (Office) …….. 39D3. Mobile …… 39D4. E.mail ID: ……..

40. Regulation of Clinical Establishment:

40A. Available □ and a copy of such regulation enclosed as enclosure No. □□; 40B. Not available □

Part-D
(For all clinical establishments)

41. Affidavit:

Self declaration and undertaking in the form of Affidavit as per Statutory CE Form III enclosed as enclosure □□

42.Any additional information:

43. Declaration

I,
Sri/Smt/Kum/Dr. _____son/daughter/wife of _____age_____years, resident of_____ hereby declare that I have read and understood the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 (West Ben. Act XXVI of 2010) and the West Bengal Clinical Establishment (Registration and Regulation) Rules, 2012.

I also undertake to explain the said Act and Rules to all employees/consultants of the Nursing Home in respect of which registration is sought and to ensure that the Act and Rules are fully complied with.

Date : (_____)
Place : Name and Signature of Applicant.

N.B. Put √ tick mark in the appropriate box. Strike out whichever is not applicable or not necessary. All enclosures are to be authenticated by signature of the applicant.

Statutory CE FORM II: Nomination of person by Company

[Refer rule 31]

Being the proprietor or a signatory authorized by the board of directors of the company, in terms of Rule 32, I do hereby gives notice that the following person is nominated as the applicant in respect of clinical establishment mentioned and shall be in-charge of establishment and shall be responsible and liable for any contravention of the Act and rules/regulations or directions issued thereunder in respect of this establishment.

The person shall take all such steps as may be necessary to prevent the commission by the Company of any contravention under and comply with the provisions of Act and the Rules and Regulations made thereunder.

Name of the Establishment:

Name of the nominee: ……..son/daughter/wife/ of ……. residing at ……..

Full signature of the nominee ……..

A certified copy of the resolution of the board regarding the authorized signatory, dated _____ is enclosed.

Place:_____ For _____ Company.

Date:_____ Authorized signatory of the company

Statutory CE FORM III: Affidavit Self-Declaration

[Refer Rule 30]

Self-Declaration

I,

Mr./Mrs./Ms/Dr. _____son/daughter/wife of _____age_____years, resident of _____ hereby declare that the statements and particulars furnished by me in Form II has been made correctly and I would make myself liable for appropriate legal action including suspension or cancellation of license in case any of the statements or particulars furnished by me are found false or incorrect thereof subsequently on inspection by the authorized representative of the licensing authority.

I also undertake to correct deficiencies, if any, as per the said Act and Rules.

Date : (_____)

Place : Name and Signature of Applicant.

Statuary CE FORM IV: Acknowledgement of Application

[Refer Rule 34]

Office Address of the Licensing Authority

Memo No. Date

Memo

Sub: Acknowledgement of application for grant or renewal of License

Ref: Memo No. of application letter (If any)…… Dated ……

The application in Form 'I' in duplicate for grant/renewal of registration of Nursing Home by applicant mentioned below for grant/renewal of registration of the clinical establishment named below situated at the address given below has been received by the Meghalaya Nursing Home Licensing and Registration Authority against acknowledgement number mentioned below.

2. The content of the application in Form 'I' along with the following enclosures attached to the application in Form 'I' will be verified in due course and the discrepancies found, if any, will be informed in due course.

3. This acknowledgement does not confer any right on the applicant for grant or renewal of License

4.a. Name of the Applicant:

……..

4.b. Address of the Applicant:

……

4.c. Name of the clinical establishment:

……..

4.d. Address of the clinical establishment

……

4.e. Registration No. of existing License (only in case of renewal):

……..

4. List of enclosures received along with the application form:

Place: Signature of the Officer in-charge on behalf of Licensing Authority & District Registrar

Date: Office Seal with designation

Statutory CE FORM V: Inspection Report

[Refer Rule 34]

01. Application form attached: Yes □, Not applicable □ (in case of unregistered establishment)
02. Name & Address of the clinical establishment inspected: ……
03. Name & Addree of the Applicant/Licensee/Occupier: ……
04. Inspection Remarks: Cannot be verified □, Checked & verified □, and no discrepancies found □; or discrepancies found and noted below under note No. □□
05. Inspection Note: The above mentioned items claimed by the applicant in the application form cannot be verified. After verification of other items, the following discrepancies are noted below: [Please begin each para with a two digit note number corresponding to note number already mentioned in different remarks]
06. Recommendations: 06A. Improvement notice may be issued □; 06B. Prohibition notice may be issued □; 06C. Suspension order may be issued □; 06D. Cancellation order may be issued □; 06E. Complaint may be lodged with the adjudicating authority 06F. Application may be refused □ 06G. Application may be granted □ 06H. Any other recommendation(s) □ (please specify below): Date Signature of the Inspection Officer/Authority Place Office seal
Remarks of the Licensing Authority Date Signature of the Licensing Authority Place Office seal

Statutory CE Form VI: District/State Register of Clinical Establishments

[Refer Rule 38]

01. Application Acknowledgement: 00A. Acknowledgement No. □□□□□□□□□□□□□□□□□□ 00B. Acknowledgement Date □□ □□ □□□□
02. Name of the Clinical Establishment: ……
03. Existing Clinical Establishment License Number (if any): 03A. License 1: □□□□□ □□□□ □□□□□, 03B. License 2: □□□□□ □□□□ □□□□□,
04. Address of the Clinical Establishment: Pin Code PS E.mail ID Ph No. (Office) (Mobile) ……
05. Name of the local Body: …… Corporation □, or Municipality □, or notified area □; or Panchayat Area □
06. Location: Metropolitan □, or Urban □, or Rural □
07. Name of the Applicant: Title ……. First ……. Middle …… Last ……
08. Address of the Applicant Pin Code PS E.mail ID Ph No. (Office) (Mobile) ……
09. Nature of ownership: 09A. Individual Proprietorship □, or Registered Partnership □, or Registered Company □ or Corporation (including a society) registered under a Central, Provincial or State Act □ (Please specify …….); or Trust (including Charitable) registered under a Central, Provincial or State Act □ (Please specify ……..); Branch of a Foreign Service provider □ (Please specify ……); or Any other □ (Please specify ……) 09B. Name of the Company: …… 09B. Address of the Company Pin Code PS E.mail ID Ph No. (Office) (Mobile ……
10. System of Medicine Offered: (Multiple options possible) Allopathy □, Ayurveda □, Unani □, Siddha □, Homeopathy □, Naturopathy □, Yoga □ Any other □ (Please specify …)
11. Subsystem of Medicine Offered: (Multiple options possible) 11A. Allopathy: General □, Specialty □, Super-specialty □, Dental □; or other Allopathy □ (Please specify …) 11B. Ayurveda: AYR01 □, AYR02 □, AYR03 □, AYR04 □, AYR05 □; AYR06 □ (Please specify ……) 11C. Unani: UNN01 □, UNN02 □, UNN03 □, UNN03 □, UNN04 □, UNN05 □ (Please specify ……) 11D. Siddha: SDD01 □, SDD02 □, SDD03 □, SDD04 □ (Please specify ……..) 11E. Homeopathy: HOM01□, HOM02 □ (Please specify ……..) 10F. Naturopathy: NTR01 □, NTR02 □ NTR03 □ (Please specify ……..) 10G.Yoga: YOG01 □, YOG02 □ (Please specify ……..) 10H. Any other recognized system of Medicine □ Please specify ……)
12. Service Facilities offered: (Multiple options possible) 12A. Outpatient based Service □, 11B. Inpatient based service □, 11C. Diagnostic laboratory service □, 11D. Diagnostic Imaging service □, 11E. Any other type □ (Please specify ……)
13. Service sub-Facilities offered: (Multiple options possible) 13A. In case of mainly Outpatient based Service: 13AA. Solo clinic □, 13AB. Polyclinic □, 13AC. Dispensary □, 13AD. Dental Clinic □, 13AE. Physiotherapy Clinic □, 13AF. Occupational therapy Clinic □, 13AG. Infertility Clinic □, 13AH. Dialysis Centre □, 13AI. MTP clinic □, 13AJ. Day care centre □, 13AK. Wellness/Fitness centre/clinic □, 13AL. Counseling Centre □, 13AM. any other clinic or OPD centre □ (Please specify ……..) 13B. In case of mainly Inpatient based Service: 13BA. Maternity Home □, 13BB. Nursing Home/Hospital □, 13BC. Sanatorium □, 13BD Any other IPD centre □ (Please specify ……) 13C. In case of Diagnostic laboratory service: 13CA. Collection centre □, 13CB. Small Laboratory □, 13CC. Medium Laboratory □, 13CD. Large Laboratory □ 13D. In case of Diagnostic Imaging service: 13DA. X-Ray Centre (Conventional or Digital) □, 13DB. Mamography centre □, 13DC. Bone Densitometry centre □, 13DD. Sonography centre □, 13DE. Colour Doppler Imaging centre □, 13DF. CT Scan Centre □, 13DG. Magnetic Resonance Imaging (MRI) Centre □, 13DH. Positron Emission Tomography (PET) Scan Centre □, 13DI. Echo □, 13DJ. Any other Imaging Centre □ (Please specify ……)
14. Bed strength: 14A. Total Bed strength: □□□□ 14B. Bed strength of special care units: □□□□ 14C. Categories as per total bed-strength for which registration is issued: Nil □, Up to 30 beds □, 30-50 beds □, 51-100 beds □, 101-300 beds □, 301-500 beds □, More than 500 beds □

15. License Fee: 15A. Amount Rs. □□□□□ deposited and 15B. Challan No □□□□□□□□□□□□ and 15C.Date □□□□□□□□
16. Other Fees & Fines: 16A. Amount Rs. □□□□□ deposited and 16B. Challan No □□□□□□□□□□□□ and 16C.Date □□□□□□□□
17. Manpower Number: 17A. Medical Staff □□□, 17B. Nursing Staff □□□, 17C. Paramedical Staff □□□, 17D. Admin-managerial Staff □□□, 17E. Total Staff □□□□
18. Registration Details: 18A. Registration No. …… 18B. Registration Date ,,,,,,,,,,,,,,,,,,,,,,,, 18C. Registration Valid upto …… 18C. Registrated by (Designation of Licensing Authority cum District Registrar):…….. 18D. Name of the District: …… 18E. Order No. issued by Licensing Authority granting License ……18F. Dated ……..
19. Present status: (only in case of digital register) Valid License □, License expired □, License Suspended □, License Cancelled □
20. Any Additional information:
Signature & Seal of Licensing Authority

Statutory CE FORM VII: License

[Refer Rule 7]

Registration No □□□□-□□□□-□□□□ Original □/ Duplicate □

सत्यमेव जयते

This is to certify that the Applicant mentioned below has been granted a license under The West Bengal Clinical Establishment (Registration and Regulation), 2010 vide order issued by the undersigned under number mentioned below in respect of the Clinical Establishment mentioned below situated at the addressed mentioned below to keep or carry on the said Nursing Home/Clinical Establishment

2. This is to certify that the licensee has been Registered vide registration No. mentioned above under rule 43 of the CE Rules, 2012, by the undersigned in respect of Clinical Establishment) mentioned below situated at the addressed mentioned below and the license shall be valid for the period mentioned below

3. The License is granted subject to the CE Act 2010, CE Rules 2012 and CE Regulation, 2012 and any contravention thereon shall result in suspension or cancellation of this license before the expiry period.

4.a. Name of the Licensee: ……

4.b. Address of the Licensee: ……

4.c. Name of the Clinical Establishment: ……

4.d. Address of the Clinical Establishment: ……

4.e. Oder No. of the Licensing Authority granting License:

No. ……..……. Date ……..

4.f. Granted/ Renewed from [Date] ……..……. 4.g. Valid upto [Date]……..

4. g. Name(s) of recognized system of medicine practiced:

……..

……

4.h. Services to be provided:

Place: Signature of the Licensing Authority & District Registrar

Date: Office Seal with designation

Statutory CE Form VIII: Granting of Application Order

[Refer Rule 34]

Office Address of the Licensing Authority

Memo No. Date

Order

Sub: Grant of application for new/renewal of License

Ref: Application Acknowledgement No……

In exercise of the power conferred under Section 13 of the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010, the Licensing Authority hereby grant the application mentioned above submitted by the applicant mentioned below for grant/renewal of registration of the clinical establishment named below situated at the address given below.

2.a. Name of the Applicant: ……

2.b. Address of the Applicant: ……

2.c. Name of the clinical establishment: ……

2.d. Address of the clinical establishment ……

2.e. Registration No. of existing License (only in case of renewal): ……

3. The license in statutory form under sub-rule 2 of the Rule 5 shall be issued in due course.

Place: Signature of the Licensing Authority & District Registrar

Date: Office Seal with designation

Copy forwarded for information to:-

1. The State Registrar ……..

2. The applicant ……..

Statutory CE Form IX: Rejection of Application Order

[Refer Rule 34]

Office Address of the Licensing Authority

Memo No. Date

Order

Sub: Rejection of application for grant/ renewal of License

Ref: Application Acknowledgement No……

In exercise of the power conferred under Section 13 of the CE Act, 2010, the Licensing Authority hereby rejects the application mentioned above submitted by the applicant mentioned below for grant/renewal of registration of the clinical establishment named below situated at the address given below for the reasons stated below.

2.a. Name of the Applicant: ……

2.b. Address of the Applicant: ……

2.c. Name of the clinical establishment: ……

2.d. Address of the clinical establishment ……

2.e. Registration No. of existing License (only in case of renewal): ……..

3. Reasons for Rejection:

Place: Signature of the Licensing Authority & District Registrar

Date: Office Seal with designation

Copy forwarded for information to:-

1. The State Registrar ……..

2. The applicant ……..

Statutory CE Form X: Appeal Form

[Refer Rule 40]

Before the Hon'ble Appellate Authority
Memorandum of Appeal No. …….. Dated…….. [Office Use only]

IN THE MATTER OF

Name of the Appellant(s) : -……
Full Address: ……..
Village/Tehsil/District: -……..

Against the decision of

Designation of the Licensing authority: -…….
Full Address: ……
District: -……
The humble appeal of Appellant(s) above named most respectfully showed:

1. This appeal is directed under Section 26 of the West Bengal Clinical Establishments (Registration and Regulation) Act, 2010 against the order of the District Registrar & Licensing Authority ……... in order No. …….. passed on ……. received by the appellant on ……

2. This appeal is filed within the time limit provided under Section 26 of the West Bengal Clinical Establishments (Registration and Regulation) Rules, 2012./ This appeal being, barred by limitation, is accompanied by an application for condonation of delay for consideration by the Appellate Authority, as per Section 26 of the West Bengal Clinical Establishments (Registration and Regulation) Rules, 2012 (delete whichever is not applicable).

3. Brief facts of the case are stated hereunder (Please furnish herein the details of the case and the decision of the District Registrar & Licensing Authority):
…….

4. The grounds on which appeal is preferred are stated here under (the grounds should be numbered consecutively without any arguments of narrative):
……..

5. The appellant has not preferred any other appeal against the order impugned herein.

6. PRAYER: It is, therefore, respectfully prayed that your Honour may be graciously pleased to allow the appeal and set aside/modify the order of the District Registrar & Licensing Authority appealed against.

7. List of enclosures:
   1. Certified copy of the order of the District Registrar & Licensing Authority appealed against.
   2. Affidavit.
   3. ……
   4. ……

Place: ……..
Date: …….. Full Signature
(To be signed by the Appellant and Authorized Representative/Associate).

Statutory CE Form XI: Annual report of Free Treatment & Concession

[Refer Rule 11]

Report of Free Treatment Provided during the months… Year…….

Name of the Clinical Establishment:……

Address……

A-Report at a glance:-

	No of OPD patients			No of In-patients			No of investigations		
Name of month	Total	Free/ Concession	% of Free	Total	Free/ Concession	% of Free	Total	Free	% of Free

B-Detailed Report:-

Sl no.	Date of Registration	Registration no	Name of patient	Father's Name	Address in full, Ph.No.	Name of illness	Nature of free Treatment

2. Yearly Report on Performances to be submitted by all the establishments in the previous year (…….)

(Previous Form no VII)

1) Name and address of the Establishment:-
2) Name of Licensee:-
3) License Number:-
4) No of Patients treated in indoor (1st January to 31st December of……..) :-
5) No of Patients treated at OPD (1st January to 31st December of……..) :-
6) No of Patients undergone investigations (1st January to 31st December of……..) :-
7) No of Patients operated(1st January to 31st December of……..) :-
8) Total charges received from the patients:
    a) Registration charges-
    b) Consultation charges
    c) …
    d) …
    e) ….

SCHEDULE VII
LICENSE FEES

[Refer Rule 32]

Part I: General

1.The clinical establishment shall submit the License Fees as specified in this schedule or any such License Fees as may be notified from time to time.

1.2. While computing the license fees, the type(s) of services offered by the clinical establishment should be considered and taken together.

Illustration. The license fee for a clinical establishment of Kolkata having X-Ray Lab (conventional) and a Ultrasonography lab should be Rs.5,000 plus Rs.5,000 that is altogether Rs.10,000.

Illustration 2. The license fee for a clinical establishment of Kolkata having 30 bedded inpatient facilities with a X-Ray Lab (conventional) should be Rs. 10,000 plus Rs. 5,000 that is altogether Rs.15,000.

1.3. While computing License fees, the total number of beds including beds of special care units and emergency observation beds should be considered.

Illustration 1. The license fee for a clinical establishment of Kolkata having 40 bedded inpatient facilities should be Rs.10,000 plus Rs.600 into 10 that is altogether Rs.16,000

Illustration 2. The license fee for a 30 bedded nursing home of Kolkata having 25 general beds and 5 ITU beds should be Rs. 10,000 plus Rs. 1,500

Part II. Specific

	Type of Establishment	**License Fee in Indian Rupees**		
		Metropolitan (1A)	Urban (1B)	Rural (1C)
1.	Outpatient based Service			
1A.	Solo clinic	5,000	2,000	1,000
1B.	Polyclinic	5,000 per specialty/ superspecialty	2,000 per specialty/ superspecialty	1,000 per specialty/ superspecialty
1C.	Dental Clinic/ Other Medical clinic with facilities for procedure	10,000	7,500	5,000
1D.	Physiotherapy Clinic	5,000	2,000	1,000
1E.	Occupational therapy Clinic	5,000	2,000	1,000
1F.	Wellness/Fitness centre/clinic	15,000	10,000	5,000
1G.	Counseling Centre	5,000	2,000	1,000
1H.	Any other OPD based Service centre without beds	10,000	7,500	5,000
1J.	Infertility Clinic, Dialysis Centre, MTP clinic, Any other Day care centre/ Any other OPD based Service centre with beds			
1L1	Up to 10 beds	7,000	5,000	2,500
1L2	More than 10 beds	600 per additional bed	400 per additional bed	250 per additional bed
6.	Inpatient based service: Maternity Home/ Nursing Home/Hospital/ Sanatorium/ Any other IPD based service centre			
6A.	Up to 30 beds	10,000	7,500	5,000
6B.	31beds and above	600 per additional bed	400 per additional bed	250 per additional bed
7.	Pathology laboratory service			
7A.	Small Laboratory	5,000	2,000	1,000

7B.	Medium Laboratory	10,000	7,500	5,000
7C.	Large Laboratory	20,000	10,00	7,500
7D.	Collection Centre	2,000	1,000	500
7E.	Genetic Laboratory	7,500	5,000	2,500
7F.	Any other Pathology laboratory	10,000	7,500	5,000
8.	Diagnostic Imaging service			
8A.	X-Ray lab (Conventional)	5,000	2,000	1,000
8B.	X-Ray lab (Digital)	7,500	5,000	2,500
8C.	Mamography lab	5,000	2,000	1,000
8D.	Bone Densitometry lab	5,000	2,000	1,000
8F.	Ultrasonography lab	5,000	2,000	1,000
8G.	Colour Doppler Imaging lab	5,000	2,000	1,000
8H.	CT Scan lab	5,000	3,000	1,500
8J.	Magnetic Resonance Imaging (MRI) lab	7,500	5,000	2,500
8K.	Positron Emission Tomography (PET) Scan lab	7,500	5,000	2,500
8L.	Electro-cardiography lab	2,000	1,000	500
8M.	Electro-encephalography lab	2,000	1,000	500
8N.	Electromyography lab	2,000	1,000	500
8P.	Other Clinical Physiology	2,000	1,000	500
8Q.	Any other Imaging lab	5,000	3,000	1,500
9.	Special Care unit (additional fees)			
9A.	Intensive Therapy unit	300 per bed	200 per bed	100 per bed
9B.	Intensive Coronary care Unit	300 per bed	200 per bed	100 per bed
9C.	Intensive Neonatal care Unit	300 per bed	200 per bed	100 per bed
9D.	Any other Special Care unit.	300 per bed	200 per bed	100 per bed
10.	Any other type not mentioned above	10,000	7,500	5,000