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PART I—Orders and Notifications by the Governor of West Bengal, the High Court, Government Treasury, etc.

Government of West Bengal
Department of Health and Family Welfare

The West Bengal Clinical Establishments (Registration, Regulation and Transparency) Rules, 2017

No. HF/O/GA/2603/HF/SPSRC/28/2017/Pt.V-A Dated: 21.08.2017

NOTIFICATION

In exercise of the power conferred by section 59 of the West Bengal Clinical Establishment (Registration, Regulation and Transparency) Act, 2017 (West Bengal Act IV of 2017), in supersession of all earlier rules on the subject, if any, the Governor is hereby pleased to make the following rules, namely:-

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CHAPTER I

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1. Short title and Commencement :

(1) These rules may be called the West Bengal Clinical Establishment (Registration, Regulation and Transparency), Rules, 2017.

(2) It extends to the whole of the State of West Bengal.

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, Regulation and Transparency) Act, 2017;

(2) "applicant" means a person who has made an application under rule 34;

(3) "appropriate receipt head" means the Head -"0210-01-800-other receipts-001-Collection from Miscellaneous service fees-14-Services fees" under the Act or GRIPS;

(4) "appropriate refund head" means the Head -"0210-01-800-other receipts-001-Collection from Miscellaneous service fees-20-Refund" under the Act;

(5) "allied-medical Professional" means a service provider as defined under rule 7;

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

(7) 'day care centre' means clinical establishment as defined under rule 12;

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

(9) "West Bengal Clinical Establishment Regulatory Commission", (hereinafter referred as the Commission), means a body constituted by the State Government as described in section 36 of the Act;.

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

(11) 'homoeopathy' means a system of Medicine as may be defined under the West Bengal Homeopathic System of Medicine Act, (West Bengal Act No XXXIII of 1963 or Act of similar kind;

(12) "informed consent" means consent given by a person for 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;

(13) "local authority" means (i) the Municipal Corporation, or Municipal Council of the concerned municipal area; (ii) the Notified Area Authority in notified area; (iii) the Gram Panchayet of the concerned rural area; (iv) any such authority as may be notified; or (v) Industrial Township Authority in industrial township area;

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

(15) "medical record" means any digital record, 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;

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

(17) "paramedical professional" means a service provider as defined under rule 7;

(18) "patient" means a service recipient who has been registered by the patient registration system of that clinical establishment and shall include any child born to a patient and is entitled to enjoy all the rights, responsibilities and obligation of being a patient;

(19) "polyclinic" means a medical clinic having more than one Registered Medical Practitioner either of the same specialty/ system of medicine or of different specialty/ system of medicine excluding dentistry;

(20) "primary consultant" means a registered Medical Practitioner as defined under rule 11;

(21) "qualified Nursing staff or paramedical or allied-medical staff" means any such professional who possesses a degree, diploma or certificate in respective course of at least two years duration, conferred by any University established by law or any other institution recognized by the Department in this behalf;

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

(23) "section" means a section of the Act unless mentioned otherwise;

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

(25) "solo clinic" means a medical clinic having only one Registered medical practitioner practicing any one of the recognized systems of medicine excluding dentistry;

(26) "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;

(27) "State Prescribing Authority for Medical Education Training and Research" means authority appointed under rule 26;

(28) "supervisory authority" means authority appointed under rule 36;

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

(30) "Unani" means a system of medicine as may be defined under the Paschim Banga Unani System of Medicine Act, 1979 (West Bengal Act XLV of 1979) or Act of similar kind;

(31) "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;

(32) "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 (West Bengal Act VI of 2010) or Act of similar kind.

(b) Words and expressions used and not defined in these rules, but defined in the Act, shall have the same meaning as respectively assigned to them in the Act.

CHAPTER II

3. Standards and License :

(1) Any person intending to commence, keep or carry on a clinical establishment (except a place used for or intended to be used for consultation and treatment by a registered medical practitioner but shall not include the set up utilized solely for the purpose of consultation and advice by the registered medical practitioner), shall have to obtain a valid license from the respective licensing authority after compliance with the terms and conditions mentioned under section 7 of the Act, and different provisions of rules applicable to such type of clinical establishment by submitting an application to the Licensing Authority as mentioned under rule 34.

(2) After considering all the relevant aspects mentioned in the application, with causing an inspection and enquiry, the licensing Authority, if satisfied, may approve and issue a new license or renewal in statutory CE Form VII mentioning the period of validity and other particulars within 90 (Ninety) days from the date of receipt of such application.

(3) No person (except a place used for or intended to be used for consultation and treatment by a registered medical practitioner but shall not include the set up utilized solely for the purpose of consultation and advice by the registered medical practitioner), shall keep or carry on any clinical activity 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) The clinical establishment offering Service facilities in more than one category classified as multi-purpose clinical establishment as mentioned in rule 33, need not apply for separate registration for each type of category but shall have to submit application under rule 34 clearly mentioning those service facilities to obtain a composite license against a composite fee.

(5) Any clinical establishment with existing valid license intending to change or bring out any expansion, modifications or additions or changes in name (ownership), service facilities, address (place of business) or any other particulars mentioned in the license, has to obtain a new license by submitting an application thereof along with the requisite fee and duplicate copy of the existing License.

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

(6) After considering all the relevant aspects of the desired modifications or additions or deletion or changes mentioned in the application under sub-rule (5), 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.

(7) Any clinical establishment with existing valid license intending 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, which does not require issuance of new license under sub-rule (5), 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 facility or any such changes as may be notified.

(8) In case of difficulty, the licensing authority with the prior approval of the State Registrar may relax any of those terms and conditions in exercising the power under section 8 of the Act while granting renewal of license for the first time under this rule to old establishments:

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.

Explanation: Old establishment means such establishment which have obtained license under the West Bengal Clinical Establishment Rules, 2003 to be governed by the provision mentioned under sub-section (4) of Section 59 of the Act.

4. Name of the Clinical Establishment :

(1) Under sub-section (1) of section 7 of the Act, [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 advertise thereof without the prior registration of that clinical establishment with such name under 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:-

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

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

(c) such name is not containing the word "RESEARCH" or any of its variation unless that clinical establishment has got prior approval under rule 26 and submitted evidence thereof along with the application;

(d) such name is not stating, suggesting, or implying a false or misleading claim;

(e) such name is not resembling the name of a healthcare establishment run by the Public sector agencies;

(f) such name is not an improper or undesirable name as determined by the licensing Authority; and

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

(3) If any such name(s) which are prohibited under sub-rule (2) is being used by any old clinical establishment, the licensee of such clinical establishment shall submit application in statutory Clinical Establishment Form-I to change such name(s) without any delay.

Provided that no application fee or license fee need to be submitted.

(4) The clinical establishment shall ensure that the name of the clinical establishment or part thereof is not confusing or misleading for anyone using that clinical establishment.

5. Accommodation Standard :

(1) Under clause (a) of sub-section (2) of section 7 of the Act, 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 and to ensure adequate reception and accommodation. 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 shall have the right to offer different standards of accommodation based upon the amenities attached to such accommodation.

Provided also that, the clinical establishment shall have the right to provide different standards of accommodation to accommodate such patient who needs such special therapy/care as mentioned under rule 13.

Provided also, that, the clinical establishment shall have the right to 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.

(2) The clinical establishment shall be located at a suitable place as specified in schedule I and 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 by the service-recipient residing nearby, may attend such house-call and provide service including collection of sample or specimen to such service-recipient confined there who is unable or unwilling to attend the clinical establishment for receiving such service which shall include collection of sample or specimen.

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.

(3) The clinical establishment shall take necessary precaution so guarding that the building or premises of clinical establishment is not being used for any purposes other than those it is registered with and the clinical establishment shall not allow the use of the building, premises or equipment by a person who is not an employee or staff of that establishment 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 Consultant or RMO

Explanation: "premises" means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance, vessels or aircraft.

(4) Any person intending to commence, keep or carry on a clinical establishment shall have to submit the following document(s) along with the application under rule 34, in relation to the ownership of the premises where that establishment is accommodated:

(a) if the person is granted rent free accommodation by the owner of the premises; the documentary proof in form of a current consent letter from the owner of the premises; or

(b) if the proprietor is a lessee; the documentary proof in form of (i) a copy of lease-deed, and (ii) current consent letter from the owner of the premises; or

(c) if the person is a tenant, the documentary proof in form of (i) copy of the current rent receipt, (ii) rent agreement and (iii) current consent letter issued by the owner of the premises; or

(d) any such documents as may be permitted by the licensing authority.

(5) The clinical establishment shall ensure that such establishment is accommodated in a building having approved plan duly certified by the local Authority concerned and if such plan is approved for residential purpose, it is converted accordingly with approval of that local Authority:

Provided that, under any circumstances, the premises of the clinical establishment should be separated from rooms or spaces for private uses or other commercial uses i.e. there should be no free access.

Provided further that the establishment shall be a composite unit i.e. there should be no public thoroughfare within the premises of the establishment.

(6) Any person intending to commence, keep or carry on a clinical establishment shall have to submit the following document(s) along with the application under rule 34, in relation to the building and premises where that establishment is accommodated:

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

(b) Copy of building completion certificate issued by the Appropriate Authority; and

(c) Sketch map showing detailed position and floor measurement of the different facilities; and

(d) any such documents as may be notified.

6. Manpower Norm :

(1) Under clause (b) of sub-section (2) of section 7 of the Act, the Clinical establishment shall provide such manpower which is reasonably adequate in number to render the services offered by that type of clinical establishment and to ensure that, the clinical establishment shall comply with the minimum number norms in respect of health service providers as specified in schedule II.

(2) 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 round the clock.

(3) 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 containing particulars like names, designation, present and permanent addresses, qualification(s), date of engagement etc. and tenure of engagement of all staff of the clinical establishment, or and such particulars as may be notified; and

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

Provided that, the Licensing Authority may consider any bio-metric or electronic attendance system if he/she is satisfied with such arrangement at the time of inspection or enquiry.

(4) (a) Notwithstanding anything contained in rule 16, no person, other than the person whose name and particulars is entered in the register under sub-rule (3) shall be allowed to provide healthcare services.

(b) Any consultant whose name has not been entered in sub-rule (3) may be allowed to manage patients in the clinic provided that the patient has been admitted under a consultant as per sub- rule (3).

(5) Subject to the provision of sub-rule (6), the clinical establishment may engage part-time staff depending upon the services offered by 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 her compliance of sub-rule (6), as the case may be, and shall submit a copy of the same along with the application.

(6) 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 2 (two); and

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

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

Provided that, the State Government may relax such norms in exercising the power under section 8 of the Act.

(7) 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 she is in the premises.

(8) No clinical establishment shall engage or empanel any person already engaged by the Government of West Bengal, or allow such person to render any healthcare service who is yet to obtain an express permission in the form of a 'No objection certificate' from the Government.

Explanation: Such 'No objection certificate' shall be issued in such manner, and in such form containing such particulars issued by the Director of Health Services or Director of Medical Education, as the case may be, or by any other subordinate officer authorized by Director of Health Services / Director of Medical Education.

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

(9) The clinical establishment shall submit the copy of such No Objection Certificate (NOC) along with the application and shall display the detail information regarding Name, government designation, hours of availability at that clinical establishment of such person(s) or any such information as may be notified as a part of mandatory display under rule 22 and the Government may publish such information in the departmental website or any such public domain as may be notified.

7. Manpower Standard :

(1) Under clause (b) of sub-section (2) of section 7 of the Act, the clinical establishment shall engage such manpower who are qualified enough to render the services offered by that 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.

(2) The clinical establishment shall permit or allow the service by any service provider only after being reasonably satisfied about the qualification of such service provider and employing an unqualified or under-qualified person shall be considered as major deficiency under section 29 of the Act.

(3) The service providers can be classified into the following categories: (a) Medical professional staff; (b) Nursing professional staff; (c) Pharmacist; (d) Allied-Medical /Paramedical professional staff; (e) Healthcare Assistant/attendant; (f) Administrative-Managerial staff; (g) Non-medical technical staff; (h) Other staff as specified in schedule II.

Explanation 1: 'Allied-medical professional' means any person having adequate professional qualification who can practice his profession to assist a registered medical practitioner in practice, or teaching or research of medicine and who can also administer appropriate non-pharmacological therapy and shall include professionals like physiotherapists, occupational therapist, clinical psychologist, Nutritionist etc. or any such professional as may be notified but shall not include Pharmacist, Nurses, or para-medical professional.

Explanation 2: 'paramedical professional' means any person having adequate professional qualification who can practice his profession to assist a registered medical practitioner in practice, or teaching or research of medicine but who cannot administer any pharmacological or non-pharmacological therapy and shall include professionals like such Medical Technician/

Technologists or any such professional as may be notified but shall not include Pharmacist, Nurses, or allied-medical professional.

Illustration: non-pharmacological therapy shall include any recognized form of therapy like physiotherapy, occupational therapy, counseling, dietary advice etc. but shall not include therapies which can only be administered by a registered medical practitioner like acupuncture, radiotherapy etc.

Explanation 3: Healthcare Assistant/attendant: means such appropriately trained and qualified personnel who has successfully undergone Education and training rendered by West Bengal Council for vocational Education training or similar institution and who can assist the (a) Medical professional staff; (b) Nursing professional staff; (c) Pharmacist; or (d) Allied-Medical /Paramedical professional staff in rendering healthcare services and shall include Assistant/attendant like such General Duty Attendant, Bedside Assistant, Dresser, Midwifery Assistant, Pharmacy Assistant or any such Healthcare Assistant/attendant as may be notified.

(4) 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; and

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

Provided that in case of any doubt regarding validity or appropriateness of registration or qualification, the Licensing Authority shall seek clarification from the State Prescribing Authority for Medical Education Training and Research constituted under rule 26.

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/ Allied-medical professional when applicable.

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

(5) 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.

(6) The clinical establishment shall retain copies of such certificates of registration and certificate of qualification under sub-rule (4) and copies of such offer letter and acceptance letter under sub-rule (5) as long as necessary to produce such documents at the time of inspection or enquiry under rule 36 or on demand by the authority and shall submit such copies along with the application:

Provided that any act of retention of originals of such certificates by the clinical establishment against the consent of any service-provider shall be a contravention of this Act and rules;

Provided further that the clinical establishment shall produce the original of such certificates on demand without delay to the Supervisory authority.

(7) Besides providing adequately qualified staff, it shall be the responsibility of the clinical establishment to ensure that all the staff including visiting consultant is well oriented with the working arrangement, regulation or SOP of that clinical establishment.

Explanation: 'working arrangement' include any such arrangements provided by the establishment in order to comply with the terms and conditions of licensing and registration and any such other additional arrangements provided by the establishment to render adequate healthcare and non-health care related services, arrangement for sanitation, hygiene, safety and security etc.

8. Standard Operating Procedures and Practices :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, in order to ensure the quality of service, the clinical establishment shall exercise reasonable care and take all necessary measures including measures to comply with the standard operating procedures and practices related to all health care operations as mentioned in schedule V.

Explanation: 'Health Care Operations' mean Institutional activities that is necessary to maintain and monitor the operations of the institution. Examples include but are not limited to: conducting quality assessment and improvement activities; developing clinical guidelines; case management; reviewing the competence or qualifications of health care professionals; education and training of students, trainees and practitioners; fraud and abuse programs; business planning and management; and customer service. Research is not considered part of health care operations.

(2) The clinical establishment shall ensure that no service provider or any person associated with the clinical establishment shall -

(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 -

(a) practice fee-splitting; or

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

(c) refer the patient to a Visiting Consultant of a different speciality when it is not medically necessary; or

(d) keep a patient in the clinical establishment as an in-patient when it is not medically necessary or longer than is medically necessary; or

(e) carry out or undertake to carry out any form of investigation and healthcare intervention which is not medically necessary; or

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

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

(h) insist upon procurement or purchase of particular brand of drug, medical device or medical supplies due to any reasons other than scientific; or

(i) 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; or

(j) engage in any such other unethical or unfair trade practice as may be notified.

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) Any act of violation mentioned under sub-rule (2) and (3) 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 of the Act and such clinical establishment shall be liable of contravention.

(5) The clinical establishment shall have the right to make its own set of regulations or standard operating procedures concerning the organization and operation of that establishment subject to the following terms and conditions:-

(a) those regulation or standard operating procedures are not contrary to the provision of any law of the land; and

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

(c) any such 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 under rule 34.

Explanation: "Regulation or standard operating procedures (SOP)' contains set of instruction for patients and patient party as well as for the service providers.

(6) 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. It should be made mandatory to provide Bed Head Ticket to the West Bengal Medical Council / Competent Authority in the event of a complaint concerning treatment lodged with the Council / Competent Authority.

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.

(7) 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, Regulation and Transparency) Act, 2017 (West Bengal Act IV of 2017) and the rules made there under as amended from time to time.

(8) 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 or standard operating procedures developed or adopted by them.

(9) 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.

(10) The clinical establishment shall actively take part in such External Quality Programme as may be formulated and set-up by the Department, in which the performance of a clinical establishment is assessed concurrently and consecutively by an external Quality Assurance Committee for maintaining high standards of performance and of improving standards where necessary.

(11) The clinical establishment shall organize mandatory capacity building programmes for the service providers of that clinical establishment regarding (a) first Aid & Cardio Pulmonary Resuscitation Technique; (b) Fire-fighting drills and mass evacuation techniques; (c) mass casualty management protocols (d) any other training programmes as may be notified.

9. Dignity, Privacy and Confidentiality :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, the clinical establishment shall ensure the rights of patients to dignity, privacy and confidentiality.

(2) The patient shall have the right that she may be subjected to any healthcare related intervention in such a manner that proper respect is shown for her 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.

(3) The patient 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 patient consents or requests otherwise; and for women patient, that intervention may be carried out only in the presence of a female service provider.

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

(4) The clinical establishment shall ensure that the patient is received, accommodated or kept in such a manner so as to maintain her dignity and privacy.

(5) 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 her under the following terms and conditions, subject to the consent obtained from the patient or patient party and authorization of the primary Consultant

(a) if it is necessary to prevent serious bodily harm to her or to another person; and

(b) if it gives her greater freedom or greater enjoyment of life; and

(c) if such other terms and conditions as may be notified for restraining a patient or for using a monitoring device on her are met.

Explanation 1: 'restrain' means, with respect to a person, to place the person under control by the minimal use of such force, mechanical means or chemicals as is reasonable having regard to the person's physical and mental condition, and "restraint" has a corresponding meaning.

Explanation 2: For the purpose of this rule, 'monitoring devices' are devices that are used to prevent serious bodily harm to a patient or to others, but not monitoring devices that are used for other diagnostic or treatment purposes.

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

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

(b) when the public health and safety so demand.

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

(8) 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 near relative or legal guardian.

(9) The clinical establishment shall maintain such privacy standard to restrict the use and disclosure of protected health information as may be notified and shall ensure that:

(a) no disclosure of any protected health information by any service provider is made to a third party who has no concern with the care and welfare of the patient without patient's written consent; and

(b) no person other than a service provider involved in the treatment and care of a patient or engaged in documentation is having access to any protected health information.

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

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

(b) in the interest of justice or upon the order of 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 or India.

Explanation: 'Protected health information' means any individually identifiable information whether oral or recorded in any form or medium that is created, or received by a health care provider, health plan or health care provider and relates to past, present, or future physical or mental health conditions of an individual; the provision of health care to the individual; or past, present, or future payment for health care to an individual.

(10) Notwithstanding anything contained in sub-rule (9), 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 as per standard protocol.

(11) The patient, 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.

10. Counseling and informed Consent :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, the clinical establishment shall ensure the right of patient mentioned in sub-rule (2).

(2) 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 or procedure, wherein the person intends to perform such procedure or administer such intervention shall provide the following information as a part of such counselling: (a) her 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.

(3) No patient shall be subjected to any healthcare intervention without her 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 such intervention or procedure is withheld or postponed; or

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

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

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

(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; or

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

(4) Informed consent shall ordinarily be obtained from a patient concerned if he/she is of legal age, conscious and of sound mind in a consent form printed or written in a language understandable by all the signatories bearing all relevant particulars like clinical establishment's name and License number and any such particulars as may be notified.

(5) If the patient is incapable of giving consent because he/she 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.

(6) Proper Counselling shall precede the signing of the consent form particularly in such cases that may involve surgical healthcare intervention that are difficult to reverse or involving removal of organs, sterilization or amputation of limbs.

11. Professional care :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, all kinds of clinical establishment including 'collection centre' shall provide for a 'patient registration system' to register all the service-recipient as a patient of that clinical establishment and generate and maintain a Service/OPD register thereof containing such particulars as may be notified as a part of mandatory record keeping.

(2) No clinical establishment shall provide or offer to provide any service to any service-recipient unless such recipient is registered under the registration system mentioned in sub-rule (1) and any such act shall be considered as a major deficiency under section 29 of the Act.

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 service recipient may be provided for and administered with the Emergency medical treatment without waiting for registration.

(3) No clinical establishment shall offer any such healthcare service facilities or keep or carry on such number of beds unless mentioned in the license granted which shall attract penalty under section 27 of the Act.

(4) The clinical establishment shall display the relevant information regarding types and availability of all healthcare and non-healthcare service facilities along with components and sub-components of services offered by that clinical establishment as a part of mandatory display under rule 22.

(5) As a part of mandatory reporting under rule 23, the clinical establishment shall generate and maintain such a performance report related to healthcare services rendered by it including report related to procedures like MTP under rule 13 in such format containing such particular and submit such reports at such intervals to the licensing authority or any such authority as may be notified.

(6) No clinical establishment shall close, discontinue or suspend or cause to close, discontinue or suspend any or all of the healthcare service facilities mentioned in sub-rule (4) for a period of more than one month without submitting a prior intimation report of such closure, discontinuation or suspension to the licensing authority.

(7) Any patient receiving health care services at a clinical establishment having out-patient or in-patient facility shall be registered under the professional care of a particular registered medical practitioner for the entire course of her treatment and care, and such registered medical practitioner shall be recorded as 'Primary Consultant' of that patient.

(8) It shall be the duty and responsibility of the Primary Consultant to examine the patient; make a provisional diagnosis; and draw up a written treatment plan, which is medically necessary, record the salient clinical findings, result of other evaluation or assessment and advice in the case-sheet containing such particulars as may be notified as a part of mandatory record keeping.

Explanation: '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.

(9) The treatment plan under sub-rule (8) shall include the following relevant information like (a) Details of investigation service; (b) Details of medical care advice including assessment & advice from Visiting Consultant; (c) Details of Nursing care advice; (d) Details of Rehabilitative care advice; (e) Detail of nutritional or dietary care advice or any such information as may be notified.

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

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

Explanation: 'encounter' means an instance of direct provider to patient interaction, regardless of the setting, between a patient and a provider for diagnosing, evaluating or treating the patient's condition, exercising independent judgment. Encounters occur in many different settings -- ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine).

(12) The patient or party shall have the right to select a Primary Consultant before commencement of care and treatment and to ensure that, the clinical establishment shall display the detail information regarding the name, qualification and hours of availability of medical staff as a part of mandatory display under rule 22.

(13) The clinical establishment shall ensure that all the care provided by the healthcare providers are according to the latest guidelines of Evidence-based medicine.

Explanation: 'Evidence-based medicine' is the integration of best research evidence with clinical expertise to aid in the diagnosis and management of patients.

12. Admission and Inpatient Care :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, the clinical establishment having in-patient facility shall ensure that any patient shall be allowed to get admitted and kept as an in-patient by that establishment only if it is medically necessary and only after being properly registered as an in-patient under a Primary Consultant:

Provided, that, the clinical establishment may deny to admit or to keep the patient if it is satisfied that (provided that the patient is not in a critical condition) -

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

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

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

(e) the patient or patient party is unwilling or unable to accept or follow the regulation or Standard Operating Procedure of that clinical establishment as mentioned under rule 8; or

(f) the patient or patient party is unwilling or unable to accept or fulfill the obligation including financial obligation as mentioned under rule 27:

(2) To render reasonably adequate in-patient care, every clinical establishment having in-patient facilities including 'Day care centre' shall comply with such standards appropriate for that type of clinical establishment as mentioned in sub-rule (3) to (12) and mentioned in different schedules.

Explanation: 'day care centre' means clinical establishment having in-patient facility 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 without any overnight stay and shall include infertility clinic; dialysis centre; Medical Termination of Pregnancy (MTP) Clinic; and any such other Day care centre as may be notified.

(3) The 'Day care centre' shall provide for such additional emergency arrangements of accommodation and service-providers in order to take care of the patients who cannot be discharged or transferred on the same date and have to stay overnight.

(4) 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 a part of mandatory display under rule 22:

Provided that such restriction may be relaxed with prior approval from the Licensing Authority in the interest of public service.

(5) As a part of mandatory record keeping, the clinical establishment shall generate and maintain an admission/In-patient register containing relevant particulars like unique identification number of every patient accommodated as in-patient and such other particulars as may be notified and shall generate and maintain a separate bed-head ticket or case-sheet for recording his care and treatment plan particulars in such format as may be notified.

(6) The clinical establishment shall ensure that every patient accommodated as in-patient or any patient accommodated in the observation beds of the emergency department or anywhere else for any length of time or any newborn whose birth has taken place in the clinical establishment is being registered in the admission register as mentioned under sub-rule (5) and be provided with a separate bed-head ticket or case-sheet.

(7) 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 clinical establishment shall ensure that the patient received or accommodated shall be attended without any undue delay by either a resident medical officer or a consultant for providing adequate professional care and to ensure their round-the-clock availability, the clinical establishment with inpatient facilities shall engage such numbers of Resident Medical Officer (RMO) as per requirement as specified in the schedule II and shall generate and maintain a duty-roster of all such Resident Medical Officer's.

(9) It shall be the duty and responsibility of the registered medical practitioner designated as Resident Medical Officer or RMO to be available within the premises of that clinical establishment at all time during duty hours; and to attend the call from the patient or on-duty nursing personnel without delay 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.

(10) After attending the emergency call of the indoor patients and doing thorough assessment, RMO shall either administer treatment as per the treatment plan or shall consult the Primary Consultant of that patient or may call for the attendance of that Consultant.

(11) The Primary Consultant shall give daily rounds and do periodical assessment of the patients admitted under him/her and shall record the salient point of his/her assessment and advice in the bed-head ticket or case-sheet under sub-rule (5).

(12) The Primary Consultant shall make suitable arrangement with the clinical establishment or the RMO so that his/her service may be called for without delay by the clinical establishment or the RMO if needed.

(13) In case of his/her non-availability for a considerable length of time, the Primary Consultant shall make suitable arrangement with the clinical establishment, the RMO or with other consultants to maintain the continuity of care after apprising the patient and patient party accordingly.

13. Procedure, Medication and Critical care :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, the clinical establishment shall ensure that the diagnostic procedure, medication, diet or treatment is being provided only on presentation of duly authenticated written requisition 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 as may be notified.

(2) 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 arrangement or affiliation as a part of mandatory display under rule 22 and shall submit a copy of such certificate along with the application mentioned in rule 34.

Explanation: "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.

(3) The clinical establishment shall ensure that all the pathology or diagnostic imaging lab reports are prepared without any errors and containing relevant particulars like measurement procedure, normal values etc. and any such particulars as may be notified.

(4) 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.

Explanation 2: 'minor surgery' means such surgical cases other than major surgery.

(5) Before performing any specific procedure which requires permission in the form of No Objection Certificate (NOC)/License/Approval/Permission under different Acts like 'The Medical Termination of Pregnancy Act', 'The Transplantation of Human Organs Act', 'The PC-PNDT Act' or any such Act as may be notified, the clinical establishment shall obtain such prior permission and submit a copy of such No Objection Certificate (NOC)/License/Approval to the licensing Authority for entering relevant particulars into the register.

(6) The clinical establishment shall display copy of such No Objection Certificate (NOC /License/Approval/Permission as a part of mandatory display under rule 22 and also generate and maintain registers, records related to such performance of such procedure as a part of mandatory record keeping under rule 18.

(7) The clinical establishment shall ensure that-

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

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

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

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

(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 maintaining such appropriate storage conditions as recommended by the manufacturer.

(8) No clinical establishment other than a maternity home or nursing home shall offer different special care/therapy/ treatment services in tune with the advance of modern medicine provided that the State Government shall have the power to relax this condition.

(9) Such special care/therapy units as mentioned in sub-rule (8) shall be classified into following mutually exclusive categories: (i) Critical 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 as may be notified. The consent of the patient party will mandatorily have to be obtained before transferring a patient to such a unit and the patient party should be explained in writing regarding the condition of the patient and the financial implications.

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 Critical Care Units (CCU) 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.

Explanation 4: Dialysis centre shall not be considered as a special care/therapy unit for the purpose of this rule.

14. Nursing and Personal Care :

(1) Under clause (c) of sub-section (2) of section 7 of the Act, the clinical establishment shall ensure that all patients received or accommodated there, particularly patients in confinement is receiving adequate nursing care rendered by a nursing professional

(2) While on duty, the nursing staff shall periodically do the assessment of the patient and administer the nursing care as per treatment plan mentioned under rule 11 and enquire about the state of health and he/she shall call for the service of RMO if necessary

(3) As per advice of the Primary Consultant or RMO, the on-duty nursing staff shall maintain a nursing assessment and care sheet containing particulars like patient's biographical details, the diagnosis, the nursing needs and problems identified for the care plan; care/intervention administered; time and date of summoning up RMO etc. or any such particulars as may be notified.

(4) As per advise of the Primary Consultant or RMO, the on-duty nursing staff shall maintain a 'fluid balance chart' and a 'Vital signs chart' containing particulars like periodical recording of temperature, pulse, respiration blood pressure, Glasgow Coma Scale, etc. or any such particulars as may be notified

(5) As per advice of the Primary Consultant or RMO, the on-duty nursing staff shall maintain a medication chart containing particulars like the patient's biographical information, weight, history of allergies and previous adverse drug reactions, medicine administered at periodic interval.

(6) The clinical establishment shall ensure that all patients received or accommodated there, particularly patients in confinement is receiving adequate personal care rendered by a nursing professional or a non-medical Healthcare Assistant or bedside attendant:

Provided that patient shall have the right to engage a suitable family member to provide such personal care subject to prior approval from the Primary Consultant.

Explanation 1: 'confinement' is a state of being placed in a clinical establishment with some restriction of movement either due to physical and mental incapacitation or the restriction being imposed to prevent further incapacitation (Communicable Disease)

Explanation 2: '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 her skill, competency and experience.

(7) The clinical establishment shall ensure that the patient received or accommodated shall be attended without any undue delay by Nursing staff and non-medical Healthcare Assistant or bedside attendant for providing adequate nursing care or personal care and to ensure their round-the-clock availability, the clinical establishment with inpatient facilities shall engage such numbers of Nursing staff and non-medical Healthcare Assistant or bedside attendant as per requirement as specified in the schedule II and shall generate and maintain a duty-roster of all such staff.

15. Discharge, Death and Terminal care :

(1) The clinical establishment shall ensure that any patient admitted in that establishment shall ordinarily be discharged by the consultant or RMO as and when further stay is not medically necessary and on issuance of a Discharge Certificate containing such particulars as may be notified:

Provided that the patient may be discharged regardless of her physical condition on a request made by him or the patient party and 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 her Primary Consultant of the medical consequences of her decision; and

(b) before such discharge, the patient releases those involved in the treatment and care from any obligation relative to the consequences of the 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; and

(c) such discharge will not prejudice public health and safety:

Provided further that the patient may be discharged so, if he/she fails to comply the advice given by the Primary Consultant.

(2) The patient or patient party shall have the right to be informed by the Primary Consultant or RMO of his/her 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.

(3) 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.

(4) 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 thereof:

Provided that the clinical establishment is not compelled to issue a death certificate in case of 'brought-dead' patient.

(5) As a part of mandatory record keeping, the clinical establishment shall generate and maintain a death register containing relevant particulars like unique identification number of every patient cause of death and such other particulars in such manner as may be notified.

(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 forthwith subject to observation of all the legal formalities. The clinical establishment should also abide by the conditions laid in section 7 sub-section(3) (k).

(7) The clinical establishment shall provide terminal care to the patients suffering from terminal illness which includes an array of services offered by team of doctors, nurses, therapists, social workers, and volunteers which provide active total care directed at maintaining or improving the comfort of a person suffering from terminal illness, including the management of pain and physical symptoms, and the provision of spiritual, psychological and emotional support for the patient and his/her family or any such care as may be notified.

Explanation 1. Terminal Illness is an illness or condition resulting in death within the foreseeable future

Explanation 2. Terminal Phase is the stage of terminal illness when there is no real prospect of recovery or remission of symptoms on either a permanent or temporary basis

(8) The patient shall have a right to execute an 'Advance Directive' on consultation with the primary consultant and patient party which includes, but is not limited to, a health care proxy or a living will in such a manner as may be notified and such Advance Directive directs health care providers to administer terminal care when the person executing such directive reaches the terminal phase of her terminal illness as may be notified.

Provided that (a) patient is informed of the medical consequences of his/her choice; (b) patient releases those involved in his/her care from any obligation relative to the consequences of her decision; (c) patient's decision will not prejudice public health and safety.

Explanation. Advance Directive is a document with written instructions made by a person before he/she reaches the terminal phase of a terminal illness or a persistent vegetative state and incapable of making decisions about medical treatment when the question of administering the treatment arises.

(9) The clinical establishment shall discharge patients maintaining the medico legal formalities.

16. Referral and Transfer :

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

Provided that the Primary Consultant may or may not agree to change or modify his/her 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 Consultant shall explain her reason for non-agreement, if any, if she feels that such consultation is not medically necessary for the treatment plan.

(3) If it is medically necessary, the clinical establishment shall have the right to permit or acquire the consultation service including telemedicine to be provided by a Visiting Consultant who is not an employee or empanelled, subject to following terms and conditions:

(a) request for such service is being made either by the Primary Consultant or by the patient / patient party in writing; and

(b) such Visiting Consultant is qualified enough to render such service; and

(c) the name and particulars of such Visiting Consultant is entered in the staff register under rule 6 before rendering service; and

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

(4) If it is medically necessary, the Primary Consultant or the RMO or any Registered Medical Practitioner may refer the patient to affect 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

(c) 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 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 should provide 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 the referral register as mentioned in sub-rule(6).

(6) The clinical establishment shall generate and maintain a referral register as a part of mandatory record keeping containing particulars like Serial Number; name and registration number of patient; name, address and signature of the patient party to whom the discharge/transfer certificate along with the custody of patient is handed over, her relation with the patient; date and time of referral etc. and any such particulars as may be notified.

(7) The clinical establishment having 100 (hundred) or more beds, shall provide and maintain one ambulance van or any such suitable conveyances for every 100 beds or part thereof with such sufficient attendants and other such requisites to transfer patients as may be notified by the Government from time to time.

(8) The clinical establishment shall refer patients maintaining the medico legal formalities

17. Equipment, Drugs and Medical Supplies Standards :

(1) The clinical establishment shall provide such equipment, machineries, medical devices, or any other medical supplies which are of acceptable standard to render the services offered by that type of clinical establishment and to ensure such standard the clinical establishment shall comply with the minimum standards of equipment, machineries, medical devices, or medical supplies as specified in schedule III.

(2) The clinical establishment shall permit or allow the use of equipment, machineries, medical devices, or any other medical supplies only after being reasonably satisfied about the quality of such medical supplies and the use of unsafe or sub-standard equipment machineries, medical devices or medical supplies shall be treated as a major deficiency under section 29 of the Act.

(3) All the medical supplies necessary for the patient accommodated in a clinical establishment shall ordinarily be supplied from the stock of that clinical establishment at a reasonable cost not exceeding Maximum Retail Price (MRP) and the cost of such medical supplies shall be recovered from the patient only after presentation of a claim in form of an itemized bill issued by that clinical establishment:

Provided that, in exceptional cases of non-availability of such supplies, the patient party may be asked to procure such medical supplies by the clinical establishment upon receiving such instruction from the clinical establishment along with the prescription from the Primary Consultant or Resident Medical Officer (RMO). The clinical establishments shall also try to abide by the conditions laid down in section 7 of sub-section 3 (r) of the Act.

(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 relevant 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.

18. Mandatory record keeping :

(1) 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 in order to ensure proper patient care, and legal formalities including medico-legal formalities. **The clinical establishments shall also abide by the conditions laid down in section 7 of sub-section 3 (n) of the Act.**

(2) 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 West Bengal 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; and

(c) the records, registers and documents are being updated and duly authenticated by an accountable person periodically at least at monthly interval.

(3) Unless mentioned otherwise, the clinical establishment shall generate and maintain all the mandatory registers and records mentioned under the 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 in any technologically appropriate medium if he/she is satisfied with such manner at the time of inspection or enquiry.

Explanation 1. Authentication of registers and records may be done by affixing a written signature, or a digital signature with identifiable initials or computer key along with date and time.

Explanation 2. "electronic form' means such term as may be defined under section 2(1) (r) of the Information Technology Act, 2000 [Act 21 of 2000].

19. User charge Standards :

(1) The clinical establishment shall have a right to impose different rates of user charges in consideration of the provision of different kind of services to be rendered by it subject to declaration of a rate-chart of user-charges describing item-wise charges for all services along with concession, if any, which shall be published in the Information brochure and shall be displayed as a part of mandatory display under rule 22:

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

Explanation: user charges are charges for service(s) rendered by the clinical establishment including diet-charges which is the maximum payable amount for that service and may include 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.

(2) Subject to the provisions of the rule 20, the clinical establishment shall have the right to 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, 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 further, 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.

Provided also, that, the clinical establishment shall not request, solicit or demand any deposit or any other form of advance payment as a prerequisite for providing such Emergency medical treatment as mentioned under rule 25 and any act of such request, solicitation or demand shall be treated as a major deficiency under section 29 of the Act. However **the clinical establishments shall also abide by the conditions laid down in section 7 of sub-section 3 (v) of the Act.**

Explanation 1: Proper receipt means a receipt bear unique number and the name of the clinical establishment along with the License number showing the exact amount paid against the bill.

Explanation 2. The term "collect" includes demand, charge or accept or try to demand, charge or accept any consideration in the form of cash, kind or service.

(3) Before collecting the user-charges, the clinical establishment shall have the obligation 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.

(4) Beside declaring the rates for separate item wise services under sub-rule (1), the clinical establishment shall have the right 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 her treatment and care:

Provided that, while offering any such package rate, the clinical establishment shall have the obligation to:

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

(b) clearly 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 therapeutic procedure to a patient

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

(5) The clinical establishment shall ensure that prior to the initiation of care or treatment, the patient and party have been informed and explained without any ambiguity about-

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

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

(c) the estimated expenditure due to medical supplies likely to be consumed for the patient under rule 17; and

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

(e) any concession or free treatment facilities available.

(6) The Commission shall be empowered to issue Regulations for the clinical establishments to provide proper estimates to service recipients or their representatives for treatments not covered under package rates and the final bill shall not exceed certain percentage of estimate provided

(7) The patient or party shall have the right-

(a) to obtain a written statement of such estimate under sub-rule (5) on demand at any point of time without any delay; and

(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; and

(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.

(8) 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 available to the supervisory authority for inspection, and to the patient party on demand.

The clinical establishments shall abide by the conditions laid down in section 7 of sub-section 3 (o, p and q) of the Act.

(9) Proper books of account including cashbook shall be generated and maintained by the clinical establishment which shall be available to the supervisory authority for inspection.

20. Free Treatment and concession :

(1) Under clause (g) of sub-section (2) of section 7 of the Act,-

(a) the clinical establishment shall have the right to provide for such concession or free treatment facilities to any such deserving candidate as it deems appropriate under any 'corporate social responsibility' **(The clinical establishments shall abide by the conditions laid down in section 7 of sub-section 3 (s) of the Act.)** scheme or any such scheme;

(b) The clinical establishments which have received land or other facilities from the Government during initiation and in course of continuance of their projects shall be responsible to provide free treatment to 20% of the Outdoor Patient Department (OPD) patients and 10% of the Indoor Patient Department (IPD) patients, calculated by the numbers of patients and the amount involved whichever is higher, who belong to the economically weaker sections, the detailed modalities in this regard may be determined by the Commission in due course of time.

(c) Over and above these schemes, 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 candidate.

Explanation 1: 'privilege' shall include but not limited to (a) full or partial exemption of any tax, duty or fees levied by the Government, or any local body or any such Authority; (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, government or local body or any such Authority.

Explanation 3: 'Deserving candidate' shall include Indigent person or any other deserving candidate as may be specified in the agreement.

Explanation 4: If not otherwise mentioned specifically in the agreement, such indigent person shall be identified by production of Below Poverty Line (BPL) card, BPL ration card or any 'Indigent Certificate' issued by any such authority as may be notified.

(d) "The Commission shall be empowered to issue Regulations for the clinical establishments to provide proper estimates to service recipients or their representatives for treatments not covered under package rates and the final bill shall not exceed certain percentage of estimate provided as may be fixed by the Commission through such regulations".

(2) The clinical establishment shall display and publish the mechanism to avail such concession or free treatment facilities in the mandatory display and information brochure under rule 22 for the benefit of all service-recipients.

(3) 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 charges for registration, consultation charges, Intervention or procedural changes, bed charges, diet charges; investigation charges, charges for drugs or medical supplies, free screening or medical checkup; reservation of certain percentage of beds or any such benefits for such patient.

(4) Depending upon the terms and conditions of the agreement the deserving candidate wanting to avail such free treatment and concession may directly approach the clinical establishment or may have to approach the agreed party which in turn will refer such deserving candidate to the clinical establishment and it shall be the duty and obligation of the clinical establishment to honor such referral.

(5) The clinical establishment shall generate and maintain such records and a register of those patients and shall submit a quarterly report thereof in such form containing such particulars in such manner as may be notified to the Licensing Authority as a part of mandatory reporting under rule 23.

(6) In the interest of public service, the licensing authority shall have the power to supervise and monitor the availability and performance of such concession or free treatment facilities mentioned in the agreement.

CHAPTER III

Responsibilities, Obligation and Rights

21. Sanitation, Hygiene, Safety and Security :

(1) The clinical establishment shall exercise reasonable care and take all necessary measures including disinfection, sterilization, infection control measures as specified in schedule IV or any such measures as may be notified in order to ensure adequate sanitary and hygienic condition.

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

Explanation. "certificate of enlistment": means a certificate of enlistment by whatsoever name called issued by the authority of the local self government like Municipal Corporation, Municipality, Panchayat, Notified Area Authority, Industrial Township Authority, as the case may be.

(3) In order to ensure the safety and security, the clinical establishment shall either obtain the authorization/license / No Objection Certificate under the West Bengal Fire and Emergency Service Act, 1950 and shall submit a copy of such authorization/license / No Objection Certificate along with the application for new clinical establishment license/renewal thereof or shall submit a self-declaration in the form of an affidavit as a part of statuary Clinical Establishment Form III along with the application that she shall abide by the provisions of such Act.

(4) In order to ensure the sanitation and hygiene, the clinical establishment shall either obtain the authorization/license / No Objection Certificate from Pollution Control Board under the Bio-Medical Waste (Management and handling) Rules, 1998 and shall submit a copy of such along with the application for new clinical establishment license/renewal thereof or shall submit a copy of application already submitted to obtain such authorization/license / No Objection Certificate under such rules.

(5) In order to ensure the safety and security, the clinical establishment shall obtain the authorization/license / No Objection Certificate (NOC) under the Atomic Energy Act, 1962 (33 of 1962) and the Atomic Energy (Radiation Protection) Rules, 2004, if applicable and shall submit a copy of such authorization/license / No Objection Certificate along with the application for new clinical establishment license/renewal thereof.

(6) In order to ensure the sanitation, hygiene, safety and security, the clinical establishment shall either obtain the authorization/license / No Objection Certificate under any such other relevant Acts or rules as may be notified and shall submit a copy of such authorization/license / No Objection Certificate along with the application for new clinical establishment license/renewal thereof or shall submit a self-declaration in the form of an affidavit as a part of statuary Clinical Establishment Form III along with the application that she shall abide by the provisions of such Acts/Rules as the case may be.

(7) The clinical establishment shall generate and maintain a register called 'bio-medical waste disposal register' in such a manner as may be notified.

(8) 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.

(9) The clinical establishment, as soon as it comes to its notice that any person, who has been received or accommodated in that establishment, is suffering from or has been suffering 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 (e) any such scientific measures as may be notified

Explanation 2: "Infectious disease" means a laboratory confirmed or clinically manifested 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.

(10) 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.

(11) 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.

(12) 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 Central Public Works Department/ Ministry of Social Welfare, Government of India.

(13) Notwithstanding anything contained in rule 15, the patient's personal belongings including corpse shall remain in the safe custody of the clinical establishment in an appropriate manner unless he/she is 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 of the same or try to do so in any manner without the consent of the patient or patient party;

Provided further, that, no clinical establishment 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 her financial obligations.

Explanation: Personal belongings shall include her specimen, sample, body, anatomical body parts, organs, tissues, X-ray film, USG film and such other images, photographs, etc.

(14) In order to maintain a conducive atmosphere and a safe and secure environment in the premises for all persons present there particularly the patient in confinement, the clinical establishment shall exercise reasonable care and take all necessary measures including 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.

Explanation 1. "Patient abuse" means the willful infliction of physical or mental injury of a patient or unreasonable confinement, intimidation, or punishment that results in pain, physical or mental harm, or mental anguish of a patient.

Explanation 2. "Misappropriation of patient property" means exploitation, deliberate misplacement, or wrongful use or taking of a patient's property, whether temporary or permanent, without authorization by the patient or the patient party.

(15) In order to ensure such atmosphere and environment under sub-rule (11), 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 or SOP thereof:

Provided that, the patient has the right to communicate with the patient party and to receive visitors subject to such reasonable restriction.

22. 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 license(s).

(2) In such display boards under sub-rule (1), the clinical establishment shall make available such appropriate, adequate and comprehensive information as mentioned below:-

(a) the system(s) of Medicine practiced along with specialty, if any;

(b) the detail information regarding Name, Government designation, hours of availability part-time of the Government staff, if any, under rule 6;

(c) the types and availability of service facilities offered under rule 11;

(d) the detail information name, qualification and hours of availability of medical staff under rule 11;

(e) the current bed occupancy status and availability of beds in case of bedded establishment under rule 12;

(f) copy of the certificate of arrangement or affiliation with reference lab, if any, under rule 13;

(g) copy of the No Objection Certificate/License/Approval under different Acts under rule 13;

(h) item-wise charges for all services under rule 19;

(i) mechanism to avail concession or free treatment facilities, if any, under rule 20;

(j) the Standard Charter of patient rights under rule 27;

(k) the information related to Grievance redressal system under rule 28;

(l) any other information for mandatory display as mentioned under different provisions of the Act and rules; and

(m) any such information as may be notified which are useful for the service recipient and general public.

(3) At reception area and other suitable place(s) including public domain, the clinical establishment shall make available an Information Brochure containing appropriate, adequate and comprehensive information including information contained in the display board and such other additional information which are too lengthily to display in the board.

Explanation. For the purpose of this rule 'other suitable place including public domain' shall include the website maintained by the clinical establishment if any.

(4) The information mentioned under sub-rule (2) and (3) shall be prepared in both the local and English language in a manner understood by a non technical person of the concerned area

(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 34.

(6) Besides having information display boards, the clinical establishment shall have adequate signage system consisting of colour coded guidelines and signages indicating access to various facilities, public utilities, exits including emergency exists, signages of bio-safety symbols etc. at strategic points in the establishment for guidance of the service recipient, service-providers and public.

(7) The clinical establishment shall display glow-sign boards indicating the name and registration number of the establishment at the main entrance and other prominent places.

(8) 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 including departmental website or to any public servant in public interest.

(9) 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.

23. Mandatory Reporting :

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

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/her duties.

(2) As a part of mandatory reporting, the clinical establishment shall generate and submit such a report regarding occurrence of any such notifiable diseases /sentinel events in that establishment, in such a manner to the licensing Authority or any such appropriate authority as may be notified, immediately after the clinical establishment has reasonable cause to believe that such event 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 of heath including disruption of service or the risk thereof needing immediate intervention.

A Notifiable disease is one that has been notified by the Government.

(3) In order to generate such reports of notifiable disease / sentinel events as mentioned in sub-rule (2), the clinical establishment shall generate and maintain a notifiable disease / sentinel event register as a part of mandatory record keeping in such a manner containing such particulars as may be notified

(4) Unless mentioned otherwise, the clinical establishment shall generate and maintain all the mandatory reports mentioned under this Act or rules in hard copy duly authenticated:

Provided that, the Licensing Authority may consider generation and maintenance of such reports in electronic form in any technologically appropriate medium if she is satisfied with such manner at the time of inspection or enquiry.

(5) Unless mentioned otherwise, Authentication of reports may be done by affixing a written signature, or a digital signature with identifiable initials or computer key along with date and time.

Provided that, any laboratory report shall be authenticated only by using a signature along with date written by the concerned doctor.

(6) Unless mentioned otherwise, the clinical establishment shall submit all the mandatory reports mentioned in the Act or rules made thereunder to the Licensing Authority or to any such Reporting Officer subordinate to him as may be nominated by the Licensing Authority in hard copy form personally, or by messenger, or by registered post or any such effective manners as may be permitted by the licensing authority:

Provided that, the Licensing Authority may consider submission in soft copy form in any technologically appropriate medium personally, or by messenger or electronically if authority is satisfied with such manner.

(7) The clinical establishment shall obtain a written or computer generated acknowledgement regarding submission of such report mentioned in sub-rule (6) and shall submit a copy of such acknowledgement along with the application for renewal of license under rule 34.

24. Access to Medical Records :

(1) As soon as possible, after the purpose for which the patient had visited or had been admitted or the episode of care is finally over, or the patient is discharged or transferred or referred, the clinical establishment shall provide the patient with a brief, written summary of medical record related to observation, treatment, test, investigation, advice diagnostic opinion and clinical outcome pertaining to the patient care free of cost:

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

Explanation1. An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete. Thus, for every new problem or set of problems that a person visits her healthcare provider, it is considered a new episode. Within that episode the patient will have one or many encounters with her clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may face a new episode that may be considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.

Explanation 2. A clinical outcome is the change in the health of an individual, group of people or population which is attributable to an intervention or series of interventions.

(2) Such Summary Medical Report under sub-rule (1) shall be provided by the Primary Consultant containing such particulars which includes but not limited to -

(a) the reasons for admission/attendance/visit, significant clinical findings, provisional diagnosis and results of investigations, particulars of treatment administered or procedure done and the nature of the health service rendered; and

(b the principal diagnosis and condition of the patient; and

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

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

Explanation. 'Principal Diagnosis' means the main medical condition that is ultimately determined to have caused a patient's admission to the hospital. The principal diagnosis is used to assign every patient to a diagnosis related group. This diagnosis may differ from the admitting and major diagnoses.

(3) In case of death, such Summary Medical Report shall be accompanied with a copy of Medical Certification of Cause of Death under the Birth and Death Registration Act, 1969 [Act No. 18 of 1969] as amended from time to time.

(4) Notwithstanding any other pending financial obligation, the patient or patient party is entitled to reproduction/get, at one's expense, the relevant part or parts of the medical record and reports pertaining to his/her healthcare, on demand in addition to the Summary Medical Report under sub-rule (1).

(5) On such demand during the course of treatment or after the discharge, transfer or death, the clinical establishment, within a reasonable period not exceeding one working day, shall 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 or any such rate as may be notified:

Provided that, the clinical establishment may refuse to deliver such records after the retention period of such records as specified in schedule VI is over.

25. Emergency Care :

(1) Any clinical establishment, having OPD or IPD service facilities, shall have the provision of administering medically necessary emergency medical treatment in order to stabilize the emergency medical condition of any person who comes in or is brought to such clinical establishment. The clinical establishment shall report to the Police Station within the jurisdiction of which it is located after providing immediate medical treatment. The clinical establishment shall have the right to recover the cost from the service recipients or his representatives in due course of time.

Explanation 1: "Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity of such a nature that the absence of immediate medical attention could reasonably be expected to result in: (i) 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.

Explanation 2: 'emergency medical treatment means' the action that is required to be taken, after screening a person who is in an emergency medical condition, for achieving the stabilization of the person and rendering such further treatment as may be necessary for the purpose of preventing aggravation of the medical condition of the person or her death and such action shall include administration of necessary first aid to administration of highest level of critical care possible under the circumstances.

(2) The clinical establishment with 30 (thirty) or more beds or any other clinical establishment that declares, or professes, in writing that it offers emergency services for 24 hours and shall provide 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 by such clinical establishment as mentioned in sub-rule (2), shall be treated as major deficiency under section 29 of the Act.

(4) The clinical establishments shall provide emergency medical treatment as mentioned in sub-rule (1) to the person in need in all cases, whether medico-legal or not, immediately without any delay or waiting for arrival of the police or completing legal formalities or waiting for the disclosure of identity of such person.

(5) The clinical establishments shall provide emergency medical treatment as mentioned in sub-rule (1) to any person including any indigent person under any circumstances, including inability to pay the user charges. This may be provided under clause (s) of sub-section (3) of section 7.

(6) After administering the first-aid and other measures mentioned in sub-rule (4), the Primary Consultant or the Resident Medical Officer (RMO) or any Registered Medical Practitioner may refer the patient to effect an appropriate transfer under rule 16 to another appropriate Healthcare establishment or Registered Medical Practitioner for further medical treatment if in its or her opinion further treatment is medically necessary

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

26. Education, Research, Training and Public Health :

(1) No clinical establishment shall conduct any training or educational course or any other capacity building programme to confer, grant or issue any such degree, diploma, license, or any such certificate of qualification shall conduct any biomedical research without obtaining prior approval in the form of a 'no objection certificate' from the State Prescribing Authority in respect thereof:

Provided that, the clinical establishment may conduct any in-service training or educational programme or any other capacity building programme for upgradation of knowledge and skill of its staff; especially in case(s) of introduction of new service(s), technique(s) or equipment by that clinical establishment.

Explanation. 'certificate of qualification' means any certificate stating or implying that the holder, grantee or recipient thereof is qualified to provide any kind of professional service

(2) To obtain such 'no objection certificate' as mentioned under sub-rule (1), the clinical establishment shall submit such application to the State Prescribing Authority containing such particulars accompanied by such supporting documents and such fee as may be notified.

(3) The State Government may, by notification, designate the Director of Medical Education (by whatever name called) or any other officer subordinate to him as the State Prescribing Authority for Medical Education Training and Research and may lay down the principles and procedure of approval under sub-rule (1).

(4) Subject to fulfillment of such terms and conditions, after conducting any inspection and/or enquiry in such a manner deemed fit, the State Prescribing Authority, if satisfied may either refuse such application by issuance of a written order thereof or grant such application by issuance of a 'No Objection Certificate' in such form containing such particulars as may be notified.

(5) For the purpose of issuance of such No Objection Certificate (NOC) as mentioned in sub-rule (4), the State Prescribing Authority shall maintain such register in such in such form containing such particulars in such manner as may be notified.

(6) Under clause (l) of sub-section (3) of section 7 of the Act, the clinical establishment shall actively participate in the implementation of all National and State public Health programmes including Immunization programme, National Program for Control of Blindness (NPCB), National Vector Born Disease Control Program (NVBDCP), Reproductive Child Health (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 the Standard diagnostic or therapeutic guidelines and protocols specified under those programmes.

(7) As a part of mandatory reporting under rule 23, the clinical establishment shall generate and maintain such reports related to the public Health programmes mentioned under sub-rule (6) in such format containing such particular and submit such reports at such intervals to the licensing authority or any such authority as may be notified.

(8) 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 diagnostic or therapeutic protocol.

(9) As soon as it comes to its notice, that any person, received or accommodated in the clinical establishment, is suffering from or has been suffering with any infectious diseases, or other dangerous diseases or any such condition of public health importance known as Notifiable Diseases and Conditions as may be notified under clause (l) of sub-section (3) of section of the Act, that clinical establishment shall take such appropriate measures to protect the public health.

Explanation : 'condition of public health importance' means a disease, syndrome, symptoms, injury, or other threat to health that is identifiable on an individual or community level and that can reasonably be expected to lead to adverse health effect in the community.

(10) The clinical establishment shall generate and submit a report regarding occurrence of such diseases as a part of mandatory reporting under rule 23 to such appropriate authority in such manner and generate and maintain a register thereof in such form containing such particulars as may be notified.

(11) The clinical establishment shall actively participate in management of any disaster, man-made or natural, and or any public health emergency/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.

Explanation. "public health emergency" means an occurrence or imminent threat, including owing to degraded environmental conditions, of an illness or health condition that:

(a) poses a high probability of any of the following harms: (i) a large number of deaths or illness in the affected population; (ii) a large number of serious or long-term disabilities in the affected population, including teratogenic effects, or; (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population; and

(b) can be caused by any of the following: (i) the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin, or; (ii) any disaster, including major accidents.

(12) Notwithstanding anything contained in rule 5, the clinical establishment or any service-provider attached to it may render service at a medical camp organized in the interest of public health only after obtaining expressed permission in the form of a camp-license from the respective licensing authority.

Explanation 1. '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.

Explanation 2. 'camp organized for the interest of public health' shall include medical relief camps organized to provide medical care during public health emergencies; or outreach camps to provide medical care to the community living in 'hard-to-reach' areas/vulnerable areas; or any mass screening camp to detect/determine any disease/disability/condition of public health importance; or any such camps but shall not include camps to generate public awareness or to impart health education only without any provision for medical care; or blood donation camp; or any such camps as may be notified.

(13) To get such a camp-license, an application containing such particulars is to be submitted to the licensing authority in such a manner accompanied by such documents and fees as may be notified.

(14) Subject to fulfillment of such terms and conditions, after conducting any inspection and/or enquiry in such a manner deems fit, the licensing authority, if satisfied, may either refuse such application by issuance of a written order thereof or grant such application by issuance of a camp-license in such form containing such particulars as may be notified.

(15) For the purpose of issuance of such camp-license as mentioned in sub-rule (12), the licensing authority shall maintain such register in such in such form containing such particulars in such manner as may be notified.

(16) Before refusing any application as mentioned in sub-rule (2) and (13), the clinical establishment shall be given an opportunity of being heard and any clinical establishment aggrieved by such order of refusal may prefer an appeal to the Appellate Authority in such a manner as mentioned under rule 41.

27. Responsibilities, Obligation and Rights :

(1) The clinical establishment shall adopt, display and observe A Standard Charter of patient rights based upon various rights provided under the Act and rules and shall orient the staff, patient and patient party thereof and the Government may publish such a model Standard Charter of patient rights by notification.

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

(a) patient shall ensure that he knows and understands the his/her' rights 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 health, including medications and past or present medical problems to the service provider;

(c) he shall report unexpected changes experienced or symptoms to the 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 about the treatment, investigation or care provided to the patient;

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

(g) he shall conduct himself 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 regulation or Standard Operating Procedure (SOP) of the clinical establishment;

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

(j) he shall ensure that financial obligations of the health care are fulfilled as promptly as possible, otherwise, he shall make an appropriate arrangements to settle unpaid bills through any mechanism agreeable to the clinical establishment; and

(k) he shall fulfill any other obligation mentioned elsewhere in the Act or the rules.

(3) If any patient refuses treatment or does 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 the obligations and responsibilities, shall forfeit any rights conferred upon him/her.

(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 [West Bengal 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 being incapacitated due to existing physical/mental/emotional state rendering him/her incapable to authorize a person as his/her Representative.

28. Grievance redressal System :

(1) The clinical establishments having two or more service providers shall establish an internal grievance redressal system so that anyone aggrieved by the denial of assured service to be known as 'aggrieved party' can have an opportunity to get a prompt redressal before taking other course(s) of action.

Explanation: "Aggrieved party" means any person who has submitted a complaint under 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.

(2) The "Denial of assured services" mentioned under sub-rule (1) means and includes-

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

(b) provision of 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 rules; or

(e) any such other deficiency, delay, defects, neglect or abuse as may be notified.

(3) As a part of the internal grievance redressal system, the clinical establishment shall generate and maintain a grievance redressal register containing such particulars in such a manner as may be notified as a part of mandatory record keeping and shall designate a specific member of the staff preferably having experience in public relations to be designated as Grievance redressal Officer as the person in charge of such internal Grievance redressal mechanism.

(4) The Grievance redressal Officer under sub-rule (3), upon receiving a complaint, oral or written, from the aggrieved party for redressal of grievance, shall -

(a) register the complaint without any delay in the public grievance redressal cell or help desk;

(b) provide the aggrieved party an acknowledgement bearing an acknowledgement number which may be used as reference by the aggrieved party in future;

(c) provide the aggrieved party, within a reasonable period not exceeding 7 (seven) working days, with a written preliminary response for his/her application, along with the action taken/proposed to be taken;

(d) contact the person concerned and remedy the situation;

(e) provide the aggrieved party with printed information in English and local language on all the remedies available to him;

(f) record all the particulars regarding any remedial action taken in the grievance redressal register; and

(g) perform any other activities as may be notified.

(5) As a part of the internal grievance redressal system, the clinical establishment shall display the procedure of laying complaints, full contact details of the Grievance Redressal Officer with clear mention of the time of availability of the same and any other detail information as a part of mandatory display under rule 22 and shall communicate the procedure to the service recipient on a regular basis.

(6) The clinical establishment shall submit such annual report containing such relevant extracts from the grievance redressal register, as may be notified, to the respective Licensing Authority as a part of mandatory reporting.

CHAPTER IV

Registration and Licensing

29. Validity and Renewal of license :

(1) Unless suspended or cancelled earlier or otherwise mentioned, the license granted shall ordinarily be valid and subsisting, for a period of 1 (one) year from the date on which it is granted:

Provided that, the licensing authority may grant a license with a validity period upto 3 (three) years if applied for and opted by the applicant in application made under rule 34 subject to advance remittance of stipulated License fee applicable for the period and compliance with all terms and conditions of licensing.

(2) The license being non-transferable under 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 remain valid until the expiry of -

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

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

(3) Under sub-section (1) of section 19 of the Act, any application for the renewal of a registration or license granted under these rules shall be submitted in statutory CE Form I along with the existing duplicate license, not later than 30 days prior to the expiry date indicated in the license: at present on line

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.

(4) In case the application for renewal is submitted beyond the period mentioned under sub-rule (3) above but before the expiry date, such application shall be accompanied by stipulated license fee along with a late fee the application for renewal is submitted after expiry date, such application amounting to ten percent of the License fee for each day of delay of submission of application.

(5) In case shall be accompanied by stipulated license fee, late fee mentioned under sub-rule (5) and an additional fee amounting to forty percent of the License fee for each day of delay of submission of application from the date of expiry of the validity of the license.

(6) The existing 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 and such clinical establishment shall be regulated by all the provisions of the Act and rules during that period.

(7) In case the renewal of license is issued after the date of expiry of the existing license, the intervening period between the date of expiry and issuance shall be considered as a period of irregular keeping or carrying on a clinical establishment subsequently regularized and as such shall be recorded in the renewed license in Statutory Clinical Establishment Form VII.

(8) Under sub-section (2) of section 19 of the Act, in the event of failure of the licensing authority to communicate the fact of granting or rejection of application for renewal of license after the expiry of 90 (ninety) days from the date of receipt of such application, such license shall be deemed to have been renewed and such license shall be valid for such a period mentioned in the application as opted by the application.

(9) For the purpose of consideration of application made under sub-rule (3) and (4), the Government may notify other terms and conditions from time to time.

(10) All communication to be made electronically and shall not require digital signature of licensing authority / applicant till further notification.

30. District and State Register :

(1) The licensing authority, as District Registrar, shall generate and maintain a register in statutory Clinical Establishment 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 the administrative district or such 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 (twelve) digit registration/License Number consisting of three parts: (a) a 4 (Four) digit district code as may be authorized by the state registrar; (b) a 4 (Four) 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 2013 of West Medinipur health district 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 electronic form or in such other form authorized by the State Registrar 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) Under section 4 of the Act, the State Registrar shall generate and maintain a register in statutory Clinical Establishment Form VII to be known as the State Register of clinical establishments that shall be an amalgamation of the District Register of clinical establishments maintained by the District Registrar.

(7) The District and State Register shall contain particulars like the registration/License Number, Name of the clinical establishment as specified in form statutory Clinical Establishment Form VII and any such particulars as may be notified by the Government from time to time.

(8) Under 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.

(9) 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.

(10) 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.

(11) To discharge her duties mentioned in this Act or rules, the State Registrar shall issue suitable instructions, co-ordinate, and supervise the work of registration in the entire State for securing an efficient system of registration.

(12) As and when necessary in the public interest, the State Registrar shall consider any information contained in the State Register or District Register or license or any application made under this Act or rules or any order or notice including order after adjudication made under this Act or rules as a public record and may make those information available in the public domain or to any public servant after due verification of the facts in such a manner as she deems fit.

31. 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 district register kept by him under this Act or any license issued by him under this Act is erroneous in form or substance, or has been fraudulently or improperly made, he/she shall conduct a suitable enquiry and cause to correct the error or cancel the entry if satisfied after such 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, shall cause to correct the error or cancel the entry in manner specified under sub-rule (2).

(5) The District Registrar shall call for and collect the original license along with all duplicates issued by him and shall issue an amended license after making any changes in the District Register kept by him, if necessary.

(6) The Government may notify other terms and conditions for correction and cancellation of any entry of District or State Register or the license from time to time.

32. System of medicine :

(1) [Under sub-section (1) of section 11 of the Act], 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 which include: (a) Allopathy, (b) Ayurveda, (c) Unani, (d) Siddha, (e) Homeopathy, (f) Naturopathy, (g) Yoga, or (h) Any other recognized system of Medicine as may be notified.

Provided that any other recognized system of Medicine to be specified by the applicant shall be allowed for the purpose of registration only after getting approval from the State prescribing Authority for Medical Education Training and Research constituted under rule 26.

(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 such other allopathy sub-group as may be notified.

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

(3) Depending upon the nature of sub-system, the clinical establishments practicing Ayurveda System of Medicine shall be further classified into mutually exclusive sub-groups: (i) Ausadh Chikitsa; (ii) Shalya Chikitsa; (iii) Shodhan Chikitsa; (iv) Rasayana; (v) Pathya Vyavastha; or (vi) Any such other Ayurveda sub-group as may be notified.

(4) Depending upon the nature of sub-system, the clinical establishments practicing Unani System of Medicine shall be further classified into mutually exclusive sub-groups: (i) Matab; (ii) Jarahat; (iii) Ilaj-bit-Tadbeer; (iv) Hifzan-e-Sehat; or (v) Any such other Unani sub-group as may be notified.

(5) Depending upon the nature of sub-system, the clinical establishments practicing Siddha System of Medicine shall be further classified into mutually exclusive sub-groups: (i) Maruthuvam; (ii) Sirappu Maruthuvam; (iii) Varmam Thokknam & Yoga; or (iv) Any such other Siddha sub-group as may be notified.

(6) Depending upon the nature of sub-system, the clinical establishments practicing Homeopathy System of Medicine shall be further classified into mutually exclusive sub-groups: (i) General Homeopathy; or (ii) Any such other Homeopathy sub-group as may be notified.

(7) Depending upon the nature of sub-system, the clinical establishments practicing Naturopathy System of Medicine shall be further classified into mutually exclusive sub-groups: (i) External Therapies with natural modalities; (ii) Internal Therapies; or (iii) Any such other Naturopathy sub-group as may be notified.

(8) Depending upon the nature of sub-system, the clinical establishments practicing Yoga System of Medicine shall be further classified into mutually exclusive sub-groups: (i) Ashtang Yoga; or (ii) Any such other Yoga sub-group as may be notified.

(9) The clinical establishment shall ensure that the patient, registered under a Primary Consultant practicing a particular system of medicine, is not administered treatment by any Registered medical practitioner practicing another system of medicine without the informed written consent of the patient.

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 her health.

(10) Any act of use or intention to use any system of medicine other than recognized system of medicine by any clinical establishment shall be considered as major deficiency under section 29 of the Act.

(11) The clinical establishment shall ensure that no service-provider of that clinical establishment shall be engaged in cross-practice or engaged in practice of any system of medicine which is not recognized or engaged in any recognized system medicine for which she is not qualified enough and any such act shall be considered as major deficiency under section 29 of the Act.

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.

33. Classification :

(1) The clinical establishments shall be classified depending upon the following criteria namely (a) Location of the clinical establishment as mentioned under rule 40; (b) System of Medicine practiced by the clinical establishment as mentioned under rule 32; (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) The service facilities offered by the clinical establishment shall be classified into following mutually exclusive categories which include: (a) Outpatient based Service Facilities; (b) Inpatient based service Facilities; (c) Pathology Laboratory service Facilities; (d) Diagnostic Imaging laboratory service Facilities.

(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 which include: (i) Solo clinic; (ii) Polyclinic; (iii) Dental Clinic; (iv) Refraction clinic; (v) Physiotherapy Clinic; (vi) Acupuncture clinic (vii) Occupational therapy Clinic; (viii) Counseling Centre; (ix) Wellness/Fitness centre/clinic; (x) any other clinic or OPD based service centre as may be notified.

(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 which include: (i) Infertility Clinic; (ii) Dialysis Centre; (iii) Medical Termination of Pregnancy (MTP) clinic; (iv) any such other Day care centre as may be notified; (v) Maternity Home; (vi) Nursing Home/Hospital/Sanatorium; or (vii) Any such other IPD based service centre as may be notified.

(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 which include: (i) Collection centre; (ii) Small Laboratory; (iii) Medium Laboratory; (iv) Large Laboratory; (v) Genetic Laboratory; (vi) any such other pathology laboratory as may be notified.

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. However Large Labs doing investigations by Radio-immunoassay technique need clearance from BARC.

Explanation 5: "genetic laboratory" means a laboratory as defined under the Pre-conception and Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994.

(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 which include: (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-cardiocraphy laboratory; (xi) Electro-cardiography laboratory; (xii) Electro-encephalography laboratory; (xiii) Electromyography laboratory; (xiv) Audiometry lab; or (xv) Other Clinical Physiological test laboratory or (xvi) Any such other Imaging laboratory as may be notified

Explanation: '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.

(8) Irrespective of types and numbers of service sub-facilities officered as mentioned in sub-rule (3) to (6), the clinical establishment shall be classified into following categories depending upon the number of service facilities offered as mentioned in sub-rule (2): (a) Uni-facility clinical establishment offering only one type of service facility or (b) multi-facility clinical establishment offering more than one type of service facility.

Illustration 1. A clinical establishment offering only X-Ray laboratory (Digital) service shall be classified as Uni-facility clinical establishment (Diagnostic imaging)

Illustration 2. A clinical establishment offering X-Ray laboratory (Digital) service and USG shall be classified as Uni-facility clinical establishment (Diagnostic imaging).

Illustration 3. A clinical establishment offering any type of Diagnostic imaging service and along with any type of OPD clinic service shall be classified as Multi-facility clinical establishment.

Illustration 4. A clinical establishment offering any type of OPD clinic service and along with any type of IPD facility shall be classified as Multi-facility clinical establishment.

34. Application and Accompanied evidence:

(1) Under sub-section (1) of section 12 of the Act, to obtain the license or renewal thereof, 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 respective licensing authority.

(2) Under sub-section (2) of section 12 of the Act, 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 the current rent receipt, rent agreement / registred lease deed, consent letter issued by the owner etc. as mentioned in rule 5;

(b) copy of plan for construction or modification, approved by the Appropriate Authority, under rule 5;

(c) copy of building completion certificate, issued by the Appropriate Authority, under rule 5;

(d) sketch map showing detailed position and floor measurement of the different facilities under rule 5;

(e) copy of 'No objection certificate' from the Government regarding government employee under rule 6;

(f) copies of Offer letters & Acceptance letters under rule 7;

(g) copies of certificates of Registration and certificate of qualification all Medical, nursing and paramedical Professional empanelled by the clinical establishment under rule 7;

(h) copy of certificate of arrangement or affiliation with reference laboratory by a collection centre under rule 13;

(i) copy of agreement related to concession or free treatment facilities as mentioned in rule 20, if applicable;

(j) copy of trade license / certificate of enlistment issued by Local body under rule 21;

(k) copies of authorization/license / No Objection Certificate or a self-declaration in the form of an affidavit in relation to compliance of 'different Acts and rules' as mentioned in rule 21;

(l) copy of Information Brochure under rule 22;

(m) copy of acknowledgement of reports under rule 23 in case of application of renewal of license;

(n) copy of the Regulation/ Standard Operating Procedure (SOP) of the clinical establishment, if any, under rule 27;

(o) duplicate license in case of application for renewal under rule 29;

(p) copy of Treasury Challan / GRIPPS (e-transfer of fee) regarding deposit of License fee under rule 40;

(q) copy of The tax receipt [property tax] from the Local body under rule 40;

(r) copy of Memorandum/Articles of Association Partnership deed, Self declaration in case of Collective proprietorship or company or organization as mentioned in rule 44;

(s) any other additional document mentioned elsewhere in the Act or rules;

(t) copy of Fire License is any; and

(u) any such other document as may be notified.

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

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

(5) 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.

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

(7) Under section 13 of the Act, the applicant, for obtaining a duplicate copy of license, shall submit an application in statutory Clinical Establishment Form I to the licensing Authority accompanied by the supporting document(s) in favour of loss, destruction mutilation or damage along with an application processing fee amounting one percent of the stipulated License fee mentioned in rule 40.

35. Processing of Application:

(1) Under section 13 of the Act, the Licensing Authority shall supervise the processing of application and conduction of inspection/enquiry in such a manner so as to pass an order either granting or refusing such application within 90 (ninety) days of receiving such application.

(2) On the receipt of an application, the Licensing Authority, or any person in office authorized in this behalf, shall, acknowledge such receipt of the application for registration, in the acknowledgment slip in statutory Clinical Establishment Form IV either issued by him/her or generated automatically by the computer.

(3) 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. At present such receipt of application shall be on the form I as per West Bengal Right to Public Service Act 2013.

(4) 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.

(5) Within a period of 15 (fifteen) days after issuance of acknowledgement, the Licensing Authority shall assign the task of further processing the application including inspection and/or inquiry to the Supervisory Authority constituted under rule 36.

(6) If, upon scrutiny of the application and inspection within 15 (fifteen) 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 (thirty) days from such order.

(7) In case the applicant fails to furnish such required information within the stipulated time period of 30 (thirty) days, the Supervisory Authority shall submit her inspection report to the Licensing Authority for recommending the rejection of such application.

(8) Within a period of 30 (thirty) days from receipt of a complete application, the Supervisory Authority shall conduct necessary inspection and/or inquiry in a manner mentioned under rule 36 and may issue an improvement notice on behalf of the Licensing Authority to the applicant, if she deems fit, guiding the applicant 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.

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

(10) In case the applicant fails to carry out such steps and intimate the Supervisory Authority within the stipulated time mentioned in that Improvement notice, the Supervisory Authority shall submit her inspection report to the Licensing Authority for recommending the rejection of such application.

(11) Within a period of 30 (thirty) days from receipt of a complete inspection report along with recommendation from the Supervisory Authority in Statutory Clinical Establishment form V, the Licensing Authority shall examine and consider the recommendation and shall either -

(a) pass an order for further inspection or inquiry by another supervisory authority with intimation to the applicant; or

(b) pass an order for grant of license in Statutory Clinical Establishment form VIII; or

(c) pass an order for refusal of license in Statutory Clinical Establishment 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.

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

36. Inspection and Inquiry:

(1) The Licensing Authority, as soon as possible after receiving an application, shall order a scheduled inspection and/or inquiry in respect of any clinical establishment in order to satisfy himself before granting or rejecting an application for new license or renewal thereof as mentioned under rule 35.

(2) The Licensing Authority, as often as may be necessary, shall order a scheduled inspection and/or inquiry in respect of any clinical establishment at periodic interval 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.

(3) The Licensing Authority, as soon as possible after reasonably being satisfied, shall order an unscheduled inspection and/or inquiry in respect of any clinical establishment 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 by that clinical establishment:

Provided that, the reason(s) for such inspection shall be recorded in writing in such order

(4) The Licensing Authority, as soon as possible, shall order an unscheduled inspection and/or inquiry in respect of any clinical establishment if she is reasonably satisfied that there is a possibility that-

(a) such clinical establishment is being kept or carried on without a valid license; or

(b) an imminent danger to the safety and security of service-user, service-provider or public at large is existing with respect to such clinical establishment; or

(c) such clinical establishment is not complying with any provision of this Act:

Provided that, 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) to (4), the Licensing Authority, by issuing a general or specific Authorization Notice, shall constitute a Supervisory Authority consisting of one or more members of Govt. servant headed by a government medical officer.

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

(6) The Adjudicating Authority, West Bengal Clinical Establishment Regulatory Commission or any such appropriate authority as may be notified under section 36 sub-section (1) of the Act, by issuing a general or specific Authorization Notice, may constitute such Supervisory Authority under sub-rule (5) consisting of such member(s) as it deems appropriate.

(7) The Authorization Notice under sub-rule (5) and (6) may impose reasonable restrictions on the powers of the Supervisory Authority and shall remain in force -

(a) until it is executed; or

(b) until it is cancelled by the person who issued it or, if such person is not available, by any person with like authority;

(c) until the expiry of three months from the day of its issue; or the purpose for the issuing of the Authorization Notice has lapsed, whichever occurs first.

(8) The Supervisory Authority, at any reasonable time, with such assistance as he/she reasonably require, shall enter the premises of a clinical establishment as per rule 39 and may-

(a) inspect the premises of the clinical establishment or any part of it; and

(b) inspect any apparatus, appliance, equipment, instrument, product, goods or item used or found in the clinical establishment; and

(c) observe and examine any activity, operation process or procedure being carried out at the clinical establishment; and

(d) require the owner or any member of staff of the clinical establishment to take reasonable steps to produce documents;

(e) inspect, make copies of or take extracts from any document, records, registers;

(f) require the owner or any member of staff of the clinical establishment to authenticate such copies and make such copies available to the Supervisory Authority at free of cost.

(9) While conducting such enquiry, the Supervisory Authority shall enter the premises of a clinical establishment as per rule 39 and may-

(a) ask relevant questions and take on the spot or otherwise the statement of any person as she deems necessary; and

(b) ask relevant questions of any patient for the purpose of ascertaining any material fact; and

(c) require the owner or any member of staff of the clinical establishment to answer a question to the best of that person's knowledge, information and belief

(10) While conducting such inspection or inquiry, a member of Supervisory Authority-

(a) shall serve a notice as per proviso clause of sub-section (1) of section 24 of the Act; and

(b) shall take utmost care not to disturb or interfere with the service(s) being provided to the patient

(c) shall exercise power vested upon him by the Act and rules reasonably for carrying out the purposes of this Act; and

(d) shall not behave in a way unbecoming of a government servant.

(11) 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

(12) Any person who refuses or fails, without reasonable cause, to furnish any information to the Supervisory Authority or; to produce any of the records, registers, reports, or any such instruments, either medical, medico-legal, mandatory or of any kind including the confidential medical records without delay 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.

(13) Nothing in this rule shall be deemed to deter any member of Supervisory Authority to inspect any medical record relating to any patient in a clinical establishment maintaining confidentiality and taking care that it doesn't come into public domain.

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

(1) The Supervisory Authority, on completion of inspection and enquiry, shall record the salient points of his observation and recommendation(s) to the clinical establishment detailing the specific deficiencies to be corrected, if any, in the inspection book (register).

(2) As a part of mandatory record keeping, the clinical establishment shall generate and maintain such inspection book (register) mentioned under sub-rule (1) in such a manner as may be notified

(3) The Supervisory Authority, on completion of inspection and enquiry, shall record her observation of inspection and recommendation(s) to the Licensing Authority in the inspection/inquiry report as specified in statutory Clinical Establishment Form V and submit such report to the Licensing Authority.

(4) 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 (3), or any such report of any scheduled or unscheduled inspection made under Rule 36, 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.

(5) Under the provision of section 20 and section 21, the licensing authority, if she 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.

(6) 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, 1908.

(7) 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.

(8) The State Registrar 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. Seal and seizure :

(1) 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; seize and take into custody any material object if she has reason to suspect that it might be used as evidence in a trial:

Provided that, for the benefit of patient, the clinical establishment shall be allowed to make copies of such document, record, register which is required to be retained for providing further healthcare already committed by that establishment.

Provided further that, the in-charge of local police station, where such seizer has taken place, shall give all reasonable assistance to the supervisory authority for safekeeping of those seized objects.

Explanation 1. - "Material object" means any equipment, sample, article, document, record, register, book, pamphlet, advertisement or any other material object for the purpose.

Explanation 2. - 'premises' shall not include the area for residential accommodation of a registered clinical establishment.

(2) The Supervisory Authority shall prepare a memo containing list of any material object, seized under sub-rule (1) at the place of affecting the seizure in Statutory Clinical Establishment Form X and get it signed on every page by himself, the witnesses and the Police officer accompanying him:

Provided that, the memo may be prepared, in the presence of the witnesses, at a place other than the place of seizure if, for reasons to be recorded in writing, it is not practicable to make the list at the place of affecting the seizure.

(3) The Supervisory Authority shall hand over, under acknowledgement, one copy of the seizure memo to the person from whose custody the material object have been seized:

Provided that, a copy of the seizure memo may be delivered under acknowledgement, or sent by registered post to the Licensee or person in control of the premises, if no person acknowledging custody of the material object seized is available at the place of affecting the seizure.

(4) If any material object seized is perishable in nature, or difficult to remove, the Supervisory Authority shall make arrangements promptly for sealing, identification and preservation of the material object and also convey it to a facility for analysis or test, if analysis or test be required:

Provided that, the refrigerator or other equipment used for preserving such perishable material object may be sealed until such time as arrangements can be made for safe removal of such perishable material object and in such eventuality, mention of keeping the material object seized, on the premises, shall be made in the list of seizure.

(5) Where the Supervisory Authority has seized any medical records, books of account, other relevant documents or any material objects in exercise of powers conferred upon under section 24 of the Act, shall return the same to the person from whom those were seized as soon as practicable after achieving the purpose for which it was removed:

Provided that, those material objects can be retained as long as necessary and disposed of subject to the direction of Adjudicating Authority, Tribunal or Court of law or any such appropriate authority as may be notified under sub-section (1) of section 24 of the Act.

Provided further, that, before returning any of those seized medical records, books of account, other relevant documents known as vital records, the Supervisory Authority shall be entitled for copies thereof or extracts there from, as the case may be.

(6) On receipt of such communication from the Supervisory Authority, the person from whom vital records were seized shall provide the Supervisory Authority free of cost with copies or extracts as the case may be, duly authenticated by that person.

(7) The person making the extracts shall not in any manner cause dislocation, mutilation, tampering or damage to the records in the course of making extracts.

(8) The extracts or the copies shall be signed and authenticated on each page of such extracts or copies by the person from whom the vital records were seized and such extracts or copies so authenticated shall be provided to the Supervisory Authority, accompanied by a self-declaration in Statuary Clinical Establishment Form XI of the person from whom the books of account and other documents were seized, certifying the authenticity of such extracts or copies.

39. Entry and Search :

(1) The Supervisory Authority, preferably in the presence of two or more independent and respectable persons in case of unscheduled inspection and/or enquiry, 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; and

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

(2) The Supervisory Authority or the Police Officer accompanying him shall immediately before entering the premises in question-

(a) audibly announce that he/she is authorized to enter the premises and demand admission to the premises; and

(b) notify the person in control of the premises of the purpose of the entry, unless there are reasonable grounds to believe that such announcement or notification might defeat the purpose of the search.

(3) The Supervisory Authority shall-

(a) hand over to the person in charge of the premises a copy of the Authorization Notice or, if such person is not present, affix such a copy to a prominent place on the premises; and

(b) on request of the person in charge of such premises, show her identity card issued by the Government to that person.

(4) The Supervisory Authority, the Licensing Authority, the Adjudicating Authority, Tribunal or Court of law or any such appropriate authority as may be notified under sub-section (1) of section 24 of the Act shall have the right to seek reasonable assistance and co-operation from any government servant including a Police Officer for assisting or witnessing the action or in the conduct of enquiry, search, seizure operation.

Explanation: 'Police Officer' means a police officer not below the rank of sub-inspector accompanying and assisting the Supervisory Authority.

(5) Any reluctance, refusal or non-cooperation noticed on the part of such Government servant to render such assistance and co-operation under sub-rule (4) shall be viewed seriously by the Government and appropriate disciplinary action may be taken.

(6) The Supervisory Authority or police official under sub-rule (1) may overcome resistance to the entry and search by using such force as is reasonably required, including the breaking of a door or window of the premises.

(7) Before using force, the Supervisory Authority or the Police Officer shall audibly demand admission and shall announce the purpose of the entry and search, unless there are reasonable grounds to believe that doing so might defeat the purpose of the search.

(8) Upon the request of the Supervisory Authority or the Police Officer accompanying him, the occupant and any other person present on the premises shall-

(a) make available or accessible or deliver to the Supervisory Authority or the Police Officer any document, record, object or material which pertains to an investigation contemplated in sub-rule (1) and which is in the possession or under the control of the occupant or other person;

(b) furnish such information with regard to the matter under investigation; and

(c) render such reasonable assistance as the Supervisory Authority or the Police Officer may require to perform his/her functions in terms of this Act efficiently.

(9) Before questioning any person at the premises in question, the Supervisory Authority or the Police Officer shall remind the right of the person to be assisted by an advocate or attorney, and allow that person to exercise that right at that time.

(10) No person is entitled to any compensation for any loss or damage of property arising out of any bona fide action by the Supervisory Authority or the Police Officer under this rule.

(11) In the case of non-completion of search and seizure operation, the Supervisory Authority may also make arrangement, by way of mounting a guard and sealing of the premises to prevent any tampering with such material object.

40. Fees :

(1) Under section 25, the clinical establishment shall deposit the whole amount of fee mentioned in the schedule VII as license fee appropriate of that type of clinical establishment.

(2) The clinical establishment shall submit a copy of Treasury challan / GRIPPS (e-transfer of fee) or any such document as may be notified as documentary evidence thereof along with the application mentioned under rule 34.

(3) Unless mentioned otherwise, 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

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

(5) The license fees of clinical establishments may be exempted or reduced, wholly or partly by issuance of order or notifications by the Government from time to time and case to case basis under section 25 of the Act.

CHAPTER V

Miscellaneous

41. The Appeal :

(1) In case of the failure of the licensing authority in communicating the grant or rejection of application, any appellant shall have the right to prefer an appeal in the Statutory Clinical Establishment Form XII to the Appellate Authority within 120 (one twenty) days from the date but not before 90 (Ninety) days of submission of such application.

(2) Any appellant, aggrieved by the order of the Licensing Authority shall have the right to prefer an appeal in the Statutory Clinical Establishment Form XII to the Appellate Authority 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 (Fifteen) 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 45 (forty five) 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 not below the rank of special secretary as may be notified by the Government from time to time shall be the Appellate Authority mentioned in 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;

42. Adjudication :

(1) 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/her to submit his/her 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 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 35 of the Act.

(2) If after receiving the complaint referred to under sub-rule (1), the accused party does not appear or omits or fails to take any action to represent 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 is accused, shall be stated to the accused party and shall be asked whether accused party pleads guilty in whole or in part or 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 or upon his/her discretion to convict thereon by recording reasons thereon.

(5) If the accused party does not admit or plead 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 proceed to hear the accused party and take all such evidence as she produces in her defense.

(6) The adjudicating authority may, on the application of the complainant or the accuser may issue a summon to any witness directing 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 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 (three) 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.

(11) Subject to the provisions of these rules, the State registrar 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.

43. Statement and Representation :

(1) The clinical establishment shall have the right to authorize a representative competent enough to make, execute or submit any claims, statement or representation in the form of any application, report, document or any such instrument which are made or submitted, or to be made or submitted by the clinical establishment under the Act or rules :

Provided that such representative shall have to authenticate those instrument by affixing a signature showing unambiguously that such authentication is made on behalf of the clinical establishment which is identified in that instrument.

Provided further, that, the clinical establishment shall have to exercise reasonable care to ensure the truthfulness, completeness, accuracy, timeliness and other aspects of quality of all such instrument.

Provided furthermore, that, the clinical establishment shall authorize a representative to make, execute or submit an application for new or renewal of license as per rule 44.

Explanation I : 'to make' includes 'to generate, maintain, or display;

Explanation II : 'competent representative' means and includes either the applicant mentioned in rule 44 or any one of the full-time employees of the clinical establishment.

(2) The clinical establishment is liable of contravention of sub-rule (1) 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 Indian Penal Code, 1860.

(3) A person under sub-rule (1) 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.

(4) Any person shall be 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.

(5) 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; and

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

(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; and

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

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

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

(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; and

(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 validly, if any.

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

44. Collective Proprietorship :

(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 under rule 34 :

(a) a copy of Memorandum/Articles of Association in case of Collective proprietorship or company or organization; or copy of the Partnership deed in case of Partnership Firm; and

(b) a copy of resolution regarding nomination mentioned in sub-rule (4).

(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) In order to fix up the responsibility, the application made under rule 34 shall be filled in with the name of a particular individual as an applicant and not with the name of a Company or organization and only such applicant shall be registered as the Licensee of that clinical establishment as and when the application is granted:

Provided that, in case of a Collective proprietorship or company or organization, the applicant shall be a competent 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.

Explanation. 'Competent representative' means a nominee who is any one of the owners and shall include a partner, director, trustee, secretary, president or chairman of that partnership firm, company, trust or organization but shall not include an employee of that firm, company, trust or organization.

(5) Any change of nomination shall be considered as change of ownership and the Company shall intimate to the Licensing Authority, as and when any such change occurs forthwith.

45. Vicarious Liability :

(1) The service recipient shall have the right to receive such health care services corresponding to state of health, as assured by the clinical establishment within its limits of declared 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 and the owner of the clinical establishment to :

(a) provide the service recipient with the assured service without any undue denial, delay, discrimination, harassment or deficiency; and

(b) provide the service recipient appropriate healthcare and non-healthcare services of reasonably 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 and treatment elsewhere, where the appropriate care and treatment can be rendered :

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

(4) The Owner or Occupier, as the case may be, of the clinical establishment shall be responsible for any act of misconduct by 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.

46. License for Clinical Establishment will not be applicable to any place utilized by a registered medical practitioner solely for the purpose of consultation and advice and named as 'Medical Consultation Clinic' :

(1) Notwithstanding anything contained in chapter II to chapter IV, 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. 'Medical Consultation Clinic' for the purpose of single doctor clinical establishment means a medical clinic having only one Registered medical practitioner who is the owner of that clinic but not for a 'Medical Consultation Clinic' used for or intended to be used for consultation & treatment by a Registered medical practitioner but shall not include the set up utilized solely for the purpose of consultation and advice by the Registered medical practitioner.

(2) Notwithstanding anything contained in rule 34, an application in Statutory Clinical Establishment 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 Clinical Establishment Form III;

(b) copy of certificate of Registration; or

(c) Copy of Certificate of qualification if the highest qualification is not recorded in the of certificate of registration; and

(d) copy of existing license in case of renewal; and

(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; and

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

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

(3) Notwithstanding anything contained in rule 40, the State Government may exempt the amount of license fee [for doctors already registered with Medical Councils of West Bengal] in terms of section 25.

(4) Notwithstanding anything contained in rule 35, the Licensing Authority, if satisfied after processing the application without causing any inquiry or inspection of that single doctor establishment that the terms and conditions as mentioned under rule 3 are fulfilled, shall grant the a license or renewal within 30 days of receipt of such application.

(5) Notwithstanding anything contained in rule 29, the license issued under sub-rule (4) shall be valid for a period of 1 (one) year which may be extended upto 5 (Five) years if opted by the applicant upon payment of necessary fees.

47. Standards for Single Doctor Establishment ('Medical Consultation Clinic') [will not be applicable for a Medical Clinic used for or intended to be used for consultation and treatment by a registered medical practitioner which shall not include the set up utilized solely for the purpose of consultation and advice by the registered medical practitioner] in terms of clause (c) of section 2 of the Act :

Explanation: 'Medical Consultation Clinic' shall mean a place used or intended to be used for consultation and treatment by a registered medical practitioner but shall not include any place solely for the purpose of medical consultation and advice except carrying out any measures taken to save the life of a patient.

(1) Notwithstanding anything contained in rule 5, 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 9, 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 18, the Doctor shall generate and maintain records as per Medical Council of India (MCI) Act or similar Acts; records related to medicolegal cases; an OPD register, and any other records or registers as may be notified.

(4) Notwithstanding anything contained in rule 21, 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.

(5) Notwithstanding anything contained in rule 22, 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 Medical Council of India (MCI) Act or similar Acts or any other information as may be notified

(6) Notwithstanding anything contained in rule 23, 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 25; and (b) participate in public health related activities under rule 26; and (c) comply with any other terms and conditions as may be notified.

SCHEDULE I

Standards for Building and Accommodation

[See rule 5]

Part I : General

1. Introduction :

1.1. The clinical establishment should maintain the Building and 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 use of the premises should conform to the land use prescribed under 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.

1.4 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 with landline connection is a must for every clinical establishment. There should be adequate provision for adequate parking facilities for staffs and visitors in case of clinical establishment with 100 or more beds.

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

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

1.7. The clinical establishment should have adequate space devoted to stairs, ramps, corridor for internal transportation of the patients on wheel chairs, trolleys etc.

1.8. The building should conform to such Building Engineering Environmental Standards as may be notified.

Part II : Specific :

1. Outpatient based Facilities :

1.1. Outpatient based Facilities should be provided with (a) The Reception and Information area for providing information to the patients and party; (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 and 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 to run OPD clinics of different types like Medicine, surgery, obstetrics & Gynaecology etc.

2. Inpatient based Facilities :

2.1. **Nursing Homes :** Provisions for OPDs, Indoor, operation theatres, ICUs, Labour room etc. should be provided depending upon the type of facilities being offered. Nursing Homes should have their own Laboratory and Diagnostic (X-ray, Ultrasound etc.) facilities which should be established as per the norms indicated against such facilities or should have working arrangements with Laboratories, Blood Bank and other diagnostic centres. In case of Hospital or Nursing homes having 100 or more beds, it should have provision for emergency laboratory tests and mobile X-ray machine for emergency X- ray.

2.2. **Casualty and emergency care area :** It should be as per norms as may be notified

2.3. **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, new born care corner should be provided. It should have Operating suite and Delivery suite as per norms. In maternity homes an arrangement should be provided to isolate a patient of eclampsia.

2.4. **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 care area; and (f) Service area.

2.5. **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 and 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.

2.6. **Ambulatory area :** In 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 and 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.

2.7. **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, including CT scan and related equipments 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.

2.8. **Intermediate area :** It should be consisting mainly of inpatient 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 and adequate space as per norms should be available. Separate ward units should be provided for male and female patients. Admission should be restricted to the number of beds to be maintained.

2.8.2. 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.

2.8.3. 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.

2.9. **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.

2.9.2. The drug and medical supplies stock should be properly maintained. 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 ideally so located that it serves both inpatient and outpatients. Regarding storage, handling and usage of medical supplies, the clinical establishment shall follow the provisions of the Drugs and Cosmetics Act, 1940 [Act 23 of 1940].

2.9.3. The nursing home should have generator/back-up power source so that in case of a power failure, all equipments, 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.

2.9.4. 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.

2.10. **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.

2.10.2. 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.

2.10.3. Room for post anesthesia recovery of outpatient surgical patients should be provided. 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 or two family members, provisions for privacy and a small space which can serve as a nurses counter.

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

2.10.4.1. **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.

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

2.10.4.3. **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.

2.10.4.4. **Disposal zone :** Also erroneously called the dirty zone. Soiled instruments and dressings are transacted through this area for washing, decontamination and sterilization or disposal.

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.

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

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. Temperature should be maintained 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 backup, 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, 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, refreshment 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 floor area mentioned in table below. 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. Table : 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 equipment	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 per bed in general ward	65 sq.ft.
(10)	Space per bed in Critical care unit	120 sq.ft.

	Item	Measurements (minimum floor area)
(11)	Distance between centre of 2 beds	6 ft.
(12)	Distance between bed and wall	1 ft
(13)	Width of a door in a ward	3 ft.
(14)	Toilet	36 sq.ft.
(15)	General operation theatre area per table	160 sq.ft. (with additional 100 sq.ft. per additional table).
(16)	CTVS and Neurosurgery operation theatre area per table	500 sq.ft.
(17)	Area for instrument sterilization	50 sq.ft.
(18)	Area for scrub up	25 sq.ft.
(19)	Area for dirty wash	25 sq.ft.
(20)	Area for pantry	80 sq.ft.
(21)	Area for Observation room with 1 bed	As above for 1 bed in ward
(22)	Area for nursing station	120 sq.ft.
(23)	Area for RMO's room including toilet	150 sq.ft.
(24)	Delivery room with 2 tables including NBCC of 50 sq.ft	170 sq.ft. (with additional 60 sq.ft. per additional table).
(25)	Collection centre	80 sq.ft
(26)	Small laboratory	160 sq.ft.
(27)	Medium laboratory	200 sq.ft.
(28)	Large Laboratory	240 sq.ft.
(29)	X Ray lab with dark room facility	270 sq.ft.
(30)	USG lab	120 sq.ft.
(31)	TMT Lab	120 sq.ft
(32)	ECG Lab	80 sq.ft
(33)	Medicine store of Nursing/maternity home	90 sq.ft
(34)	Any other space not mentioned above	240 sq.ft

SCHEDULE II

Standards for Service Provider

[See rule 6 and 7]

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. 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.

1.3. All the medical, nursing and paramedical /allied-medical professional of the clinical establishment who are already registered with councils of other state should be registered with the respective councils of West Bengal within 90 days of commencement of this rule within a reasonable period of time as notified by the concerned authorities. If there is no such council in the state of West Bengal, registration certificate awarded by such councils of other state or All India Council may be considered as valid for the purpose of this act. They should have adequate communication skill and should be able to speak in Bengali (and Nepali in GTA area).

1.4. No staff on shift duty should be on-duty for more than 12 continuous hours in a day (24 hour period) so that every staff remains reasonably alert, attentive and energetic enough to respond to all needs of a patient.

2. Medical Staff :

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

Illustration. (a) One Ophthalmologist in case of eye clinic; (b) One dental surgeon in case of Dental clinic; (c) one Radiologist in case of X-Ray lab; (d) One sonologist/radiologist in case of Ultrasonography 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 notified 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) Resident Medical Officers (RMO). As soon as a patient arrives at a clinical establishment he or she should immediately be attended by a Resident Medical Officer or consultant.

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 her opinion or advice or to perform a particular procedure in her capacity of being a Consultant having specialized knowledge, skill, expertise or experience.

2.5. There should be at least one doctor to act as Resident Medical Officer (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 x 3 that is 6 Resident Medical Officers (RMO) plus reserve.

2.6. In case of nursing home with OT facilities, at least one Resident Medical Officer (RMO) or one consultant should be available to assist the consultant-surgeon which conducting any major operation. In case of maternity home, every delivery should be conducted /supervised by a Resident Medical Officer (RMO) or one consultant- obstetrician and every delivery case of high-risk pregnancy/ fetal distress should be attended by a pediatrician.

2.7. In addition to the Resident Medical Officer (RMO), 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 consultant-physician available on call round the clock. A nursing home providing surgical facilities should have a consultant-surgeon and anesthetist available on call round the clock..

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

3. Nursing staff :

3.1. There should be one qualified registered 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 and if on different floors then in same proportion on different floors.

Illustration. A twenty bedded Nursing home without any special care units with a 3-shifts arrangement should have at least 4 x 3 that is 12 Nurses plus reserve.

3.2. There should be at least one qualified (at least GNM) nurse on duty round the clock per labor /OT table. The nurses for operation theatres and special care units need additional training/experience/expertise.

3.3. One of the senior nursing staff should be entrusted with the sterilization and should act as Delivery suite/OT suite in-charge.

4. Allied- Medical /Paramedical Staff :

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

Illustration.; (a) physiotherapist in case of physiotherapy clinic; (b) Medical Technician/Technologist (Lab) in case of Pathology lab; (c) Medical Technician/Technologist (X-Ray) in case X-Ray lab etc.

4.2. With effect from such notified date, the clinical establishment shall provide for Minimum One OT technician, One Anaesthesia Technician in per OT and other such type and number of Allied-Medical or paramedical professional as may be notified

4.3. No paramedical or Allied-Medical professional should run the establishment or practice his profession without the direction or supervision of a registered medical/dental practitioner.

Illustration. In case of physiotherapy clinic, it should be under the direction or supervision of a registered medial practitioner.

5. Healthcare Assistant/attendant and Sweeper :

5.1. Depending upon the nature of service offered by the clinical establishment and the expected workload, at least one on-duty qualified Healthcare Assistant/attendant should be engaged.

Illustration 1. Each OPD clinic or laboratory should have at least one helping hand General Duty Attendant (preferably female). There should be at least one General Duty Attendant (Female) for obstetrics and gynaecology OPD; one GDA for surgical and medical OPD.

Illustration 2. In case of all inpatient based facilities, there should be (a) at least one Bedside 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 Midwifery Assistant (Female) for labour room available round the clock; one Healthcare Assistant/attendant for O.T. suite available round the clock; (c) 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.

5.2. With effect from such date, the clinical establishment shall provide for such type and number of Healthcare Assistant/ attendant having such qualification as may be notified.

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 to the satisfaction of the Licensing Authority.

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

7. Non-Medical technical staff :

Depending upon the type of facilities being offered, extent of outsourcing etc, support staff like Cook, Plumber, Electrician, Telephone operator, Central heating/AC operators, Driver 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 be at least two resident medical officers exclusively for Critical 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. To supervise the Laboratory work, to interpret and give the result; every Small Laboratory should have at least one registered medical practitioner of modern medicine having minimum qualification of a DCP or equivalent post-graduate diploma or a MBBS degree with at least five years experience in laboratory medicine

3.2. To carry-out the laboratory work; every Small Laboratory should also have at least one qualified medical technician/ technologist on duty having minimum qualification of 2 years diploma in Medical Laboratory technology like DMLT or equivalent and at least one Healthcare attendant/assistant.

3.3. To supervise the Laboratory work, to interpret and give the result, every Medium Laboratory should have (a) all the medical professionals as mentioned under the small laboratory; and (b) at least another qualified person having a minimum qualification of MD (Biochemistry) or equivalent post-graduate degree like MSc (Medical Biochemistry).

3.4. To carry-out the laboratory work; every Medium Laboratory should also have (a) all the paramedical professionals as mentioned under the small laboratory; and (b) at least another qualified medical technician/ technologist on duty having minimum qualification of 3 years degree in Medical Laboratory technology like BMLT or 2 years post-graduate diploma like PGMLT or equivalent.

3.5. To supervise the Laboratory work, to interpret and give the result; 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 like MSc(Medical Microbiology); (c) at least one registered medical practitioner having minimum qualification of a MD (Biochemistry) or equivalent post-graduate degree like MSc (Medical Biochemistry).

3.6. To carry-out the laboratory work; every large Laboratory should also have (a) all the paramedical professionals as mentioned under the medium laboratory; and (b) at least another qualified medical technician /technologist on duty having minimum qualification of 2 years post-graduate degree in Medical Laboratory technology like MSc(MLT), MSc (Bio-med Laboratory Science and Management) or equivalent.

3.7. Multi-disciplinary laboratories should identify a group leader, with specific qualification for each. One medical technician /technologist with adequate qualification/experience shall act as in-charge of quality control of lab work in cases of laboratories having more than one medical technician /technologist.

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

3.8. 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/technologist or support staff having Higher secondary (with bioscience) certificate with a minimum five year experience in an established medium sized laboratory or certificate in Laboratory-Assistant (Blood transfusion/Phlebotomy) or such relevant courses.

4. X-ray Lab :

4.1. The X-ray lab should have at least one Radiologist or registered medical practitioner of modern medicine having minimum qualification of a DMRD or equivalent post-graduate diploma/degree to supervise the test, to interpret and give the result.

4.2. The Radiologist should have at least one helping hand preferably one on-duty qualified paramedic like Radiographer or Medical Technician (X-Ray) in that X-Ray lab and at least one GDA (preferably female) in that X-Ray Lab.

5. Ultrasonography Laboratory :

5.1. Notwithstanding anything contained in the PC-PNDT Act, the Ultrasonography lab/clinic should have at least one Radiologist or a Sonologist to perform the test, to interpret and give the result.

Explanation 2. 'Sonologist' means a registered Medical Practitioner of modern medicine as defined under PC-PNDT Act.

5.2. The Radiologist/ Sonologist should have at least one helping hand preferably one GDA (preferably female) in that Ultrasonography Laboratory.

6. Clinical Physiological test laboratory :

6.1. In case of laboratories conducting Electro-cardiography, Electro-encephalography; Electromyography or other Clinical Physiological tests, there should be at least one registered medical practitioner of modern medicine having minimum qualification of a post-graduate diploma/degree in physiology or equivalent in the relevant field to supervise/ perform/conduct the test, to interpret and give the result

6.2. The Physiologist should have at least one helping hand preferably one on-duty qualified paramedic like Medical Technician (ECG), Medical Technician (EMG) etc. and at least one GDA (preferably female)in that laboratory.

7. Other Diagnostic Imaging Laboratory :

7.1. In case of other Diagnostic Imaging Laboratory, there should be at least one registered medical practitioner of modern medicine having minimum qualification of a post-graduate diploma/degree in concerned discipline to supervise/ perform/conduct the test, to interpret and give the result

7.2. The Doctor of such lab should have at least one helping hand preferably one on-duty Medical Technician qualified in concerned discipline and at least one GDA (preferably female).

SCHEDULE III

Standards for Equipment, Medical Devices, Medical Supplies

[See rule 17]

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.

1.1.1. 'Medical device' means any instrument, apparatus, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: (i) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease, (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury, (c) investigation, replacement, modification, or support of the anatomy or of a physiological process, (d) supporting or sustaining life, (e) control of conception, (f) disinfection of medical devices, (g) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and (ii) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

1.1.2. 'Medical supplies' means artificial limbs, teeth or eyes, or any prosthesis, orthopedic or surgical appliances or supplies, optical appliances, supplies or equipment, devices for aid of hearing, or any other medical devices, drugs, medication or any other goods, consumables, or supplies prescribed for medical diagnosis, care or treatment.

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.

1.5. 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.

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

1.7. The list of equipment and medical supplies mentioned in this schedule is only indicative in nature not exhaustive. The Licensing authority shall have the power to add, delete or modify the name or number of required articles mentioned in the list if he is reasonably satisfied.

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) Two standby Oxygen cylinders for each case in the 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 flow meter 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 for 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 for each Delivery room/ Recovery room/ Emergency area/ward. In these entire areas one O2 cylinder should be kept as spare.

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

2.4. 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 : OPD Facilities

1. Examination /Treatment /Dressing room of OPD and IPD facilities :

1.1. Each Examination Room should be provided with equipment with such minimum numbers like: (a) Chair for consultants (One for each consulting room); (b) Chairs for patient and persons accompanying patient (Two/three per consulting room and casualty); (c) Revolving stool (metallic - One for each consulting room); (d) Doctor's table (One for each consulting room); (e) Examination table with safe footsteps, mattress and pillow (One for each consulting rooms); (f) Examination table for Obstetrics and Gynaecology clinic (with appropriate light fixture and stool for doctor); (g) X-ray viewing box; (h) Bowls; (i) Wash basin with liquid soap dispenser and towel rail (One in each consulting room and in casualty), (j) Weighing machine; Screens for every examination table etc.

1.2. Each Examination Room should be provided with instruments and medical supplies for patient examination like (a) torch, (b) tongue depressor, (c) stethoscope, (d) Blood Pressure Apparatus, (e) Thermometer, (f) Kidney trays, (g) Proctoscope, (small medium and large for surgical OPD), (h) Percussion hammer, (i) Tuning fork, (j) Anterior vaginal wall retractor, Cusco's speculum, Sims speculum (For Obstetrics and Gynaecology OPD); (k) Sterilizer; (l) Gloves; (m) Disposable Syringes, (n) Gloves and Masks; (o) Towels, (p) Bed-sheets; (q) Post exposure Prophylactic kit, (r) First Aid equipments, (s) emergency Drugs etc.

1.3. Treatment/Dressing room and Injection room should be provided with Equipment and Furniture like: (a) IV stands; (b) Examination table with mattress to carry out dressings (c) Dressing trolley; (d) Ambu bag; (e) Suction apparatus; (f) Oxygen cylinder with flowmeter; (g) One trolley for oxygen cylinder; (h) Laryngoscope with blades; (i) Resuscitation measures (j) 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 cc); 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. Steroid; Inj. 25% glucose I.V. fluids etc.

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

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; suture materials; One bowl; Lubricating jelly etc.

Part III : IPD Facilities

1. General :

1.1. 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 and quality of equipment and medical supplies like (a) equipment for emergency (b) equipment for ward (c) Trolley and Stretcher; (d) Hospital furniture; (e) Linen etc.

1.2. Each IPD facility should be provided with such equipments for emergency like suction machine with generator connection and standby foot suction machine; all instruments /equipments required for emergency and Basic life support (CPR); Emergency Tray; ECG Machine; Dressing trolley; Resuscitation tray.

1.3. Each IPD facility with OT should have at least one OT table per 30 beds of part thereof.

1.4. In case of IPD facility having 30 or more beds, it should be provided such equipment and medical supplies like : (a) Desk/counter; (b) Wall clock; (c) Wash basin with liquid soap dispenser and towel rail; (d) Sink unit; (e) Notice boards; (f) Firefighting equipment; (g) Enema can-set (One per ten beds); (h) Vohler-Braun splint (for limb elevation); (i) Ophthalmoscope; (j) Torch (One large size -3 batteries and one small size -pin-point source); (k) Percussion hammer; (l) Laryngoscope with blades of all sizes; (m) Medicine trolley; (n) X-ray viewing box for one X-ray plate; (o) Refrigerator 300 litres; (p) Weighing machine; (q) Speculum and retractors; (r) Height scale (s) Stethoscope; (t) Glucometer; (u) Suture removal sets; (v) Dressing sets; (w) Venesection sets etc.

1.5. Each IPD facility should be provided with such Trolley and Stretcher for each ward as follows: Minimum of two stretchers/ trolleys and two wheel chairs should be provided. These stretchers/ trolleys/ wheel chairs should always be functional in noiseless condition.

1.6. Each IPD facility 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 separate IV stands need not be provided); drip stand; One dustbin with lid; Indoor papers stand/holder.

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

1.8. Each Ward store should be provided such equipment and medical supplies like (a) Storage racks; (b) Oxygen cylinders; (c) IV stands; (d) Suction apparatus; (e) IV fluids and IV sets; (f) Foley's catheters with urine bags; (g) Naso-gastric tubes etc.

1.9. Each IPD facility having Operation theatre should be provided with OT equipment like: (a) Anaesthesia machine with complete accessories; (b) Multi Channel Monitor; (c) Pulse Oxymeter; (d) Suction apparatus – Electric/ Battery/ Foot operated; (e) Operating Room lights; (f) Bipolar Electro –Surgical Cautery; (g) Resuscitation Trolley; (h) Facilities for Blood Transfusion; (i) Surgical operating instruments for type of surgery which is being conducted in the Nursing Home; (j) High pressure autoclave with modern system of quick sterilization of surgical instruments, operating linen and other items; Defibrillator with automatic external defibrillator and Ventilator etc.

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

2. Maternity Home :

2.1. All Maternity homes should have at least one Labor table and one OT table per 15 beds or of part thereof and one OT table per 30 beds or of part thereof.

2.2. All Maternity home should have the following additional instruments and equipment for emergency obstetric care including LUCS at the rate of at least one such per labour table like:, Low mid cavity foreceps/ Kielland foreceps, Vacuum extractor and suction machine; D and 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.

2.3. All Maternity home should have the following additional instruments and equipment for Labour Room and Newborn corner at the rate of at least one such per labour table like: Delivery set; Doppler Foetal monitor; suction machine with generator connection and standby foot suction machine; Neonatal Resuscitation kit; oxygen cylinder; radiant warmer; phototherapy unit weighing machine for the babies.

3. CCU / HDU :

3.1. 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.

3.2. It should be provided with adequate quantity and 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 CCU 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 Transcutaneous pacing facility; (8) ICU Beds (Shock Proof) (Fibre) Electronically Maneuvered 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 CCU and 1 for HDU; (12) Pulse Oxymeter (Small Units 2 as stand-by units; (13) Refrigerator (1 per CCU) with freezer compartment; (14) HD Machines (2 per CCU) 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 CCU); (17) Intermittent Leg Compressing Machine to prevent DVT (2 per CCU); (18) Airbeds to prevent Bed sores (1 per 2 beds); (19) Intubating Video scope to make difficult intubations easy (1 per CCU); (20) Glucometer (2 for ICU, 1 for HDU); (21) ICU Dedicated Ultrasound and Echo machine (1 per CCU) with recent advances to look instantly even at odd hours. Vascular filling, central lines, etc,; (22) Bedside X ray (1 per CCU); (23) ETO sterilization to sterilize ICU disposables regularly (1 per CCU); (24) Spinal Board for spine trauma patients (2 per CCU); (25) Rigid Cervical Spine collars for stabilizing cervical spine (2 per CCU); (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 CCU); (30) Fibro-optic Bronchoscope (1 per CCU); (31) Computers with LAN, Internet facility and printer to be connected with all departments.

Part IV : Pathology Laboratory

1. General : Should be as per NABL accredited norms

1.1. Equipment performance should be verified from Internal Quality Control assessment and External Quality Assessment. 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

1.2. In case of large laboratory, all analytical equipment should be calibrated and calibration certificate provided by authorized agency. 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).

1.3. The pathology laboratory should be provided with the Furniture & Fixtures as per following norms: (a) 600mm wide and 900mm high bench/table/counter/cabinet 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 under counter cabinet.

1.4. 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. as per standards of the manufacturer of the machine to be used for in-house procedures should be defined in SOP. Those reagents are to be recorded in stock register.

1.5. 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.

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

1.7. 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.

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

1.9. 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.

2. Specific :

2.1. 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.

2.2. 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, slide trays, test tube stands, stop watch etc.

2.3. 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.

2.4. 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 and 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.

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

2.6. Equipment for Haematology: Microscope; Cell Chamber; Cell Counter, Haemocytometer; Centrifuge etc.

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

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

2.9. 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 provisions as per Environmental Protection Act.

Part V : Diagnostic Imaging Laboratories

1. X-Ray laboratory :

1.1. 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.

1.2. 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 laboratory 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. and other such as per AERB guideline.

1.3. The laboratory 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.

1.4. 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 must for Dark room. There should be appropriate resuscitation equipment and drugs available on site for management of contrast reactions.

1.5. 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.

1.6. 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.

1.7. Notwithstanding anything mentioned above, X-Ray lab with digital X-ray facilities, appropriate equipment should be provided.

2. Mamography Laboratory :

2.1. There should be dedicated mammographic equipment with a grid and appropriate compression device. Mammographic biopsy attachment is desirable. (Certificate of "Type Approval" to be obtained from AERB).

2.2. 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) Artifact evaluation; (f) Breast compression deice check; (g) Screen cleanliness check.

3. Ultrasongraphy :

3.1. The equipment should be registered under the Pre-conception and Prenatal-diagnostic Techniques Act and rules and the certificate should be displayed along with mandatory display. 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.

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

4. Bone mineral densitometry :

4.1. 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.

4.2. 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.

5. MRI :

5.1. 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.

5.2. 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.

5.3. The equipment should be registered under the PC-PNDT act as per rules and the certificate should be displayed along with mandatory display.

6. CT scan :

6.1. 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.

6.2. 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).

6.3. 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.

7. Interventional radiology :

7.1. 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.

7.2. 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.

7.3. 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.

7.4. 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).

SCHEDULE IV

Standards for Water, Sanitation, Hygiene, Safety & Security

[See rule 21]

Part I. Introduction

1. General :

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

1.2. Service-provider should be thoroughly trained in managing fire, and non-fire emergencies such as large spillage, gas leakage etc.

1.3. Periodic checking of all safety equipment and accessories should be ensured.

1.4. Accident/incident/injuries record of service-provider and service-recipient, and public 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.

1.5. Following sentinel events should be recorded, registered and reported to the authorities: (a) deaths of patients of the clinical establishment from unexplained cause or under suspicious circumstances, assault, or abduction of any patient, attempt of suicide by any patient; events of missing presumed to be absconding patient that are required to be reported to police; (b) fires in the clinical establishment resulting in death or personal injury or damage to the property; or (c) any act of violence or damage to the property as specified in the West Bengal Medical service persons and Medicare Service Institution (Prevention of Violence and Damage to Property Act, 2009 [West Bengal Act XI of 2009]; or (d) malfunction or intentional or accidental misuse of patient care equipment that occurs during treatment or diagnosis of a patient of the clinical establishment and that did, or if not averted would, have significant adverse effect on the patient or staff of the clinical establishment; or (e) confirmed or suspected outbreak of any disease; or (f) any form of closure of suspension of work; (g) any other sentinel events as may be notified.

2. Location and surroundings :

2.1. The clinical establishment should be situated in a site having clean and 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.

Explanation: 1. The term "Unsanitary condition" means a condition or circumstance: (a) that is, or may be, or might become injurious to health; or (b) that prevents or hinders the suppression of disease; or (c) that contaminates or pollutes, or may contaminate or pollute food, air, or water; or (d) that might render food, air, or water injurious to the health of any person; and includes a nuisance and any circumstance or condition declared to be an unsanitary condition by notification.

Explanation: 2. The term "Filth" means: (a) night soil and other contents of latrines cesspools and drain; or (b) dung and the refuse of useless or offensive material thrown out in consequence of any process of manufacture, industry or trade; or (c) putrid and putrefying substances and (d) all other substances causing danger to the public health.

Explanation 3. The term "Nuisance" includes any act, omission, place or thing which causes or is likely to cause injury, danger, annoyance or harassment offence to the sense of sight, smell or hearing or disturbance to rest or sleep or which is or may be dangerous to life or injurious to the health or property of the public or the people in general who dwell or occupy property in the vicinity or person or persons who may have occasion to use any public right.

2.2. 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 appropriate authority.

2.3. 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 Environmental Protection Act and other relevant Acts and rules.

2.4. No clinical establishment shall be allowed to function from an unsafe building.

Explanation: Unsafe Building is a building which (a) is structurally unsafe, (b) is not sanitary; (c) is not provided with adequate means of egress; (d) constitutes a fire hazard; (e) is dangerous to human life; and (f) in relation to its existing use constitutes a hazard to safety or health or public welfare by reasons of inadequate maintenance, dilapidation or abandonment.

2.5. The clinical establishment shall not conduct in any way which may lead to environmental problems including unsanitary condition, filth or nuisance.

3. Health, Clothing and Sanitary Requirements of staff :

The staff should be free from contagious disease and should be provided with clean uniforms suitable to the nature of their duties. The staff should be medically examined at the time of employment and periodically so examined thereafter. The clinical establishment should generate and maintain proper records thereof.

4. Sanitation and 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. Arrangement should be made for sanitary fitments as mentioned in this schedule. There should be adequate Sewage Disposal arrangement.

5. General Water Supply :

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

5.2. 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.

5.3. 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.

5.4. In case of inpatient facilities with 30 or more 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.

6. Signage :

The clinical establishment should have 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) public utilities like toilet, water fountain etc, (d) signs to delineate public areas from area of restricted access etc;

7. Standard Fire safety measures :

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

7.2. Adequate fire/ smoke detection equipment; extinguishers etc. should be readily available in the premises.

8. Standard Biosafety Measures :

8.1. 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.

8.2. Gloves should be worn for 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.

8.3. 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.

8.4. 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.

8.5. The clinical establishment shall comply with all the provisions of Bio-Medical waste management handling rules as applicable for that type of establishment.

9. Safety measures against Disaster :

It should be provided as per IPHS guideline.

Explanation. "Disaster" and "Disaster Management" shall have the meaning as defined under The Disaster Management Act, 2005 [Act 53 of 2005].

10. Personal Security :

10.1. Before engaging or empanelling anyone under rule 8 as service provider particularly who will have direct access or provide direct services to a patient, the clinical establishment shall require that person to submit to a background search particularly related to criminal history and patient abuse background search.

Explanation. 'Direct access' means physical access to a patient or resident and "direct services" means services provided to a patient or resident, which access or service gives the provider an opportunity to commit abuse or neglect or misappropriate the patient's property.

10.2. In case of hospital, adequate number of private security guard, preferably under the contract with a private security agency having license under Private Security Agencies (Regulation) Act, 2005 [Act 29 of 2005], should be provided.

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 as 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 separate toilet facilities in case it carries out procedures like IVP, Barium X-ray, etc.

3.2. Sanitary Fitments for IPD and 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 forward 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 patient and the environment from hazardous materials in order to minimize (a) the risk of persons from various chemicals, infectious materials, fire hazard, gas leak etc. and (b) the risk of environment 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).

4.3. 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. 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.

4.4. Biohazard symbol should be used on all such 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.

SCHEDULE V

Standard for Operating Procedures

[See rule [8, 9, and 10]

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.

Explanation. 'medico-legal case' means any medical case which has legal implications either of a civil or criminal nature, and includes but is not limited to cases relating to accidents, assault, sexual assault, suicide, attempt to murder, poisoning, injuries on account of domestic violence, injuries on workers during course of employment.

1.3. The clinical establishment shall follow the standard procedure regarding display of information as mentioned in rule 22.

Explanation: "display of information" means any form of display and includes any advertisement (a) printed in any medium for the communication of information; (b) appearing in, communicated through or retrievable from, any mass medium, electronic or otherwise; or (c) contained in any medium for communication produced or for use by an institution.

1.4. The licensing authority shall not allow the clinical establishments to be registered with any improper or undesirable name including the words and abbreviation thereof if (a) such name is identical with the name of any society/corporation or local body which has been set up by the Central or State Government under any law for the time being in force; or (b) such name gives the impression of the patronage of Central Government or State Government; or (c) such name is too nearly resembling a name of body corporation or local authority set up by Government under any law for the time being in force; or (d) such name is connoting Government's participation or patronage unless circumstances justify it; or (e) such name is resembling the name of a healthcare establishment run by the Public sector agencies; or (f) such name is not conforming to the clinical establishment's function and the facilities available and services offered thereof; or (g) such name is containing any statement which states, suggests, or implies a false or misleading claim in any particular concerning the services offered thereof (h) such name is not offensive to any section of people, e.g., proposed name does not contain profanity or words or phrases that are generally considered a slur against an ethnic group, religion, gender or heredity.

1.5. The clinical establishment shall ensure that the name of the clinical establishment or part thereof is not confusing, misleading or undesirable for anyone using that clinical establishment.

1.6. for effective implementation of quality assurance programme under sub-rule (10) of rule 8, shall, inter-alia, refer to: (a) the composition of the committee including the authority, which will be in-charge of such; (b) the requisite qualification and terms of office for the committee members including experts; (c) the power and function of the committee; (d) the periodicity and manner of such assessment and other standard operation procedures to be followed by the Committee; (e) the manner in which the clinical establishment will be participating in that scheme; (f) the financial implications including recovery of expenses of such committee; (g) any such other details which may result in an of such scheme of reimbursement of expenses incurred.

1.7. The programme mentioned above and subsequent changes, if any, made thereto from time to time, shall be notified.

1.8. The one-word descriptions mentioned under sub-rule (10) of rule (9) are not medical terms, and they are more art than science. They're based on a doctor's best judgment of a patient's condition, as relayed to hospital spokespersons.

Explanation 1. The term 'Undetermined' means a condition when the Patient is awaiting physician and assessment.

Explanation 2. The term 'Good' means a condition when the 'Vital signs' are stable and within normal limits; the patient is conscious and comfortable; and Indicators are excellent.

Explanation 3. The term 'Fair' means a condition when the 'Vital signs' are stable and within normal limits; Patient is conscious, but may be uncomfortable; and/or Indicators are favorable.

Explanation 4. The term 'Serious' means a condition when the 'Vital signs' may be unstable and not within normal limits; Patient is acutely ill; and/or Indicators are questionable.

Explanation 5. The term 'Critical' means a condition when the 'Vital signs' are unstable and not within normal limits; Patient may be unconscious and/or the Indicators are unfavorable.

Explanation 6. The term "vital signs" means indicators such as blood pressure, pulse, temperature, and respiration.

1.9. Regarding obtaining consent mentioned under sub-rule (5) of rule 10, if such third party refuses to give consent to a healthcare intervention necessary to save the life or limb of a patient incapable or giving consent, the appropriate Court of law, upon the petition of the service-provider or any person interested in the welfare of the patient, in a summary proceeding, may issue an order giving consent.

1.10. Regarding mentioned under sub-rule (6) of rule 10, whenever possible, the clinical establishment shall either engage a professional counselor or orient the staff regarding the scientific techniques of counseling to obtain informed consent.

1.11. Service of such counselor may be utilized in different situation which includes but not limited to obtaining informed consent related to (i) HIV related procedures and testing, (ii) transfer or referral of patient; (iii) treatment compliance of patient; (iv) Family planning measures; (iv) organ transplant; (v) care and treatment of terminal illness etc.

Part II: OPD and IPD Facilities

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. Adequate and wholesome diet should be provided to the patients as per advice of the attending Doctor and Dietician and hygiene with 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.

1.2. All the Operating Procedure standards as mentioned in Chapter II should be maintained.

Part III: Pathology Laboratory Facilities

1. Collection :

1.1. Appropriate counseling 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 except phlebotomy.

1.2. All pathology Laboratories including Collection centers should have a "primary specimen collection manual", containing information on (a) patient preparation before specimen collection (if any); (b) exact methodology of specimen collection; and (c) 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.) should be used wherever required. Specimen should be sent to the reference laboratory along with the proper requisition form.

2. Analytical work or Test :

2.1. The laboratory should maintain an accession list which 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, lab 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. The laboratory should maintain a worksheet which 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; (c) Findings and result; (d) Name and signature of the analyst.

2.4. Laboratory number assigned to the specimen should be mentioned in the worksheet before sending the specimen to the analyst.

2.5. The specimen should be analyzed according to the plan mentioned in the Standard Operating Procedure (SOP). Any deviations from the analysis plan should be mentioned giving reasons. Wherever applicable the laboratories should use requisition form cum worksheet instead of two separate forms.

3. Reporting Test Results :

Test results approved, signed and dated by the authorized signatory should be made available in a sealed cover to authorized person(s) like Patient/Patient party/Medical attendant only. 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 year. All pathological laboratories should provide for a mechanism of 'Critical values reporting' and maintain the Standard Operating Procedure (SOP) thereof. The Government may publish ranges of such critical values by notification.

Explanation. 'Critical values (or panic values) reporting' is the mechanism by which potentially life-threatening laboratory results are reported to responsible healthcare professionals without any delay.

4. Quality Control :

Medium/large labs should adopt the external and internal quality control measures to have accuracy and precision. At least two samples per month should be sent to the other registered accredited labs and the results should be compared and recorded properly in the Quality Control Register, which should be produced on demand for inspection.

Part IV: Diagnostic 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, no patient party should 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. In clinics where Radiographic contrast is administered, adequate resuscitation drugs should be available. 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 Milliamp Seconds (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/TLD 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 radiation only after due consideration by the radiologist of the relative risks and benefits of such exposure and informed consent of the mother. A warning that "X-ray's are potentially harmful and should be done only when advised by the attending doctor" should be displayed in English and local language with warning that "pregnant ladies and small children and infants should not stand near the X-ray machine as a spectator/ patient party with the patient when he/she is X-rayed".

SCHEDULE VI

Standards for Records, Reports & Registers

[See rule 18 & 22]

Part I. Introduction

1. General :

1.1. The clinical establishment should maintain the standards and norms related to Records, Reports and Registers as specified in this schedule or any such standards and norms as may be notified from time to time. The state government may publish standard model formats for such registers by notification from time to time.

1.2. All clinical establishments shall generate and maintain following mandatory registers and records - (a) a staff register under rule 6; (b) a staff attendance register under rule 6; (c) stock-book under rule 17; (d) Dead stock register under rule 17; (e) logbook of major equipment under rule 17; (f) books of account and cashbook under rule 19; (g) Service/OPD register under rule 11; (h) bio-medical waste disposal register under rule 21; (i) Police intimation register under rule 23; (j) Inspection book (register) under rule 37; (k) grievance redressal register under rule 28; and (l) any other records or registers as may be notified.

1.3. All clinical establishments with in-patient facilities including day-care centres shall generate and maintain following additional mandatory registers and records - (a) a record of case-sheet of every patient as per rule 11; (b) an admission/ In-patient register for in-patient as per rule 12; (c) Birth register [Log book] under rule 12, if applicable; (d) OT logbook (register) under rule 13, if applicable; (e) register(s) related to procedure under Acts like Pre-conception and Pre-natal Diagnostic Techniques Act under rule 13, if applicable; (f) Referral register under rule 16; (g) Death Register under rule 12; (h) records related to free treatment & concession under rule 20, if applicable; and (i) any other records or registers as may be notified.

1.4. The clinical establishment shall generate, maintain and submit following mandatory reports - (a) Performance report under rule 11; (b) report related to procedures like MTP under rule 13; (c) Annual reports of free treatment and concession, if any, under rule 20; (d) reports of sentinel events, if any, under rule 23; (e) reports of National/state health programmes under rule 26; (f) reports of notifiable diseases, if any, under rule 26; (g) reports of extract of grievance redressal register under rule 28; and (h) any other reports as may be notified.

2. Maintenance :

2.1. For maintaining various ledgers / registers, the guidelines and protocol as may be notified should be followed strictly. Medico legal documents should be prepared and maintained then and there properly and promptly and be kept safely and separately. Care should be taken to leave none of them incomplete. Statutory Format should be used for preparing those and be identified by marking "MLC" at the right hand top corner of the cover page or identified by any colour code.

2.2. A 'Record keeping Register' should be maintained in all section / wards of the clinical establishment 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.

2.3. 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. The overall responsibilities of record keeping should lie with the licensee.

3. Preservation and Disposal :

3.1. All records should ordinarily be preserved in a suitable manner for a minimum period as per the prevalent orders and notifications.

3.2. 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.

3.3. When preservation period of a document is over, it should be treated as inactive and should be disposed in a proper manner/method. The custodian of that document 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. The procedures of disposal and destruction should be transparent and the file regarding this should be kept safely as this could be produced before the licensing authority on his demand.

Part II: Statutory Forms

Statutory CE FORM I: Application for Registration

[See rule 34]

Part –A

Common for all establishments including Single Doctor Establishments. [will be applicable to a Medical Clinic used for or intended to be used for consultation and treatment by a registered medical practitioner but shall not include any place utilized by a registered medical practitioner solely for the purpose of consultation and advice**]**

01. Application Acknowledgement: (For office use only)

01A. Acknowledgement No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
01B. Acknowledgement Date ☐☐ ☐☐ ☐☐☐☐

02. Purpose of Application:

02A. Applied for: New License ☐, 02B. Renewal ☐, 02C. Change or modification of particulars ☐, 02D. Composite License ☐, 02E. Issuance of Duplicate Copy ☐, 02F. Submission of additional license fee ☐,

02F. 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 (if any):

04A. Not applicable ☐, Applicable ☐

04B. If applicable, License:

04B1. License 1: ☐☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐☐,
04B2. License 2: ☐☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐☐,
04B3. License 3: ☐☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐☐,
04B4. License 4: ☐☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐☐,
04B5. License 5: ☐☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐☐,
04B6. License 6: ☐☐☐☐☐ - ☐☐☐☐ - ☐☐☐☐☐,

03C. Copy/ copies of existing license enclosed as enclosure ☐☐

03D. Particulars for any additional license is enclosed as separate sheet in enclosure ☐☐

05. Address of the Clinical Establishment:

05A. ☐☐

05B. Pin Code: ☐☐☐☐☐☐☐
05C. PS: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
05D. District : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

05E. E.mail ID: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

05F. Ph No. 05F1. (Office) ☐☐☐☐☐☐☐☐☐☐☐☐
05F2. (Residence) ☐☐☐☐☐☐☐☐☐☐
05F3. (Mobile) ☐☐☐☐☐☐☐☐☐☐

05G. Nearest Landmark: ☐☐

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 ☐

06E. Located at vulnerable area: Yes ☐, No ☐

07. Name of the Applicant:

07A. Title ☐ ☐☐

07B. First ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

07C. Middle ☐☐☐☐☐☐☐☐☐☐☐☐

07D. Last ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

07E. Son/Daughter/wife of: 07E1. Title ☐☐☐

07E2. First ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

07E3.Middle ☐☐☐☐☐☐☐☐☐☐☐☐

07E4. Last ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

08. Address of the Applicant:

08A. ☐☐

08B. Pin Code: ☐☐☐☐☐☐☐ 08C. PS: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

08D. District : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

08E. E.mail ID: ☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐

08F. Ph No. 04E1. (Office) ☐☐☐☐☐☐☐☐☐☐☐☐

08E2. (Residence) ☐☐☐☐☐☐☐☐☐☐

08E3. (Mobile) ☐☐☐☐☐☐☐☐☐☐

08G. Nearest Landmark: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

09. System of Medicine Offered: (Multiple options possible)

Allopathy ☐, Ayurveda ☐, Unani ☐, Siddha ☐, Homeopathy ☐, Naturopathy ☐, Yoga ☐,

Any other ☐ (Please specify ____)

10. Subsystem of Medicine Offered: (Multiple options possible)

10A. Allopathy: General ☐, Specialty e.g. Medicine, Surgery, Pediatrics etc. ☐, Super-specialty e.g. Plastic Surgery, Pediatric Surgery etc. ☐, Dental ☐; or Any other Allopathy ☐ (Please specify ______________________________)

10B.Ayurveda: Ausadh Chikitsa ☐, Shalya Chikitsa ☐, Shodhan Chikitsa ☐, Rasayana ☐, Pathya Vyavastha ☐; Any other Ayurveda ☐ (Please specify ____)

10C. Unani: Matab ☐, Jarahat ☐, Ilaj-bit-Tadbeer ☐, Hifzan-e-Sehat ☐,

Any other Unani ☐ (Please specify ____)

10D. Siddha: Maruthuvam ☐, Sirappu Maruthuvam ☐, Varmam Thokknam & Yoga ☐,

Any other Siddha ☐ (Please specify ____)

10E.Homeopathy: General Homeopathy ☐,

Any other Homeopathy ☐ (Please specify ____)

10F. Naturopathy: External Therapies with natural modalities ☐, Internal Therapies ☐,

Any other Naturopathy ☐ (Please specify _____)

10G. Yoga: Ashtang Yoga ☐, Any other Yoga ☐

(Please specify _____)

11. Service facilities offered:

11A. Uni-facility ☐, or Multi-facility ☐

11B. If uni-facility then, service facility offered: Outpatient based Service ☐, or Inpatient based service ☐, or Diagnostic laboratory service ☐, or Diagnostic Imaging service ☐,

11C. If multi-facility then, service facility offered (Multiple options possible): Outpatient based Service ☐, and Inpatient based service ☐, and Diagnostic laboratory service ☐, and Diagnostic Imaging service ☐

11D. This is a single doctor establishment: Yes ☐, No ☐

12. Sanitation and hygiene requirements (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 report and registers requirements (Part I):

13A. Reports

13A1. Reports of National/state health programmes: Not applicable ☐, Applicable but not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 13A2. enclosure ☐☐

13A3. Reports of notifiable diseases: Not applicable ☐, Applicable but not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 13A4. enclosure ☐☐

13B. Registers

13B1. Service/Out-patient register: generated/maintained ☐ not generated/maintained ☐

13B2. Inspection book (register) generated/maintained ☐ not generated/maintained ☐ not applicable ☐

13B3. Police intimation register generated/maintained ☐ not generated/maintained ☐ not applicable ☐

14. Mandatory display requirements (Part I):

14A. Signboard at entrance and other places

14A1. The name **and** address of the establishment: Displayed ☐, Not displayed ☐

14A2. Clinical establishment license Number: Displayed ☐, Not displayed ☐, Not applicable (in case of new) ☐

14B. Display boards

14B1. Copy of clinical establishment license(s): Displayed ☐, Not displayed ☐, Not applicable (in case of new) ☐

14B2. The system(s) of Medicine practiced: Displayed ☐, Not displayed ☐

14B3. Types and availability of health care and other services: Displayed ☐, Not displayed ☐

15. License Fee:

15A. Exemption

15A1. Claim for exemption due to locality [under rule 40(5)]: Yes ☐, No ☐; if yes

15A2. Supporting document enclosed as enclosure no. ☐☐

15A3. Claim for exemption due to free treatment/concession [under rule 40(8)]: Yes ☐, No ☐; if yes

15A4. Supporting document enclosed as enclosure no. ☐☐

15B. License fee deposited with the application

15B1. Amount Rs. ☐☐☐☐ deposited vide 15B2. Challan No ☐☐☐☐☐☐☐☐☐☐☐☐ and
15B3. Date ☐☐☐☐☐☐☐☐ and

15B4. The copy of Treasury Challan enclosed as enclosure No. ☐☐

15.C. Subsequent additional license fee deposited as directed by the licensing authority

15C1. Amount Rs. ☐☐☐☐ deposited vide 15C2. Challan No ☐☐☐☐☐☐☐☐☐☐☐☐ and
15C3.Date ☐☐☐☐☐☐☐☐ and

15C4. The copy of Treasury Chalan enclosed as enclosure No. ☐☐

Part-B

(Only for establishments other than Single Doctor Establishments solely used for the purpose of consultation and advice)

16. Particulars of ownership:

16A. Individual Proprietorship ☐, Collective proprietorship or company or organization ☐

16B. 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

16B. In case of Collective proprietorship or company or organization, such organization is registered under a Central, Provincial or State Act ________________________________ (Please specify)

16C. Name of such organization: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐

16D. Supporting document for above statement enclosed as enclosure No. ☐☐

16E.In case of Collective proprietorship or company or organization, such organization is a branch of a Foreign Service provider or not: Yes ☐, No ☐

16F. Name of the Company (in case of collective proprietorship): ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

16G. Address of the company (in case of collective proprietorship):

16G1.☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐
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16G2. Pin Code: ☐☐☐☐☐☐☐ 17G3. PS: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

17G3. District : ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

16G4. E.mail ID: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

16G5. Ph No. (Office) ☐☐☐☐☐☐☐☐☐☐☐☐ 17G6. (Residence) ☐☐☐☐☐☐☐☐☐☐

16G7. (Mobile) ☐☐☐☐☐☐☐☐☐☐

16G8. Nearest Landmark: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

17. Particulars of service sub-Facilities offered:

17A. In case of Outpatient based Service:

17A1. Solo clinic ☐, 17A2. Polyclinic ☐, 17A3. Dental Clinic ☐, 17A4. Acupuncture Clinic ☐, 17A5. Physiotherapy Clinic ☐, 17A6. Occupational therapy Clinic ☐, 17A7. ☐, 17A8. Wellness/Fitness centre/clinic ☐, 17A9. Counseling Centre ☐, 17A10. any other clinic or OPD based service centre ☐

(Please specify ____________________________________);

17B. In case of Inpatient based Service:

17B1. Infertility Clinic ☐, 17B2. Dialysis Centre ☐, 17B3. MTP clinic ☐, 17B4. Any other Day care centre

(Please specify ____________________________________);

17B5.Maternity Home ☐, 17B6. Nursing Home/Hospital/Sanatorium ☐, 17B7 Any other IPD based service centre ☐ (Please specify ____________________________________)

17C. In case of Pathology laboratory service:

17C1. Collection centre ☐, 17C1. Small Laboratory ☐, 17C3. Medium Laboratory ☐, 17C4. Large Laboratory ☐, 17C5. Genetic laboratory, 17C6. Any other Pathology laboratory service ☐

(Please specify ____________________________________)

17D. In case of Diagnostic Imaging service:

17D1. X-Ray lab (Conventional) ☐, 17D2. X-Ray lab (Digital) ☐, 17D3. Mamography lab ☐, 17D4. Bone Densitometry lab ☐, 17D5. Ultrasonography lab ☐, 17D6. Colour Doppler Imaging lab ☐, 17D7. CT Scan lab ☐, 17D8. Magnetic Resonance Imaging (MRI) lab ☐, 17D9. Positron Emission Tomography (PET) Scan lab ☐, 17D10. Echo-cardiography lab ☐, 17D11. ECG lab ☐, 17D12. EEG lab ☐, 17D13. EMG lab ☐, 17D14. Other Clinical physiology lab ☐ (Please specify ____________________________________), 17D15. Any other Imaging Centre ☐ (Please specify ____________________________________)

18. Particulars of OPD based Service (if any):

18A. Provided ☐, Not provided ☐, if provided then:

18B. Practice: General Practice ☐, Specialty Practice ☐, Maternity Practice ☐

18C. Specialty Services: Single ☐, Multispecialty ☐, Super-specialty ☐

18D. No. of Consultation Room: 19D1. Existing: ☐☐☐☐; 19D2. Proposed: ☐☐☐☐;

18E. Name of the Specialties:

18E1. Specialty 1: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 18E2. Specialty 2: ☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 18E3. Specialty 3: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐ 18E4. Specialty 4: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 18E5. Specialty 5: ☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 18E6. Specialty 6: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐ 18E7. Particulars for any additional Specialty is enclosed as separate sheet in enclosure ☐☐

19. IPD based Service (if any):

19A. Provided ☐, Not provided ☐, if provided then:

19B. Practice: General Practice ☐, Specialty Practice ☐, Maternity Practice ☐

19C. Specialty Services: Uni-specialty ☐, multispecialty ☐, Super-specialty ☐

19D. Service: Operation Theatre ☐, Maternity ☐, Emergency Casualty ☐, Special care Unit ☐

19E. Name of the Specialties:

19E1. Specialty 1: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 19E2. Specialty 2: ☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 19E3. Specialty 3: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐ 19E4. Specialty 4: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 19E5. Specialty 5: ☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ 19E6. Specialty 6: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐

19E7. Particulars for any additional Specialty is enclosed as separate sheet in enclosure ☐☐

20. Particulars of Regulation/SOP of Clinical Establishment:

20A. Available ☐ and a copy of such regulation enclosed as enclosure No. ☐☐; 20B. Not available ☐

21. Accommodation requirements:

21A. Premises ownership: 21A1. Owned ☐, Rented ☐, Leased ☐, Granted rent free by the owner of the premises ☐ and 21A2. Copy of Rent receipt, agreement or any such supporting document enclosed as enclosure ☐☐

21B. Consent letter from owner of premises: 21B1. Not applicable ☐, applicable ☐ and 21B2. a copy enclosed as enclosure ☐☐

21C. Plan for construction or modification approved by the Appropriate Authority: 21C1.Not obtained or ☐ Obtained ☐ and 21C2. a Copy of approved Plan enclosed as enclosure No. ☐☐;

21D. Building completion certificate issued by the Appropriate Authority: 21D1. Not obtained ☐, or Obtained ☐ and 21D2. Copy of Building completion certificate enclosed as enclosure No. ☐☐

21E. The tax receipt [property tax] form the Local body: 21E1.Not available ☐, or available and 21E2. a copy enclosed as enclosure No. ☐☐

21F. Premises separate from rooms or spaces for private uses or other commercial uses: yes ☐, no ☐

22. Bed strength :

22A. Bed strength (excluding Special care/therapy facilities beds: 22A1. Existing: ☐☐☐☐,
22A2. Proposed: ☐☐☐☐

22B. Special care/therapy facilities beds: 22B1.Existing bed strength: ☐☐☐☐,
22B2. Proposed bed strength: ☐☐☐☐

22C. Special care/therapy facilities beds breakup:

22C1. Intensive Care/Therapy unit: 22C1A. Existing bed strength: ☐☐☐☐;
22C1B. Proposed bed strength: ☐☐☐☐

22C2. Intensive Coronary care Unit: 22C2A. Existing bed strength: ☐☐☐☐;
22C2B. Proposed bed strength: ☐☐☐☐

22C3. Intensive Neonatal care Unit: 22C3A. Existing bed strength: ☐☐☐☐;
22C3B. Proposed bed strength: ☐☐☐☐

22C4. High Dependency Unit: 22C4A. Existing bed strength: ☐☐☐☐; 22C4B. Proposed bed strength: ☐☐☐☐;

22C5. Nuclear Medicine therapy Unit: 22C5A. Existing bed strength: ☐☐☐☐;
23C5B. Proposed bed strength: ☐☐☐☐

22C6. Any other care/therapy unit _____ (to be specified by the applicant):

22D. Total bed strength: ☐☐☐☐; 21I1. Existing: ☐☐☐☐, 21I2. Proposed: ☐☐☐☐

23. Layout, design and space requirements:

23A. Separate Reception Counter: Yes ☐, No ☐

23B. Separate Waiting room/space/area: Yes ☐, No ☐

23C. Separate Record room: Yes ☐, No ☐

23D. Sketch map showing detailed position and floor measurement enclosed as enclosure No. ☐☐

23E. Entrance area: Adequate ☐, not adequate ☐

23F. Ambulatory area: Adequate ☐, not adequate ☐, not applicable ☐

23G. Diagnostic area Adequate ☐, not adequate ☐, not applicable ☐

23H. Intermediate area Adequate ☐, not adequate ☐, not applicable ☐

23I. Critical area Adequate ☐, not adequate ☐, not applicable ☐

23J. Service area Adequate ☐, not adequate ☐

24. Sanitation and hygiene measures requirements (Part II) :

24A. General water supply as per standard norm provided: Yes ☐, No ☐

24B. Drainage system as per standard norm provided: Yes ☐, No ☐

24C. General waste disposal arrangement as per standard norm provided: Yes ☐, No ☐

24D. Separate cooling arrangement: Central AC ☐, Separate AC ☐, Fans ☐

24E. The type of Drinking Water Supply: Piped Water Supply ☐ Underground ☐ Others ☐

24F. Whether the quantity of Drinking water is Adequate: Yes ☐, No ☐

24G. Whether the quality of Drinking water is satisfactory: Yes ☐, No ☐

24H. Sanitary fitments as per standard norm provided: Yes ☐, No ☐

24I. Water closets Number: 25I1. For Male ☐☐, 25I2. For Female ☐☐, 25I3. Common ☐☐

24J. Lavatory Number: 25J1. For Male ☐☐, 25J2. For Female ☐☐, 25J3. Common ☐☐

25. Safety and Security:

25A. Authorization from Pollution Control Board for biomed waste handling: 25A1. applicable, Not applicable ☐, if applicable then: 25A2. Already obtained and the copy of Authorization enclosed as enclosure No. ☐☐; Not obtained but self-declaration in the form of an affidavit enclosed as enclosure No. ☐☐

25B. Method of treatment and/or disposal of Bio-medical waste: Through Common Facility, Onsite Facility ☐, Any other (please specify: ____)

25C. Backup Electric Supply: Generator ☐, Invertors ☐, None ☐

25D. Electrical arrangements as per standard norm provided: Yes ☐, No ☐

25E. Authorization / No Objection Certificate (NOC) /License of Fire safety: 25E1. applicable ☐, Not applicable ☐, if applicable then: 25E2. Already obtained and the copy of Authorization enclosed as enclosure No. ☐☐; Not obtained but self-declaration in the form of an affidavit enclosed as enclosure No. ☐☐

25G. Biosafety arrangements as per standard norm provided: Yes ☐, No ☐

25H. Authorization / No Objection Certificate (NOC) /License of AERB: 25H1. applicable ☐, Not applicable ☐, if applicable then: 25H2. Already obtained and the copy of Authorization enclosed as enclosure No. ☐☐; Not obtained but self-declaration in the form of an affidavit enclosed as enclosure No. ☐

25I. adequate Security arrangement available: Yes ☐, No ☐

25J. Certificate of Enlistment particulars

25J1. Applied for ☐ and the copy of application enclosed as enclosure No. ☐☐ or

25J2. Already obtained ☐ and the copy of Trade License enclosed as enclosure No. ☐☐ and

25J3. Trade License Number: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ and

25J4. Name of the Issuing Authority: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐ and

26J5. Date of issue: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

26. Mandatory reporting requirements (Part II):

26A. Performance report: 26A1. Not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 26A2. enclosure ☐ ☐

26B. Reports related procedures like MTP: 26B1. Not applicable ☐, Applicable but not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 26B. enclosure ☐ ☐

26C. Annual reports of free treatment **and** concession: 26A1. Not applicable ☐, Applicable but not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 26A2. enclosure ☐ ☐

26D. Reports of sentinel events: 26D1. Not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 26D2. enclosure ☐ ☐

26E.Reports of extract of grievance redressal register: 26E1. Not applicable ☐, Applicable but not submitted ☐, submitted and copy of acknowledgement receipt (only in case of renewal) enclosed as 26E2. enclosure ☐ ☐

27. Mandatory Display requirements (Part II):

27A. Display board :

27A1. Name, govt. designation, hrs of availability of part-time govt. staff: Displayed ☐, Not displayed ☐, Not applicable ☐

27A2. Name, qualification and hours of availability of medical staff: Displayed ☐, Not displayed ☐

27A3. Current bed occupancy status and availability of beds: Displayed ☐, Not displayed ☐, Not applicable ☐

27A4. Certificate of arrangement or affiliation with reference lab: Displayed ☐, Not displayed ☐, Not applicable ☐

27A5. License/ No Objection Certificate (NOC) /Approval of different Acts like PC-PNDT Act: Displayed ☐, Not displayed ☐, Not applicable ☐

27A6. Item-wise charges (Rate-chart) for all services: Displayed ☐, Not displayed ☐

27A7. Mechanism to avail concession or free treatment facilities: Displayed ☐, Not displayed ☐, Not applicable ☐

27A8. Standard Charter of patient rights: Displayed ☐, Not displayed ☐

27A9. Information related to Grievance redressal system: Displayed ☐, Not displayed ☐, Not applicable ☐

27B. Information Brochure :

27B1. Information Brochure not available ☐, available ☐ and a copy enclosed as enclosure ☐☐

27B2. If available, Brochure contains adequate information: Yes ☐, No ☐

27C. Signage system :

27C1. Biohazard symbols: Displayed ☐, Not displayed ☐, Not applicable ☐

27C2. Other signages: Adequate ☐, Not Adequate ☐

28. Mandatory register requirements (Part II):

28A. For all clinical establishment (other than single doctor establishments):

28A1. Dead stock register: generated/maintained ☐ not generated/maintained ☐

28A2. Book of accounts: generated/maintained ☐ not generated/maintained ☐

28A3. Cashbook: generated/maintained ☐ not generated/maintained ☐

28A4. Grievance register: generated/maintained ☐ not generated/maintained ☐ not applicable ☐

28A5. Record keeping register: generated/maintained ☐ not generated/maintained ☐

28A6. Lab Register: generated/maintained ☐ not generated/maintained ☐ not applicable ☐

28B. For all clinical establishment having in-patient facilities :

28B1. In-patient register: generated/maintained ☐ not generated/maintained ☐

28B2. Birth Register: generated/maintained ☐ not generated/maintained ☐ not applicable ☐

28B3. Death Register: generated/maintained ☐ not generated/maintained ☐

28B4. OT logbook (register): generated/maintained ☐ not generated/maintained ☐ not applicable ☐

28B5. Register(s) related to procedure under Acts like MTP Act under rule 13 generated/maintained ☐ not generated/maintained ☐ not applicable ☐

28B6. Record of health case sheet/BHT: generated/maintained ☐ not generated/maintained ☐

28B7. Referral register: generated/maintained ☐ not generated/maintained ☐

28B8. Records of free treatment/concession generated/maintained ☐ not generated/maintained ☐ not applicable ☐

29. Equipment and Medical supplies requirements:

29A. Equipment availability: Adequate ☐, not adequate ☐

29B. Equipment register: generated/maintained ☐, not generated/maintained ☐

29C. Medical supplies availability: Adequate ☐, not adequate ☐

29D. Medical supplies stock book: generated/ maintained ☐, not generated/maintained ☐

30. Education and Research particulars:

30A. Whether intend to conduct (or conducting) research: Yes ☐, No ☐;

30B. If yes then No Objection Certificate (NOC): 33B1. Not obtained ☐,or obtained ☐; and 33B2. a copy of No Objection Certificate (NOC) enclosed as enclosure ☐☐

30D. Whether intend to conduct (or conducting) training/education: Yes ☐, No ☐;

30E. If yes then No Objection Certificate (NOC): 33B1. Not obtained ☐, or obtained ☐; and 33B2. a copy of No Objection Certificate (NOC) enclosed as enclosure ☐☐

31. Manpower requirements (Medical Staff) :

31A. Number: 31A1. No. of Full-time Medical staff ☐☐☐, 31A2 No. of Part-time Medical Staff ☐☐☐

31A3. Total ☐☐☐

31B. Types of medical staff: 31B1. Consultant ☐☐☐ 31B2. RMO ☐☐☐ 31B3. Total ☐☐☐

31C. Shift duty of RMO (in case of IPD only): No. of shift per 24 hr cycle: ☐

31D. Particulars of individual medical staff

31D 01A. Name ☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

31D 01B. Qualification (Highest): ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

31D 01C. Name of the University:
☐☐ ☐☐☐☐☐

31D 01D. Copy Certificate of qualification enclosed as enclosure ☐☐

31D 01E. Registration No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

31D 01F. Name of the Council registered with: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐☐

31D 01G. Copy Certificate of registration enclosed as enclosed □□

31D 01H. Designation as per offer letter: □□□□□□□□□□□□□□□□□□□□□□□□□

31D 01J. Type: Full-time □, Part-time □, only empanelled □

31D 01K. Already engaged by any Public sector agency: Yes □, No □; If yes No Objection Certificate (NOC) enclosed as enclosed No. □□

31D 01L. Already engaged by any Private sector agency: Yes □, No □; If yes Number of such agencies □□

31E. Particular for any additional staff is enclosed as separate sheet in enclosed □□

32. Manpower requirements (Nursing Staff):

32A. Number: 32A1. No. of Full-time Nursing staff □□□, 32A2. No. of Part-time Nursing Staff □□□

32A3. Total □□□

32B. Shift duty of nursing Staff (in case of IPD only): No. of shift per 24 hr cycle: □

32C. Particulars of individual Nursing staff

32C 01A. Name □□□ □□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□

32C 01B. Qualification (Highest): □□□□□□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□

32C 01C. Name of the University: □□□□□□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□

32C 01D. Copy Certificate of qualification enclosed as enclosure □□

32C 01E. Registration No. □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□□□

32C 01F. Name of the Council registered with: □□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□□□

32C 01G. Copy Certificate of registration enclosed as enclosure □□

32C 01F. Copy of Offer letter enclosed as enclosure □□

32C 01G. Copy of Acceptance letter enclosed as enclosure □□

32C 01H. Designation as per offer letter: □□□□□□□□□□□□□□□□□□□□□□□□□

32C 01J. Type: Full-time □, Part-time □, only empanelled □

32C 01K. Already engaged by any Public sector agency: Yes □, No □; If yes No Objection Certificate (NOC) enclosed as enclosure No. □□

32C 01L. Already engaged by any other Private sector agency: Yes □, No □; If yes Number of such agencies □□

32D. Particulars for any additional staff is enclosed as separate sheet in enclosure □□

33. Manpower requirements (Allied-medical Staff):

33A. Number: 33A1. No. of Full-time Allied-medical staff □□□, 33A2. No. of Part-time Allied-medical Staff □□□ 33A2. Total □□□

33B. Particulars of individual Allied-medical staff

33B.01A. Name □□□ □□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□
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33B.01B. Qualification (Highest): □□□□□□□□□□□□□□□□□□□□□□□□□□□□
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33B.01C. Name of the University: □□□□□□□□□□□□□□□□□□□□□□□□□□□□
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33B.01D. Copy Certificate of qualification enclosed as enclosure □□

33B.01E. Registration No. □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□
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33B.01F. Name of the Council registered with: □□□□□□□□□□□□□□□□□□□□□□□□
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33B.01G. Copy Certificate of registration enclosed as enclosure □□

33B.01F. Copy of Offer letter enclosed as enclosure □□

33B.01G. Copy of Acceptance letter enclosed as enclosure □□

33B.01H. Designation as per offer letter: □□□□□□□□□□□□□□□□□□□□□□□□□

33B.01J. Type: Full-time □, Part-time □, only empanelled □

33B.01K. Already engaged by any Public sector agency: Yes □, No □; If yes No Objection Certificate (NOC) enclosed as enclosure No. □□

33B.01L. Already engaged by any other Private sector agency: Yes □, No □; If yes Number of such agencies □□

33C. Particulars for any additional staff is enclosed as separate sheet in enclosure □□

34. Manpower requirements (Paramedical Staff):

34A. Number: 34A1. No. of Full-time Paramedical staff □□□,

34A2. No. of Part-time Paramedical Staff □□□ 34A2. Total □□□

34B. Particulars of individual Paramedical staff

34B.01A. Name □□□ □□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□
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34B.01B. Qualification (Highest): □□□□□□□□□□□□□□□□□□□□□□□□□□□□
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34B. 01C. Name of the University: □□□□□□□□□□□□□□□□□□□□□□□□□□□
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34B.01D. Copy Certificate of qualification enclosed as enclosure □□

34B.01E. Registration No. □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□
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34B.01F. Name of the Council registered with: □□□□□□□□□□□□□□□□□□□□□□□□
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34B.01G. Copy Certificate of registration enclosed as enclosure □□

34B.01F. Copy of Offer letter enclosed as enclosure □□

34B.01G. Copy of Acceptance letter enclosed as enclosure □□

34B.01H. Designation as per offer letter: □□□□□□□□□□□□□□□□□□□□□□□□□□

34B.01J. Type: Full-time □, Part-time □, only empanelled □

34B.01K. Already engaged by any Public sector agency: Yes □, No □; If yes No Objection Certificate (NOC) enclosed as enclosure No. □□

34B.01L. Already engaged by any other Private sector agency: Yes □, No □; If yes Number of such agencies □□

34C. Particulars for any additional staff is enclosed as separate sheet in enclosure □□

35. Manpower requirements (General Duty Attendant) :

35A. Number: 35A1. Full-time General Duty Attendant staff □□□,

35A2.Part-time General Duty Attendant Staff □□□ 35A3. Total □□□;

35B. Outsourced: Yes □, No □, If yes agreement copy enclosed as enclosure No. □□

35C. Particulars of individual General Duty Attendant staff

35C 01A. Name □□□ □□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

35C 01B. Age □□ yrs,

35C 01C. Sex (M/F): □,

35C 01D. Qualification (Highest): □□

35C 01E. Copy of Offer letter enclosed as enclosure □□

35C 01F. Copy of Acceptance letter enclosed as enclosure □□

35C 01G. Designation as per offer letter: □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

35D. Particulars for any additional staff is enclosed as separate sheet in enclosure □□

36. Manpower requirements (Administrative-Managerial staff) :

36A. Chief Executive Officer designated: 36A1. Applicant himself □, 36A2. Any other staff □, if other staff

36B. Particulars

36B1. Name □□□ □□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

36B2. Ph (Office) □□□□□□□□□□□ 36B3. Mobile □□□□□□□□□□□ 36B4. E.mail ID: □□□□□□□□□□□□□□□□□□□□□□□□□□□□

36C. Grievance Redressal Officer designated: 36C1. Applicant himself □,

36C2. Any other staff □, if other staff

36D1. Name □□□ □□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

36D2. Ph (Office) □□□□□□□□□□□ 36D3. Mobile □□□□□□□□□□□

36D4. E-mail ID: □□□□□□□□□□□□□□□□□□□□□□□□□□□□

37. Staff Attendance/availability:

37A. Staff Register: generated/maintained ☐ not generated/maintained ☐

37B. Staff requirement:

37B1. No. of medical staff provided as per norm: Yes ☐, No ☐

37B2. No. of Nursing staff provided as per norm: Yes ☐, No ☐

37B3. No. of Allied-medical staff provided as per norm: Yes ☐, No ☐

37B4. No. of Para-medical staff provided as per norm: Yes ☐, No ☐

37C. Staff Attendance register: generated/maintained ☐ not generated/maintained ☐ biometric attendance ☐

37D. Staff availability on duty:

37D1. No. of medical staff provided as per norm: Yes ☐, No ☐

37D2. No. of Nursing staff provided as per norm: Yes ☐, No ☐

37D3. No. of Allied-medical staff provided as per norm: Yes ☐, No ☐

37D4. No. of Para-medical staff provided as per norm: Yes ☐, No ☐

Part-D

(For all clinical establishments)

38. Affidavit: Self declaration and undertaking in the form of Affidavit as per Statutory CE Form III enclosed as enclosure ☐ ☐

39. Any additional information furnished by the applicant:

40. DeclarationI, 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, Regulation and Transparency) Act, 2017 (West Bengal Act IV of 2017) and as per the West Bengal Clinical Establishment (Registration, Regulation and Transparency) Rules, 2017.I also undertake to explain the said Act and Rules to all employees/consultants of the clinical establishment 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.

[for Office use only]

Statutory CE FORM II: Nomination of person by Company

[See rule 44]

Partner, Director, Trustee, Secretary, President or Chairman of that partnership firm, company, trust or organization but shall not include an employee of that firm, company, trust or organization.

I, being the proprietor or a signatory authorized by the board of partners/ directors/ trustees/ executive committee of the firm/ company/ trust/ organization company, in terms of rule 44 of the West Bengal Clinical Establishment (Registration **and** Regulation) Rules, 2017, do hereby give notice that the following person, being a partner/ director/ trustee, secretary/ president/chairman of this firm/ company/ trust/ organization, 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 nominated applicant 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 the Act and the Rules and Regulations made thereunder.

Name of the Establishment : .....

Name of the nominated applicant: .....……..son/daughter/wife/of …….....…. residing at ……..

Full signature of the nominated applicant ….....……..

A certified copy of the resolution of the board regarding the authorized signatory, dated _____ is enclosed.

Place:_____ For _____ (Name of the Company.)

Date:_____ Authorized signatory of the company

Statutory CE FORM III: Affidavit Self-Declaration

[See rule 34]

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 Clinical Establishment Form I as per rule 34 of the of the West Bengal Clinical Establishment (Registration, Regulation and Transparency) Rules, 2017 in respect of the Clinical Establishment _____ (Name) situated at _____(address) 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.

Place : (_____)

Date : Signature of Applicant.

Statuary CE FORM IV: Acknowledgement of Application

[See rule 35]

Office Address of the Licensing Authority

Memo No. Date :

Memo

Ref: Memo No. of application letter (If any) .....…… Dated ….....……

The application in Form 'I' in duplicate submitted by applicant mentioned below for registration of the clinical establishment named below situated at the address given below has been received by the Licensing 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 of this application

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 (if any) : …….....

Place : Signature of the Officer in-charge

Date : Office Seal with designation

Statutory CE FORM V: Inspection Report

[See rule 35]

01. Application form attached: Yes ☐, Not applicable ☐ (in case of unregistered establishment)

02. Name and Address of the clinical establishment inspected : ……

03. Name and Address of the Applicant/Licensee/Occupier : ……

04. Inspection Remarks: Cannot be verified ☐, Checked and verified ☐, and found acceptable ☐; or found not acceptable as 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 Registrar of Clinical Establishments

[See rule 30]

सत्यमेव जयते

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/occupant :

09A. Individual Proprietorship ☐, or Registered Partnership ☐, or Registered Company ☐ or Corporation (including a society) registered under a Central, Provincial or State Act ☐ (Please specify .....); orTrust (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.....)

Classification

10. System of Medicine Offered: (Multiple options possible)Allopathy ☐, Ayurveda ☐, Unani ☐, Siddha ☐, Homeopathy ☐, Naturopathy ☐, Yoga ÿ 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 .....)

12. Service Facilities offered:

12A. Uni-facility ☐, or Multi-facility ☐

12B. If uni-facility then, service facility offered: Outpatient based Service ☐, or Inpatient based service ☐, or Diagnostic laboratory service ☐, or Diagnostic Imaging service ☐,

12C. If multi-facility then, service facility offered (Multiple options possible): Outpatient based Service ☐, and Inpatient based service ☐, and Diagnostic laboratory service ☐, and Diagnostic Imaging service ☐

12D. It is a single doctor establishment: Yes ☐, No ☐,

13. Service sub-Facilities offered: (Multiple options possible)

13A. In case of mainly Outpatient based Service:

13AA. Solo clinicÿ, 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. Sanatoriumÿ, 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. Particulars related to No Objection Certificate (NOC)/License/Approval obtained to perform procedures like MTP

16. License Fee:

16A1.Amount Rs. ☐☐☐☐☐ deposited and 16A2. Challan No ☐☐☐☐☐☐☐☐☐☐☐☐☐ and 16A3.Date ☐☐☐☐☐☐☐☐

16B1.Amount Rs. ☐☐☐☐☐ refunded and 16B2. Challan No ☐☐☐☐☐☐☐☐☐☐☐☐☐ and 16B3.Date ☐☐☐☐☐☐☐☐

17. Other Fees and **Fines:**

17A. Amount Rs. ☐☐☐☐☐ deposited and 17B. Challan No ☐☐☐☐☐☐☐☐☐☐☐☐☐ and 17C. Date ☐☐☐☐☐☐☐☐

18. Manpower Number:

18A. Medical Staff ☐☐☐, 18B. Nursing Staff ☐☐☐, 18C. Paramedical & Allied-medical Staff ☐☐☐, 18D. Admin-managerial Staff ☐☐☐, 18E. Total Staff ☐☐☐☐

19. Registration Details:

19A. Registration No. ……

19B. Registration Date ..... 19C. Registration Valid upto ……

19C. Registrated by (Designation of Licensing Authority cum District Registrar):……..

19D. Name of the District: ……

19E. Order No. issued by Licensing Authority granting License ……18F. Dated ……

19F. Period of irregular running (if any)

19F1. From Date ☐☐☐☐☐☐☐☐

19F2. To Date ☐☐☐☐☐☐☐☐

20. Present status: (only in case of digital register)20A1. Valid License ☐, 20A2. License expired ☐, 20A3. License Suspended ☐, 20A4. License Cancelled ☐

21. Any Additional information:

Signature and Seal of Licensing Authority

Statutory CE FORM VII: License

[See rule 3]

Registration/License 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, Regulation and Transparency) Act, 2017 vide order issued [by the undersigned] under such number in respect of such clinical establishment situated at such address to keep or carry on the said clinical establishment having such number of beds offering such service facilities in such recognized system of medicine as mentioned below.

2. This is to certify that the licensee has been Registered vide registration No. as mentioned above under the Rule 3 of the West Bengal Clinical Establishment Rules, 2017, [by the undersigned] in respect of the clinical establishment as mentioned below and the license shall be valid for the period ……..

3. The License is granted subject to the West Bengal Clinical Establishment (Registration, Regulation and Transparency), Act 2017, Clinical Establishment Rules 2017 and any contravention thereon shall result in suspension or cancellation of this license before the expiry period.

4. This is to certify that such amount of license fee was collected as mentioned below which is non-refundable in case of any closure, suspension or withdrawal of any services as mentioned below.

5. This license is non-transferable.

6. Particulars of the Licensee:

6.a. Name of the Licensee: …….....
6.b.Son/daughter/wife of: ……....
6.c. Address of the Licensee: ……...

7. Particulars of the Establishment:

7.a. Name of the Clinical Establishment: …….....……
7.b. Address of the Clinical Establishment: (Place of Business) ……
8.a. Order No. of the Licensing Authority granting License: . ……...

8.b.Date …….....

9. Validity of the license:

9.a. Granted/ Renewed from [Date] ……..…….
9.b. Valid upto [Date]……..
9.c. Period of irregular running from [Date] ……
9.d.to [Date] ……..

10. Stipulated License fee: Rs…….. (Rupees in words) ……..

11.Service facilities:

11.a. Name(s) of recognized system of medicine practiced:……....……
11.b. Number of beds: General ……
11.c.Special care beds ……
11.d. Types of service facilities to be provided:…….....

Place:
Date:

Signature of the Licensing Authority
DistrictRegistrar
Office Seal with designation

Statutory CE Form VIII: Granting of Application Order

[See rule 35]

Office Address of the Licensing Authority

Memo No. Date:

Order

Ref: Application Acknowledgement No……

In exercise of the power conferred under section 13 of the West Bengal Clinical Establishment (Registration, Regulation and Transparency) Act, 2017, 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 Rule 7 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 …….....…….

3. The ADHS/DADHS/ACMOH ……..

Statutory CE Form IX: Rejection of Application Order

[See rule 35]

Office Address of the Licensing Authority

Memo No. Date

Order

Ref: Application Acknowledgement No……

In exercise of the power conferred under Section 13 of the West Bengal Clinical Establishment (Registration, Regulation and Transparency) Act, 2017, the Licensing Authority, after providing opportunity of being heard, 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 on the ground 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. Ground for Rejection:

Place: Signature of the Licensing Authority
and District Registrar

Date: Office Seal with designation

Copy forwarded for information to:-

1. The State Registrar …….
2. The applicant …….
3. The ADHS/DADHS/ACMOH ……..

Statutory CE Form X: Seizure Memo

[See rule 38]

Ref: Authorization Notice No……. Dated ……

In exercise of the power delegated to me under section 24 of the West Bengal Clinical Establishment (Registration, Regulation and Transparency), Act 2017 (West Bengal Act IV of 2017), I hereby seize the under mentioned material objects/documents at the premises of (Name of clinical establishment) …….....……..…
located at (address of place of business) ……...
and kept/occupied by (name of the occupier/proprietor ……..
Son/daughter/wife of …….....
residing at (address of the occupier/proprietor) …….....

Sl. No. Description

1.

2.

3.

Date of seizer:

Time of seizer:

Place of seizer:

Person from whom the material objects were seized (name) ……...…….
Son/daughter/wife of …….....
residing at (address of the occupier/proprietor) ……..……..

The seizure has been made and the inventory has been prepared in presence of the following witnesses.

Name and address of the witness signature.

1.

2.

The material objects seized have been duly sealed and are left in the custody of Shri……
Designation ……. with the instruction not to tamper with the seals and not to dispose of the object till further order.

This memo is handed over to the person mentioned above from whom the material objects were seized

Signature of occupier/proprietor

Name…….

Place-……..

Date:……

Signature of the
Authorized Officer
Designation

Statutory CE Form XI: Self-Declaration

Seizure of Vital records

[See rule 38]

I, ……, son of/wife of/daughter of ……, aged about …….. years and residing at ……..do hereby solemnly affirm and sincerely state as follows:

1. I am the proprietor/occupier of the clinical establishment at ……. styled as …….
2. I say that on _____ at about ___a.m./p/m., the Supervisory Authority,……..(here give the name and designation of the Authorized Officer) inspected/searched the premises at _____ where I am keeping/carrying on clinical establishment. During the course of such inspection/search, the Supervisory Authority has seized certain medical records, books of account, other relevant documents and records.
3. I say that the medical records, books of account, other relevant documents and records seized during the inspection/search are required for keeping/carrying on clinical establishment and hence it is necessary that they be returned to me immediately.
4. At my request, the Supervisory Authority has agreed to return the books of account and other documents so seized during the inspection/search, subject to my providing him extracts or copies of such books of account and other documents. The Supervisory Authority has given me the details of the extracts or the copies required by him.
6. I say that I have caused the extracts/copies so required to be taken in the presence of …….. (here give the name & designation of the Authorized Officer).
7. I confirm and declare that the extracts/copies annexed to this Affidavit are the true, authentic and genuine extracts/copies of books of account/other documents seized on _____ and in confirmation thereof, I have initialed each page of such extracts/copies.
8. I am aware that based on the solemn declarations given in this Affidavit, the Supervisory Authority has agreed to return the books of accounts and other documents seized as soon as possible.
9. I hereby undertake to retain the medical records, books of account, other relevant documents and records in may safe custody without causing any dislocation, mutilation, tampering, damage or destruction to the records in the course of safe-keeping for such a period as long as necessary.
10. I hereby undertake to produce the books of accounts and other documents or any part thereof at any time as may be required by the Licensing Authority or by the Supervisory Authority or before any inquiry proceedings or before any adjudication proceedings that may be initiated by the Licensing Authority against me.

Name……

(SIGNATURE OF THE DEPONENT)

Designation ……..

Place-……..

Date:……

Statutory CE Form XI: FORM NO.II

Electronic Application Form (PATHOLOGY)

FORM OF APPLICATION FOR REGISTRATION AND LICENCE

Establishment

Name of establishment:

PT Verification No:

Previous License No:

Address of establishment:	District:	Local Authority:
Municipality:	Sub Division:	Block:
Landline:	Mobile:	Email:

Type of Application:

Application Detail

Name of Applicant:

Address of Applicant:

Landline:	Mobile:

Type of establishment:

Date of establishment of Centre, if already started:	Renewal for:

Nature of firm:

Trade Licence

Name of Authority:	Licence Number:	Date of issue:

File attached:

Affidavit.pdf, Appointment Letters.pdf, Approve Building Plan.pdf, Challan.pdf, Clinical Waste Disposal.pdf, Current Rate Chart.pdf, Electricalinstallation.pdf, Fire No Objection Certificate (NOC)

Licence fees requirement status:

Challan

Challan Number:	Date:

Amount:

Clearance from pollution control board:

Clinical Waste disposal licence (From Panchayat/Municipality/Municipal Corporation):

Premises

Construction approved by authority?:	Premises Type:	Reception Counter:
Waiting Room:	Record Room:	Ventilation Sufficient?:
Lighting Sufficient?:		

Drinking Water Supply

Source:		Quantity:
Quality:		Cooling Arrangement:

Exemption Granted By

Customs Department:		H&FW Dept.:

Registers (to be maintained)

Staff Register Available:	Attendance Register:	Stock Register:
Cashbook Register:	Admission Register:	Inspection Book:

Whether training of medical or paramedical courses are present?:

Sanitary Arrangement

Drainage System:

Water Closet for Male:	Water Closet for Female:
Lavatory for Male:	Lavatory for Female:

System of garbage disposal:

Electric Supply:

STAFF

Total number of staffs:	No. of permanent staff:	No. of temporary staff:

STAFF TABLE

General

Category of Staff–	Name Qualification Registration	Name of Nature Appo
Number	Faculty of Service	Letter

DECLARATIONS

Regarding display of Rate Charges

Doctor's Charges:	Bed Charges:	OT Charges:
Investigation Charges:	Service Charges:	

Regarding Operation Theatre

Total OT Space:	List of Equipments:	Shadow-less Light:
Boyle's Apparatus:	Anaesthetist List:	Auto Cave:

Regarding Maternity Home

Labour Room Space: List of Equipments: Sucker Machine:

Regarding Installation

Regarding Electrical Installation and Supply:

Regarding Cooking, Storing and Distribution of Food for Patients:

Regarding Accommodation

Regarding Accommodation of Residential Staff:

Download attachments:

Statutory CE Form XI: FORM NO.II

Electronic Application Form (HOSPITAL)

FORM OF APPLICATION FOR REGISTRATION AND LICENCE

Establishment

Name of establishment:

Address of establishment: Local Authority:

Landline: Mobile: Email:

Type of Application:

Application Detail

Name of Applicant:

Address of Applicant:

Landline: Mobile:

Type of establishment: Nursing Home, OPD Center [OPD run by PG Doctors and above – Poly], Other 9HUF, FFA, LASER, ECG&OCT), Pathological Clinic – Small, Nursing Center[OPD run by PG Doctors and above – Poly], Other (HUF, FFA, LASER, ECG & OCT), Pathological Clinic – Small

Date of establishment of Centre, if already started: Renewal for:

Nature of firm:

Trade Licence

Name of Authority: Licence Number: Date of issue:

File attached:

Affidavit.pdf, Appointment Letters.pdf, Approve Building Plan.pdf, Challan.pdf, Clinical Waste Disposal.pdf, Current Rate Chart.pdf, Electricalinstallation.pdf, Fire No Objection Certificate (NOC)

Licence fees requirement status:

Challan

Challan Number: Date:

Amount:

Clearance from pollution control board:

Clinical Waste disposal licence (From Panchayat/Municipality/Municipal Corporation):

Premises

Construction approved by authority?: Premises Type: Reception Counter:

Waiting Room: Record Room: Ventilation Sufficient?:

Lighting Sufficient?:

Drinking Water Supply

Source: Quantity:

Quality: Cooling Arrangement:

Exemption Granted By

Customs Department: H&FW Dept.:

Registers (to be maintained)

Staff Register Available: Attendance Register: Stock Register:

Cashbook Register: Admission Register: Inspection Book:

Whether training of medical or paramedical courses are present?:

Sanitary Arrangement

Drainage System:

Water Closet for Male: Water Closet for Female:

Lavatory for Male: Lavatory for Female:

System of garbage disposal:

Electric Supply:

IN CASE OF NURSING HOME

Expected patient at ESH per Day: Total Number of beds:

Number of cabins: Space for each patient:

Number of cubicle: Space for each patient:

Number of wards: Space for each patient:

Number of beds in ICCU: Space for each patient:

Number of beds in ITU Space for each patient:

Number of beds in RCU: Space for each patient:

Number of beds in NCU: Space for each patient:

Number of beds in Dialysis Unit: Space for each patient:

Number of beds in Other Units: Space for each patient:

Space for OT: Space for Labour Room:

STAFF

Total number of staffs: No. of permanent staff: No. of temporary staff:

STAFF TABLE

General

Category of Staff	**Name Qualification Registration**	**Name of Nature Appo**
Number	**Faculty of Service**	**Letter**

DECLARATIONS

Regarding display of Rate Charges

Doctor's Charges: Bed Charges: OT Charges:

Investigation Charges: Service Charges:

Regarding Operation Theatre

Total OT Space: List of Equipments: Shadow-less Light:

Boyle's Apparatus: Anaesthetist List: Auto Cave:

Regarding Maternity Home

Labour Room Space: List of Equipments: Sucker Machine:

Regarding Installation

Regarding Electrical Installation and Supply:

Regarding Cooking, Storing and Distribution of Food for Patients:

Regarding Accommodation

Regarding Accommodation of Residential Staff:

Download attachments:

I accept on behalf of myself and the company/association/body hereby declare that the statements above are correct and true to my knowledge and I shall abide by all the rules and declarations (from A to F as stated above) in respect of my clinical establishment, that already exists / proposed to be established.

I further declare that this clinical establishment is not and will not be used for immoral purpose.

I undertake that I shall intimate to the Licensing Authority any change in the particulars given above.

Statutory Clinical Establishment Form XII: Appeal Form

[See rule 41]

Before the Hon'ble Appellate Authority

Memorandum of Appeal No. ……. Dated……. [Office Use only]

IN THE MATTER OF

Name of the Appellant(s) : ……

Son/daughter/wife of: ……..

Full Address: ……..

Village/Tehsil/District: ……..

Against the decision ofDesignation of the Licensing authority:

……

Full Address: ……

District: -……

The humble appeal of Appellant(s) above named most respectfully sheweth:

1. This appeal is directed under Section 26 of the West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017 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 rule 41 of the West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017 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, Regulation and Transparency) Act, 2017 (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 and Licensing Authority): …….....

4. The grounds on which the 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 and Licensing Authority appealed against.

7. List of enclosures:

   1. Certified copy of the order of the District Registrar and Licensing Authority appealed against.
   2. Affidavit.
   3. ……
   4. ……

Place: …….

Date: …….. Full Signature

(To be signed by the Appellant and Authorized Representative).

SCHEDULE VII

LICENSE FEES

[See rule 40]

Part I: General

1. The clinical establishment shall submit the License Fees as specified in this schedule.

1.2. While computing the license fees, the type(s) of service facilities offered by the clinical establishment should be considered and taken together.

Illustration 1. The license registration fee for a clinical establishment having X-Ray Lab (conventional) and a Ultrasonography lab should be Rs.10,000 plus Rs.10,000 that is altogether Rs.20,000.

Illustration 2. The license registration fee for a clinical establishment having 10 bedded inpatient facilities with a X-Ray Lab (conventional) should be Rs.10,000 plus Rs.10,000 that is altogether Rs.20,000.

1.3. While computing the license fees, the total number of beds including beds of special care units and emergency observation beds should be considered together.

Illustration 1. The license registration fee for a clinical establishment having 15 bedded inpatient facilities should be Rs.10,000 plus Rs.500 into 5 that is altogether Rs.12,500.

Illustration 2. The license registration fee for a 15 bedded nursing home having 10 general beds and 5 ITU beds should be Rs.10,000 plus Rs.3,750 that is altogether Rs.13,750.

Part II. Specific

	Type of Establishment	License Fee in Rs. for Registration	License Fee in Rs. for Renewal
1.	Outpatient based Service		
1.A.	Solo clinic - only for consultation and advice by a registered medical practitioner	Nil	
1.B.	Solo clinic- used for medical practice and treatment by a registered medical practitioner other than 1 A as above	5,000	3,000
1.C.	Polyclinic	5,000 per specialty / super specialty	3,000 per specialty/ super specialty
1C.	Dental Clinic/ Refraction clinic/ Acupuncture clinic/ Physiotherapy Clinic / Other Medical clinic with facilities for procedure	10,000	7,000
1.D.	Occupational therapy Clinic	10,000	7,000
1.E.	Wellness/Fitness centre/clinic	15,000	10,000
1.F.	Counseling Centre	10,000	7,000
1.G.	Any other OPD based Service centre	5,000 per specialty/ super specialty	3,000 per specialty/ super specialty
2.A	Inpatient based service as day care centers: Infertility Clinic, Dialysis Centre, MTP Clinic, Any other Day care Centre		
2.A.1.	Up to 10 beds	10,000	7,000
2.A.2.	11 beds and more	500 per additional bed	300 per additional bed
2.B	Inpatient based service: Maternity Home/ Nursing Home/Hospital/ Sanatorium/ Any other IPD based service centre		
2.B.1.	Up to 10 beds (excluding special care/therapy beds)	10,000	7,000
2.B.2.	11 beds and more beds (excluding special care/ therapy beds)	750 per additional bed	500 per additional bed

	Type of Establishment	License Fee in Rs. for Registration	License Fee in Rs. for Renewal
2.C.	Special Care unit (additional fees)		
2.C.1.	Critical Therapy unit (in addition to normal beds)	750 per bed	500 per bed
2.C.2.	Intensive Coronary care Unit (in addition to normal beds)	750 per bed	500 per bed
2.C.3.	Intensive Neonatal care Unit (in addition to normal beds)	500 per bed	300 per bed
2.C.4.	Any other Special Care unit (in addition to normal beds)	750 per bed	500 per bed
3.	Pathology laboratory service		
3.A.	Small Laboratory	5,000	3,000
3.B.	Medium Laboratory	10,000	7,000
3.C.	Large Laboratory	20,000	15,000
3.D.	Collection Centre	3,000	2,000
3.E.	Genetic Laboratory	20,000	15,000
3.F.	Any other Pathology laboratory	30,000	20,000
4.	Diagnostic Imaging service		
4.A.	X-Ray lab (Conventional)	10,000	7,000
4.B.	X-Ray lab (Digital)	15,000	10,000
4.C.	Mamography lab	10,000	7,000
4.D.	Bone Densitometry lab	10,000	7,000
4.F.	Ultrasonography lab	10,000	7,000
4.G.	Colour Doppler Imaging lab	10,000	7,000
4.H.	CT Scan lab	20,000	15,000
4.J.	Magnetic Resonance Imaging (MRI) lab	30,000	20,000
4.K.	Positron Emission Tomography (PET) Scan lab	35,000	30,000
4.L.	Echo-cardiography lab	10,000	7,000
4.M.	Electro-cardiography lab	5,000	3,000
4.N.	Electro-encephalography lab	10,000	7,000
4.P.	Electromyography lab	10,000	7,000
4.Q.	Audiometry lab	5,000	3,000
4.R.	Other Clinical Physiology	10,000	7,000
4.S.	Angiography	25,000	20,000
5.	Ayurvedic/Homeopathy/Unani/Acupuncture with recognized qualification.	5,000	3,000

By order of the Governor,

ANIL VERMA
Principal Secretary to the Government of West Bengal

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