Government of West Bengal
Department of Health & Family Welfare
Swasthya Bhavan, Wing-B, 4th Floor,
GN-29, Sector-V, Bidhannagar,
Kolkata- 700091

No. HF/SPSRC/20A/2009/ 143 Dated February 23, 2011

NOTICE

The West Bengal Clinical Establishments (Registration & Regulation) Act 2010, West Bengal Act XXVI of 2010 has been published on 5th October 2010. In pursuant to the power conferred in Section 57 of the Act, preparation of the West Bengal Clinical Establishments (Registration & Regulation) Rule 2011 is under consideration of the government. A draft Rule in this regard has been prepared and placed in ñNoticeò under the official website of the Department of Health & Family Welfare under URL www.wbhealth.gov.in for wide publicity. Suggestions / opinions are invited from all the stakeholders within 10 days to be addressed to :

The Director, SPSRC , CFW & Secretary,
Department of Health & Family Welfare
Swasthya Bhavan, Wing-B, 4th Floor,
GN-29, Sector-V, Bidhannagar, Kolkata- 700091
cfw@wbhealth.gov.in

By order

Sd/- Dilip Ghosh
Director, SPSRC,
CFW & Secretary

The West Bengal Clinical Establishment Rules, 2011

GOVERNMENT OF WEST BENGAL

Department of Health & Family Welfare

MEDICAL SERVICES

Arrangement of Clauses

NOTIFICATION

No. : HF/O/MS/57/4C-04/2é é dated,é é , 2011. In exercise of the power conferred by section 57 of the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 (West Ben. Act XXVI of 2010), and in super session of all earlier rules on the subject, the Governor is pleased hereby to make the Following rules, namely:-

RULES

1. Short title and Commencement.

(1) These rules may be called the West Bengal Clinical Establishment (Registration and Regulation) Rules, 2011.

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

2. Definition.

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

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

(2) ñaccounting recordsò includes invoices, receipts, orders for the payment of money, bills of exchange, cheques, vouchers and other documents of prime entry and also includes such working papers and other documents as are necessary to explain the methods of calculations by which accounts are made up;

(3) ñAmbulanceò means any privately or publicly owned motor vehicle or vessel or aircraft that is especially designed, constructed or modified, and equipped and is intended to be used and is maintained or operated for the overland, water or air transportation of patients upon the streets, roads, highways, waterways, river, airspace, or public ways in this state, or any other motor vehicles, vessels or aircraft used for such purposes;

(4) ñapplicantò means a person who has made an application under rule 52 or rule 58;

(5) ñappropriate receipt head means the Head ï ñ0210-01-800-other receipts-001-Collection from Miscellaneous service fees-14-Services feesò under the Act;

(6) ñappropriate refund headò means the Head ï ñ0210-01-800-other receipts-001-Collection from Miscellaneous service fees-20-Refundò under the Act;

(7) ñaggrieved partyò means any person who can make an application for grievance redressal under the Act or rules, and includes

(a) Patient Party; or

(b) Any person/persons whose collective community rights are alleged to be/have been violated.

(8) ñbuildingò includesð

a) a house, out-house, stable, latrine, godown, shed, hut, wall(other than a boundary wall not exceeding two meters in height) and any other such structure, whether of masonry, bricks, wood, mud, metal or any other material whatsoever:

b) a structure on wheels or simplify resting on the ground without foundations; and

c) a ship, vessel, boat (when outside the port limit of major ports as defined under the Indian Ports Act 1908), Aircraft, and

d) tent, van and any other structure used for human habitation, but do not include a temporary shed erected on ceremonial or festival occasions.

(9) ócareô means measures taken by a care provider or that are taken in a healthcare establishment in order to determine a service recipientôs state of health or to restore or maintain it;

(10) ñCollection centreò means a clinical Laboratory as may be explained in rule 51;

(11) ñConsultantò means a registered medical practitioner as defined in rule 16;

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

(13) ñDepartmentò means the department of Health and Family Welfare of the Government of West Bengal if not mentioned otherwise;

(14) ñdisplay of informationò means any form of display and includes any advertisementï

(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,

(15) ñDisasterò and ñDisaster Managementò shall have the meaning as defined under The Disaster Management Act, 2005 [Act 53 of 2005];

(16) ñemergency medical conditionò means a medical condition as may be defined under rule 15;

(17) ñemergency medical treatment meansò the treatment as defined under rule 35;

(18) ñemergency medical serviceò means the service defined under rule 15;

(19) ñemployeeò means a person wholly or principally employed in, or in connection with, a clinical establishment, whether working on permanent, periodical, contractual or piece-rate wages or on commission basis even though he receives no reward or payment for his labour;

(20) ñFirst Aidò means such medical treatment as may be defined under rule (15);

(21) ñgenetic laboratoryò means a laboratory as defined under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 [Act No. 57 of 1994];

(22) ñhandleò means manufacture, possess, store, use, transfer by sale or otherwise, export, import, transport or dispose of;

(23) ñhealthcare establishmentsò means any clinical establishment run by private or public sector agencies;

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

(25) ñindigent personò means a a person who has no visible means of income or whose income is insufficient for the subsistence of his family and shall include (i) Any person who has received a ration card in the category of Below Poverty Line (BPL); and (ii) Any person not included in sub-clause (i) but has been identified as an indigent person by such designated authority as may be notified;

(26) ñInformed consentò means consent given to a proposed specific intervention, without any force, undue influence, fraud, threat, mistake or misrepresentation, and obtained after disclosing to the person giving consent 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;

(27) ñinpatient facilitiesò means any establishment having beds as defined under rule 51;

(28) ñimaging centreò means any establishment or premises used or intended to be used in production of images or visual display of structural or functional patterns of organs or tissues with the aid of any kind of electro-magnetic or sound wave for the purpose of diagnosis, treatment or research of diseases;

(29) ñisolationò means the physical separation and confinement of an individual or groups of individuals who are infected or reasonably believed to be infected with a contagious or possibly contagious disease from non-isolated individuals, to prevent or limit the transmission of the disease to non-isolated individuals;

(30) ñlarge Laboratoryò means a clinical laboratory as defined in rule 51;

(31) ñlocal areaò means the area within the jurisdiction of a local authority;

(32) ñlocal authorityò means,ð

(a) in any municipal area, the Corporation, or Municipal Council concerned;

(b) in notified area, the Notified Authority;

(c) in any other area, the Village Panchayat concerned.

(33) ñmedical deviceò means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article as may be defined under rule 23;

(34) ñmedically necessaryò means a service or procedure that is scientific, appropriate and consistent with diagnosis and which, using accepted standard treatment protocol, standard operating procedures or any other standards of medical practice, could not be omitted without adversely affecting the patientôs conditions

(35) ñmedical recordò means any paper, film, print out, slide, solution or medium, or any documentation of services performed at the direction of a service provider 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;

(36) ñmedical suppliesò means the supplies as defined under rule 23;

(37) ómedico-legal caseô 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.

(38) ñmedium Laboratoryò means a clinical Laboratory as defined under rule 51;

(39) ñnear relativeò means any of the following relatives of the deceased [or patient] namely, a wife, husband, parent, son, daughter, brother and sister and includes any other person who is related to the deceased or any other person as may be defined under Indian Succession Act, 1925 [Act XXXIX of 1925];

(40) ñNew Establishmentò means the clinical establishment registered under the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 after the date of commencement of these rules;

(41) ñnormò means a statistical normative rate of provision or measurable target outcome over a specified period of time;

(42) ñOld establishmentò means the clinical establishment already registered under the Clinical Establishment Act, 1950 prior to the date of commencement of these rules;

(43) ñProprietorò of clinical establishmentò means an applicant as may be defined in rule 52 who has been granted a license;

(44) ñpackage of serviceò or ñpackageò means a group of health care related services with clear item wise explanation wrapped under a fixed price to be provided to the service recipient;

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

(46) ñpatientò means a service recipient who has received any kind of service or care from any Clinical establishment with or without being registered by the patient registration system of that CE and shall include any child born to a patient and is entitled to enjoy all the rights, responsibilities and obligation of being a patient;

(47) ñpatient partyò means a person as defined under rule 44.

(48) ñpersonal careò means specialized care as may be defined under rule 13;

(49) ñPolyclinicò means a medical clinic where the proprietor and the service provider are different persons.

(50) ñpremisesò 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;

(51) ñPrimary Consultantò means a registered Medical Practitioner as defined under rule 11;

(52) ñpublic health emergencyò 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;

(b) And 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.

Explanation: Public health emergency can be due to communicable infectious diseases; chronic non-infectious, non-communicable conditions affecting large population, notifiable diseases, and conditions of public health importance or locally endemic diseases.

(53) ñpublic sector agencyò means any State Government, Central Government, Union territory, Local self-Government, any local Authority, Armed forces, Railways, Employees State Insurance Corporation or any such agencies;

(54) ñqualified technicianò means any paramedical professional who possesses a degree, diploma or certificate in any paramedical course of at least two years, granted by any University established by law or any other institution recognized by the Department in this behalf.

(55) ñquality assuranceò means any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily, in compliance with quality control standards specified by the competent authority, and includes safety standards;

(56) ñquality controlò means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of performance;

(57) ñReference laboratoryò means a laboratory, registered under the Act or similar Act of other state, Union territory, Government of India or accredited by ónational Accreditation Board for Testing and Calibration Laboratories or NABLô or organization of similar repute, which accepts sample or specimens from other clinical establishments for testing and examination;

(58) ñResident Medical Officerò or ñRMOò means the Duty Medical Officer as per rule 12;

(59) ñrehabilitationò means a goal-orientated and time-limited process aimed at enabling impaired persons to reach an optimum mental, physical or social functional level;

(60) óscientificô means anything that has been substantiated and proved on the protocol of evidence-based medicine.

(61) ñscheduleò means a Schedule appended to these rules;

(62) ñSectionò means a section of the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010;

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

(64) ñsmall Laboratoryò means a clinical Laboratory as defined under rule 51;

(65) ñsolo clinicò means a medical clinic used for consultation and treatment by a single doctor where the proprietor and the service provider is the same person.

Explanation: Single Doctor shall include any registered medical practitioner other than a dental practitioner.

(66) ñsonologistò means a qualified registered medical practitioner as defined under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 [Act No. 57 of 1994]

(67) ñsummary Medical Reportò means reports as defined under rule 33;

(68) ñStaffò means a service provider or other categories of employees or any other person who provides any service within the premises of the healthcare institution, whose services are utilized in the clinical establishment for providing any kind of service includes those working on part-time, temporary, contractual, consultancy, honorary or on any other basis whether on payment basis or not;

(69) ñStatutory CE FORMô means a form as specified in the schedule;

(70) ñtelemedicineò means the practice of medicine using audio, visual and data communications;

(71) ñtestò or ñexaminationò means the terms as may be defined under sub-rule (rule (51)

(72) ñtrade licenseò: means a certificate of enlistment by whatsoever name called issued by the authority of the local self government like Municipality or Panchayat

(73) ótreatmentò means administration of any one or combination of therapies under any recognized system of medicine by a Registered Medical practitioner to a person for restoring or maintaining his health;

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

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

(75) ñuniversityò 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.

(76) ñunwarranted public exposureò means a situation where the patient is subjected to exposure, private or public, either by photography, publication, videotaping, discussion, TV broadcasting or radio broadcasting, or by any other means that would otherwise tend to reveal his person or identity and circumstances under which he has or will be under medical or surgical treatment without his consent;

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

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

3. The Standards & License.

(1) Every clinical establishment shall fulfill at all times the requirements of a clinical establishment as specified in the Schedule:

Provided that the old establishment shall fulfill the requirements within a period of ninety days from the date of coming into force of these rules which can be extended for another 90 days on the request from the concerned Clinical establishment.

(2) Every license shall be issued in statutory CE FORM V and on the terms indicated on the backside of the license.

(3) The registration and the license shall ordinarily be valid for one year with effect from the date of issuance of the license.

(4) The license may be issued for a validity period up to 3 years if applied for such provided that the required License fee is deposited in advance.

Explanation: óRequired License feeô shall be computed by adding the Whole amount for the first year and the 50% of the whole amount for the subsequent year(s) of License fee as mentioned in rule 65.

(5) The Clinical establishment offering Service facilities in more than one category as specified in sub-rule (5) of Rule 51, need not apply for separate registration for each type of category but shall have to submit application as per rule 52 clearly mentioning those service facilities.

(6) If a clinical establishment with an existing valid license intends to add more service facilities including enhancement of bed strength, it has to submit a fresh application for new License and surrender the duplicate copy of the existing License.

(7) Until such new license is granted, the Proprietor shall not provide or cause to provide such additional services.

(8) If the application mentioned in sub-rule (6) is granted, a fresh License shall be issued in favour of the applicant, which shall be valid for the remaining period of validity as mentioned in the existing License.

4. Accommodation.

(1) Every Clinical establishment shall comply with the minimum standard of accommodation as may be specified in schedule I:

Provided that such terms and condition may be relaxed in case of Medical Camp or other outreach services provided by the Clinical establishment;

Provided further that such medical camp can only be organized after obtaining a permission in the form of a ôNo objection certificateô from the concerned Licensing Authority and the local Authority where such camps are going to be held.

(2) After receiving relevant information from the applicant like intention and period of running, service(s) offered, qualification of service provider(s); location and space of running, fee for services to be rendered and any such information which he deems to be fit for that purpose, the concerned licensing authority shall issue such ôNo objection certificateô as mentioned in sub-rule (1) subject to such terms and conditions as may be notified by the Government from time to time.

(3) To accommodate the patient, suffering from any infectious disease, the clinical establishment shall have isolation cabin, or ward or any such arrangement including but not limited to negative pressure ventilation and air-conditioning as may be necessary.

(4) Every clinical establishment shall install such safety measures and physical amenities as may be specified in schedule II.

(5) The Proprietor shall ensure that the admission is restricted to the number of beds as mentioned in the application for grant of new license or renewal.

5. Manpower.

(1) The Proprietor of the Clinical establishment shall ensure that all service providers engaged or empanelled by him-

a) are registered 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) have such qualification, training, experience and skill to practice in his particular speciality or subspecialty in the field of medicine or dentistry, nursing or other health care profession as are recognized by the Government.

(c) have such appropriate qualification, training, experience and skill to provide necessary health care service as expected and applicable of him.

(2) Each such engagement or empanelment shall be substantiated by an offer letter issued by the proprietor and an acceptance letter by the service provider:

Provided that no such offer letter or acceptance letter shall be required where the proprietor and the sole service provider is the same person.

(3) No clinical establishment shall engage any person already engaged by any Public sector agency, without obtaining expressed permission from that agency.

Explanation 1: ôPersonô means any service provider, or other staff engaged in the agencies even as honorary or stipendiary basis or who are bound under bond-cum-agreement executed with or under Contract with the agencies and shall include any House-staff, Internee or student.

Explanation 2: ó expressed permissionô means written permission in the form of a óNo objection certificateô mentioning the period of validity of such certificate issued by the agency in a manner as may be determined by them.

(4) The Proprietor of the Clinical establishment shall ensure that any service providers engaged in the clinical establishment submits all particulars relating to his registration, qualification, training, experience and skill as specified in sub-rule (1) and the NOC as specified in sub-rule (3).

(5) The Proprietor of the Clinical establishment shall retain such offer letter or acceptance letter under sub-rule (2) and copies of such certificates of Registration and certificate of qualification under sub-rule (4) as long as necessary and shall produce such documents at the time of inspection or enquiry under rule 60 or on demand by the authority.

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

Explanation: óCertificate of qualificationô means the certificate, diploma or degree awarded by university or any such competent authority.

(6) Every Clinical establishment shall comply with minimum qualification in respect of health service providers and other persons as specified in schedule III.

(7) The Licensing authority shall have the power to seek reasonable assistance from any authority to verify the authenticity, the applicability and appropriateness of any such qualification under sub-rule (1) in such a manner as he deems fit.

(8) A patient or patient party has the right to knowð

(a) the method of identification of staff through uniforms, badges or other methods; and

(b) the names and professional status of the staff providing care or treatment to the patient.

(9) An identity card issued under the signature of the Proprietor shall include but not limited to the following particulars ï

(a) the name of the clinical establishment and its License Number;

(b) the name, designation, and prefix, suffix, where applicable

(c) a recent photograph of the staff; and

(d) the signature of the staff; and

(e) any other relevant particulars

and shall be worn by the staff when he is in the premises.

6. Availability of Manpower.

(1) Every Clinical establishment shall comply with the minimum number and norms in respect of health service providers and other persons as specified in schedule III.

(2) The Proprietor of the clinical establishment shall ï

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

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

(3) Failure to put signature in daily attendance by any staff shall be considered as contravention resulting in minor deficiency under section 29 of the Act.

(4) A pathologist, microbiologist, biochemist, radiologist, sonologist and Specialist (Physical medicine) may render services at any registered clinical establishment:

Provided that numbers of such establishment should not exceed five.

Provided further that no such restriction shall be imposed upon the services rendered by telemedicine.

(5) A technician or paramedical professional may render services at any registered clinical establishment:

Provided that number of such establishment should not exceed two.

(6) An affidavit by concerned medical and paramedical professionals in this regard has to be submitted with application for registration or renewal.

7. Rights of service provider.

(1) The Proprietor of the clinical establishment shall take appropriate measures to minimize the undue risk for the service provider which includes but not limited to ôUniversal work precautionsô, chemoprophylaxis, vaccination, post-exposure prophylaxis and adequate capacity building.

Explanation: ôUniversal work precautionsô 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.

(2) He shall take appropriate measures to ensure the congenial working atmosphere, and the dignity, safety and security of the staff.

(3) He shall take such steps under the West Bengal Medical service persons and Medicare Service Institution (Prevention of Violence and damage to Property Act, 2009 [WB Act XI of 2009].

8. Dignity, Privacy & Confidentiality.

(1) Every service recipient, including an indigent person, once registered by the Clinical establishment, shall have the right to be treated by health care providers with patience, empathy, respect, tolerance for that personôs culture and values, and humanness; further, this shall mean that no one shall be subjected to any coercive health measures or subjected to indiscriminate denials.

(2) Every service recipient shall have the right that he may be subjected to any examination, procedure or treatment or health care in a manner that proper respect is shown for his privacy and dignity, and that a particular health care intervention may be carried out only in the presence of those persons who are necessary for the intervention,

unless the service recipient consents or requests otherwise; and for women service recipient they may be carried out only in the presence of a female attendant or female nursing staff, or female service provider, unless the service recipient herself waives this right or unless it is not feasible at all in given circumstances:

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

(3) Any service recipient accommodated in Clinical establishments shall have the right to expect physical facilities, which ensure privacy and dignity, particularly when service providers are offering them health care or carrying out examinations of personal nature.

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

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

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

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

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

(6) Any healthcare provider or practitioner involved in the treatment of a patient and all those who have legitimate access to the patientôs record is not authorized to divulge any information to a third party who has no concern with the care and welfare of the patient without his written consent, except:

(a) when such disclosure will benefit public health and safety; or

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

(c) when it is needed 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) when it is needed for the purpose of Licensing Authority or Medical Council of any state of India.

(7) Informing the spouse or the family to the first degree or near relative of the patientôs medical condition may be allowed:

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

9. Informed Consent.

(1) The patient shall have the right to a clear, truthful and substantial explanation, in a manner and language understandable to the patient, of all proposed procedures, invasive or non-invasive, whether diagnostic, preventive, curative, rehabilitative or therapeutic, wherein the person who will perform the said procedure shall provide his name and credentials to the patient, possibilities of any risk of mortality or serious side effects; problems related to recuperation; probability of success and reasonable risks involved; alternative procedure available; medical consequence of refusal etc:

Provided that, the patient shall not be subjected to any procedure without his written informed consent, except in the following cases:

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

(b) when the health of the population is dependent on the adoption of a mass health program to control epidemic;

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

(d) when the patient is either a minor, or legally incompetent, in which case, a third party consent is required;

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

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

(2) Informed consent shall ordinarily be obtained from a patient concerned if he is of legal age, conscious and of sound mind in a consent form printed or written either as a part of clinical notes or in separate sheets with the Clinical establishmentôs name and License number boldly indicated.

(3) The Proprietor shall ensure that the consent form, as per MODEL CE FORM II, is also signed by witness(es) and written in a language understandable by all the signatories.

(4) If the patient is incapable of giving consent because he is under-age, or is unconscious or is in a state of mind constituting a mental impairment and third party consent is required, the following member of the patient party, in the order of priority stated hereunder, may give consent:

(i) spouse;

(ii) son or daughter of legal age;

(iii) either parent;

(iv) brother or sister of legal age,

(v) guardian, or

(vi) Any near relative or any one of the patient party

(5) If next of kin, parents, legal guardians or near relative refuse to give consent to a medical or surgical procedure necessary to save the life or limb or a minor or a patient incapable or giving consent, courts, upon the petition of the physician or any person interested in the welfare of the patient, in a summary proceeding, may issue an order giving consent.

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

10. Counseling.

(1) Whenever possible, the clinical establishment shall either engage a professional counselor or orient the staff regarding the scientific techniques of counseling.

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

11. Professional care.

(1) A patient receiving health care services at a clinical establishment, with or without inpatient department, shall be under the professional care of a particular registered medical practitioner during the entire course of his care.

(2) Such Registered medical practitioner under sub-rule (1) shall be recorded as ôPrimary Consultantô of that patient.

(3) The Primary Consultant shall, after examining the patient, record the salient clinical findings; make a provisional diagnosis; and draw up a written treatment plan, which is medically necessary.

(4) The treatment plan under sub-rule (3) shall include but not limited to:-

(a) Details of Investigation service; and

(b) Details of Professional care services including services from Visiting Consultant; and

(c) Details of Nursing services; and

(d) Details of Rehabilitative services and

(e) Detail of Nutritional or dietary service

(5) In the course of his treatment and hospital care, the patient or patient party shall have the right to be informed of the result of the evaluation of the nature and extent of his disease, any other additional or further contemplated medical treatment on surgical procedures, including any other additional medicines to be administered and their generic counterpart including the possible complications and other pertinent facts, statistics or studies, regarding his illness, any change in the treatment plan before the change is made, the personôs participation in the plan of care and necessary changes before its implementation.

(6) 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.

(7) The patient or party shall have the right to select a Primary Consultant before commencement of care.

12. Inpatient Care.

(1) The Proprietor of the clinical establishment shall ensure that the registered medical practitioner(s) be on duty at all times during the clinical establishmentôs operating hours designated as Duty Medical Officer to provide different kind of services assured by that Clinical establishment.

Explanation: registered medical practitioner means a person as defined in the Act and shall include registered Dental Practitioner practicing that particular system of medicine for which the license of the clinical establishment is granted.

(2) The Proprietor of the clinical establishment with inpatient facilities shall ensure the round-the-clock availability of a Duty Medical Officer to be known as Resident Medical Officer.

(3) The Resident Medical Officer under sub-rule (2) shall be

(a) preferably a whole-time staff of that clinical establishment; and

(b) residing within the premises of the Clinical establishment during his duty hours;

(4) The Proprietor of the clinical establishment shall generate and maintain a roster of all the RMOs, for the date and the roster shall be exhibited in a conspicuous part of the clinical establishment.

(5) The minimum number and qualification of such Resident Medical Officer(s) to be engaged by the Clinical establishment shall be as per requirement as specified in the schedule

(6) Besides making any such necessary arrangement for the betterment of the patient, it shall be the duty of RMO to

(a) attend the call from the patient or on-duty nursing personnel,

(b) administer suitable treatment according to the treatment plan prepared by the Primary Consultant

(c) timely refer the case to the Primary Consultant or any other competent person

13. Personal Care.

(1) The patient shall have the right to receive high quality personal care from a non-medical attendant engaged by the clinical establishment:

Provided that such personal care may be provided by a family member subject to the permission from the Primary Consultant and Proprietor of the clinical establishment.

Explanation: ópersonal careô means specialized care which will include-

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

(b) physical assistance for persons with mobility problems; or

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

(d) the provision of substantial emotional support; or

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

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

but shall not include professional care of any kind.

(2) The Proprietor of the clinical establishment shall not engage or continue to engage a person to act as a non-medical attendant if that person is not ð

(a) literate enough; or

(b) having enough skill, competency or experience; or

(c) physically, intellectually or emotionally capable of adequately performing the work required of him; or

(d) a fit and proper person, having regard to guideline of underage and other guidelines issued by the government.

14. Diagnostic procedure, medication or treatment.

(1) The Proprietor of the clinical establishment shall ensure thatð

(a) diagnostic procedure, medication, diet or treatment shall only be given on the written order of a registered medical practitioner; and

(b) the orders shall be written legibly in ink and shall be signed mentioning date and time by the Primary Consultant or RMO.

(2) The Proprietor of the clinical establishment shall ensure thatð

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

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

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

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

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

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

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

(4) Authentication of orders under this rule may be in a written signature, or digital signature with identifiable initials or computer key.

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

(5) No service provider or the Proprietor or any person associated with the Clinical establishment shall insist upon the patient or party to get the investigation done from a particular clinical establishment due to any reasons other than the scientific reason

15. Emergency Care.

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

Explanation 1: ñFirst Aid meansò such medical treatment which will include but not limited to clearing of the airway, mouth to mouth breathing, external cardiac message, starting an IV line, arresting external bleeding by pressure bandage, removal of foreign bodies; dressing of wounds; proper positioning of the unconscious patient etc.

Explanation 2: ñEmergency medical conditionò means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result inð

(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 3: "to stabilize (with its grammatical variations and cognate expressions)" means, with respect to an emergency medical condition specified in clause (d), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

(2) The clinical establishment having more than 25 beds must have separate emergency department or facility with requisite manpower, infrastructure, equipment and medical supplies to render emergency medical service round the clock.

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

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

16. Referral of Patient.

(1) If it is medically necessary, the Primary Consultant may refer the patient to another Registered medical Practitioner who shall be asked to render his opinion or advice or to perform a particular procedure in his capacity of being a Consultant having specialized knowledge, skill, expertise or experience:

Provided that the Primary Consultant may not agree to change or modify his treatment plan according to the advice of the Consultant or allow him to carry out any procedure.

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

(3) Such Consultant as mentioned in sub-rule (1) shall ordinarily be recorded as an employee or be empanelled as a Consultant of that Clinical establishment and shall be treated as staff of that clinical establishment.

(4) The Proprietor may permit the service including telemedicine to be provided by a Visiting Consultant who is not an employee or empanelled, on the request of the Primary Consultant or the patient or the patient party:

Provided that ï

(a) he shall be qualified enough; and

(b) he shall be empanelled on the spot and

(c) the related documents including the offer letter, acceptance letter and credentials for qualification are being kept by the Clinical establishment.

(5) No service provider or the Proprietor or any person associated with the Clinical establishment shall insist upon the patient or party to get admission in a particular clinical establishment due to any reasons other than the scientific reason:

17. Transfer of Patient.

(1) If it is medically necessary, the Primary Consultant or the RMO or any Registered Medical Practitioner may refer the patient to effect an appropriate transfer to another such appropriate clinical establishment or Registered Medical Practitioner for receiving and/or accommodating the patient that in his opinion has the necessary facilities for such.

(2) A transfer to another Health care establishment or Registered Medical Practitioner 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 or his 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 receiving Health care establishment has available space, qualified personnel and infrastructure for providing

(i) further health care to the service recipient, or

(ii) further medical treatment in so far as the treatment of patient mentioned in sub-rule (1) of Rule (35) are concerned,

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

(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 patientôs medical condition, observation of signs or symptoms, preliminary diagnosis, treatment provided, results of any investigation and the informed written consent, if any, and

(ii) a Discharge Certificate or

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

patient so far as the treatment of persons mentioned in sub-rule (1) of Rule (35) are concerned,

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

(3) The Proprietor of the transferring or receiving clinical establishment shall provide and maintain ambulance van or any such suitable conveyances, with such sufficient attendants and other such requisites as may be notified by the Government from time to time.

18. Discharge of Patient.

(1) Any patient admitted in any inpatient department of the clinical establishment shall ordinarily be discharged, on issuance of a Discharge Certificate when further stay is not medically necessary as determined by the Primary Consultant of that patient.

(2) The patient may be discharged, on issuance of a Discharge Certificate for the sake of transfer to another Clinical establishment or Healthcare establishment following the procedure of appropriate transfer as per Rule 17.

(3) In case of discharge under sub-rule (1) & (2), the Primary Consultant shall issue a Discharge Certificate as per Model CE FORM III.

(4) The patient shall have the right to leave the clinical establishment regardless of his physical condition:

Provided that ï

a) he is informed adequately by his Primary Consultant of the medical consequences of his decision;

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

c) his decision will not prejudice public health and safety.

(5) The patient may be discharged, if he fails to comply the advice including the advice for transfer given by the Primary Consultant.

(6) In case of discharge under sub-rule (3) and (4), the Primary Consultant shall issue a Discharge against Medical advice Certificate.

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

(8) No patient shall be detained against his will in any health care institution on the sole basis of his failure to fully settle his financial obligations which may be amounting to confinement under Section 97 Cr.P.C..

(9) If any patient leaves the Clinical Establishment without making appropriate arrangements to settle the unpaid bills he shall be treated as defaulter and the Proprietor may take any appropriate action as per law.

19. Vicarious Liability.

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

(2) It is the responsibility of not only the service provider but also the Proprietor of the CE

(a) to provide the service recipient with the assured service without any undue delay or harassment.

(b) to provide the service recipient appropriate healthcare and non-healthcare services of good quality.

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

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

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

20. Personal belongings of Patient.

(1) At the time of discharge or death all the personal belongings of the patient shall be handed over to the patient party.

Explanation: Personal belongings shall include

(i) such specimen that can be used for reference during future health care including histopathological slides etc.; and

(ii) x-ray film, USG film and such other images, photographs and documents generated as a result of receiving health care including investigation; and

(iii) Such reports generated as a result of receiving health care;

but does not include Medical records generated as a result of receiving health care which is the property of the Clinical Establishment

(2) Until it is handed over, the Proprietor of the Clinical establishment shall preserve the personal belongings in an appropriate manner.

(3) At the time of death corpse of the patient shall be handed over to the patient party or near relative after observing all the legal formalities

Explanation: Corpse means dead body of the patient, new born or still born or anatomical parts thereof

(4) Under no circumstances, the Proprietor of the Clinical establishment shall detain a corpse, which may be amounting to confinement under Section 97 Cr.P.C.

(5) Until it is handed over, the Proprietor of the Clinical establishment shall preserve the corpse in an appropriate manner without showing any disregard for it under Section 297 Cr.P.C.

21. Unclaimed dead body.

(1) Whenever a person dies at a Clinical establishment and his body is unclaimed, the Proprietor of the Clinical establishment shall, without any delay, report the fact to the Competent Authority and the Competent Authority shall hand over the unclaimed body to the authorities in charge of an approved institution for the purpose notified.

Explanation 1: ñunclaimed bodyò means the body of a deceased person [or patient] who has no near relative or whose body has not been claimed by any of his near relatives within such period as may be notified by the Government from time to time.

Explanation 2: óCompetent Authorityô means such authority to do so as may be notified by the Government from time to time

(2) Where there is any doubt regarding the cause of death or when for any other reason the authorized officer consider it expedient so to do, he shall forward the matter to a police officer referred to in section 174 of the Code of Criminal Procedure, 1898 [Act V of 1898]

(3) If any doubt or dispute arises as to whether a person claiming the body of a deceased person is a near relative of the deceased or not, the matter shall be referred to the Appropriate Authority.

(4) Pending such decision, the Competent Authority shall take all reasonable care and steps to preserve the body of the deceased person from decay.

22. Quality Assurance Programme.

(1) Every clinical establishment shall maintain such quality of service as assured by them and shall formulate and set up Internal Quality Assurance programme to guarantee that quality.

(2) In addition to following the standard operating procedure as mentioned in schedule XXX, the clinical establishment shall formulate and set up its own standard operating procedures and other appropriate mechanism including Medical audit.

(3) It must actively take part in such External Quality Assurance scheme as may be framed 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.

(4) Such a scheme under sub-rule (3) 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 other details which may result in an effective implementation of such scheme of reimbursement of expenses incurred.

(5) The Government may allocate necessary funds for the purpose of effective implementation of such scheme.

(6) The scheme framed under sub-rule (3) and subsequent changes, if any, made thereto from time to time, shall be notified.

23. Equipment, Drugs and Medical Supplies.

(1) Every Clinical establishment shall comply with the installation of equipments and machineries as specified in schedule IV.

(2) The Proprietor of the clinical establishment shall ensure that ï

(a) the medical devices of acceptable standard are being used or proposed to be used by the service provider while providing serve to the patient;

(b) the medical devices are being calibrated, handled and maintained as per the instruction of the manufacturer.

Explanation: ôMedical device' means any instrument, apparatus, implement, 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:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

- investigation, replacement, modification, or support of the anatomy or of a physiological process,

- supporting or sustaining life,

- control of conception,

- disinfection of medical devices,

- 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.

(3) Ordinarily, all the drugs, medical devices and medical supplies necessary for the patient accommodated in a clinical establishment shall be supplied from the stock of that clinical establishment and the cost of such medical supplies shall be recovered from the patient presented in form of a common bill issued by that Clinical establishment.

Provide that the patient or the party shall be given an option by the clinical establishment to supply those drugs, medical devices and medical supplies upon receiving such instruction from the Clinical establishment along with the prescription from the Primary Consultant or RMO

Explanation: ñmedical suppliesò means artificial limbs, teeth or eyes, 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, services or supplies prescribed for medical diagnosis, care or treatment.

(4) No service provider or the Proprietor or any person associated with the Clinical establishment shall insist upon ï

(a) procurement or purchase of particular brand of drug, medical device or medical supplies; or

(b) procurement or purchase of drug, medical device or medical supplies from a particular shop, establishment, manufactures or vender;

due to any reasons other than the scientific reason.

(5) 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]

24. Biomedical waste.

(1) Under of the Act, every clinical Establishment shall possess óauthorization or consent to operateô from the State Pollution Board for disposal of its Biomedical Waste under the Bio-Medical Waste (Management and handling) Rules, 1998

(2) It shall be the duty of every proprietor of the clinical establishment to take such necessary steps to ensure that all biomedical waste is handled without any adverse effect to human health and the environment as per the provision of the Bio-Medical Waste (Management and handling) Rules, 1998.

25. Patient Registration System.

(1) Each CE shall have own patient registration system to register all the service recipients as indoor-patient or outdoor-patient including newborn whose birth has taken place in the Clinical establishment with a unique identification number.

(2) No person shall be provided with service unless he is registered as per the patent registration system of that CE:

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

Further provided, that any person shall be provided for and administered with the highest possible Emergency medical treatment without waiting for registration under rule 35.

26. The records and registers.

(1) The Proprietor of the clinical establishment shall generate & maintain -

(a) a record of health case sheet of every patient containing the information as per Model CE FORM IV;

(b) a register for in-patient containing the information as per Model CE FORM V;

(c) a staff register under rule 6,

(d) a staff attendance register under rule 6

as specified in schedule V in addition to any other register that may be required by the Licensing Authority.

Explanation: In the in-patient register, the name and particulars of all the patients admitted including the child born to a woman admitted there have to be registered and recorded even if the newborn may not be sick.

(2) Where an entry made in the IPD register referred to in sub-rule (1) relates to a woman who has been admitted for delivery, and a child born to such woman is removed with the consent of the Proprietor of clinical establishment and of the parents, or near relative, the Proprietor of such clinical establishment shall in addition to the particulars specified in sub-rule (1) also specify in the register the name and address of the person to whose custody and the date on which and the reasons for which the child was so removed.

(3) The hard copy of the registers under sub-rule (1) shall have machined-pressed page number and shall be duly authenticated by the Proprietor.

(4) The records and register under sub-rule (1 to 4) shall bear the name of the clinical establishment along with the License number.

(5) Similarly all documents and stationary including treatment charts, reports, cash memo, bills etc. used by the clinical establishment shall bear the name of the clinical establishment.

(6) Hard Copies of all records, register and documents shall be kept in the record room for at least Five years or in the event of any proceeding till the final disposal of the proceeding.

(7) The records, registers and documents under sub-rule (1 to 4) shall be entered fully, chronologically and legibly and shall not be tampered with.

(8) The Proprietor of the clinical establishment shall ensure that all the Registered Medical Practitioners of the CE are following the guideline of Medical record keeping issued by the Medical Council of India or the guidelines as may be notified from time to time.

(9) Every records, register and documents generated and maintained by the Clinical Establishment shall be open to inspection, in due discharge of his duties, by the Licensing Authority or any other officer specifically empowered on his behalf.

(10) All reports, medical, medico-legal, mandatory or of any kind generated by the Clinical establishment shall be signed in ink and properly dated and shall be produced at the time of inspection or enquiry under rule 60 or on demand by the authority

27. Sanitation & Hygiene.

(1) Every Clinical establishment shall comply with the installation of measures including disinfection and sterilization which shall be taken to keep the clinical establishment in the satisfactory sanitary and hygienic condition and as specified in schedule VI.

(2) Every 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.

(3) Every clinical establishment shall take such necessary measure for handling and disposal of biomedical waste as mentioned under rule 24.

(4) In case of a patient suspected or known to be suffering from an infectious disease, the Clinical establishment shall take appropriate precautionary measures for the protection of other patients and service providers.

Explanation: ó appropriate precautionary measuresô includes but not limited to ï

(a) Universal work precautions;

(b) Barrier Nursing;

(c) Isolation; and

(f) any other scientific measures

28. Display of Information.

(1) No person carrying on or intending to carry on any clinical establishment shall take any part in the publication of any advertisement or paid news or display of information relating to that clinical establishment if the advertisement or information may

(a) directly or indirectly gives a false impression regarding the true character of the clinical establishment; or

(b) contains any matter which may be offensive, flamboyant or other than in good taste or be contrary to the interest of the public or the honour and dignity of the profession; or

(c) imply that they can obtain results from treatment not achievable by other Clinical or Healthcare Establishment or create an unjustified expectation from the treatment provided; or

(d) compare or contrast the quality of their services with those provided by other Clinical or Health care Establishment or deprecate the services of other Clinical or Health care Establishment; or

(e) contain any laudatory statements (including statements of prominence or uniqueness) or superlatives to describe the services or premises of the Clinical Establishment; or

(f) bring disrepute to State or Country or any health-related profession in State or Country

(2) While taking part in displaying any information about the services of the Clinical Establishment, it shall be the responsibility of the person concerned to ensure that:

(a) the clinical establishment has got a valid license

(b) any information relating to its services comply with sub-rule (1);

(c) the information must be factually accurate and capable of substantiation, and must not be exaggerated, false, misleading or be reasonably capable of being misinterpreted;

(d) the information of the services of the Clinical Establishment shall only refer to the services provided at that Clinical Establishment;

(e) All advertisements shall conform with the prevailing standards of advertising and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 [Act 21 of 1954] or any relevant written laws of the land, and with any guideline or direction that may be issued by the Licensing Authority from time to time.

(3) Where required to do so, the person concerned shall forthwith withdraw or cause to be withdrawn any offending advertisement from publication or circulation.

29. Mandatory Display.

(1) At a conspicuous place in the premises the Proprietor of the clinical establishment shall display the license in original in such manner so as to be visible to everyone visiting such establishment under section 16 of the Act.

(2) At reception area and other conspicuous place(s), the Proprietor of the clinical establishment shall make available Information Display Board(s) containing appropriate, adequate and comprehensive information written in both the local and English language in a manner understood by a non technical person of the concerned area.

(3) Information mentioned in sub-rule (2) shall be included but not limited to ð

(a) The name of the Establishment with names of the Proprietors along with the license Number;

(b) The system(s) of Medicine practiced, types and availability of health care and other services;

(c) Schedule of name, of empanelled service providers including visiting consultant, if any;

(d) Availability of concession of rate of charges if any;

(e) Full contact details of the Grievance Officer mentioned in rule 46, with clear mention of the time of availability of the same;

(f) any other notice or information that may be required by the Licensing Authority or any other statuary authority;

(g) in case of collection centre, the name & License No. of the mother laboratory and a certificate of affiliation of such; and

(h) Any other aspects of healthcare services, which may be of use to the public.

(4) At reception area and other conspicuous place(s), the Proprietor of the clinical establishment, for the benefit of the service recipient, shall make available an Information Brochure containing appropriate, adequate and comprehensive information written in both the local and English language in a manner understood by a non technical person of the concerned area

(5) Information mentioned in sub-rule (4) shall be included but not limited to ð

(a) All information mentioned under sub-rule (3);

(b) Schedule of name, qualification Number of empanelled service providers including visiting consultant, if any;

(c) Schedules and timetables of visits of empanelled service providers including visiting consultant, if any;

(d) Working hours/timings of each Unit of the Establishment;

(e) Schedule of rate of charges payable for each type of service as mentioned in rule 33 and 37;

(f) Charter of rights and responsibilities of the Service recipient; and

(g) Procedures for making an application for a grievance.

(6) The Proprietor of the clinical establishment shall submit a copy of Information Brochure mentioned under sub-rule (4) to the Licensing Authority along with the application for grant or renewal of license under rule 55.

(7) The Proprietor of the clinical establishment shall inform the Licensing authority without delay on the amendments if any made in the information displayed under sub-rule (2) & (4).

30. Mandatory Reporting.

(1) The Proprietor of the clinical establishment shall submit the mandatory reports of such National & State Health Program in which their participation is desired under Rule 39 such as NPCB, NVBDCP, RCH etc. in such interval on such standard format as may be notified by the respective State or District Programme Officers.

Explanation: ó State or District Programme Officersô means officers directed to act such by the Department.

(2) The Proprietor of the clinical establishment shall submit the reports of hospital statistics on such standard format as may be notified by the Director, State Bureau of Health Intelligence.

(3) The Proprietor of the clinical establishment shall submit Compiled Yearly Report on the working of the establishment for each calendar year on and before 31st April each year in statutory CE FORM VII.

(4) The Proprietor of such clinical establishment where MTP is being provided shall submit such reports in such interval on such standard format as may be prescribed under the Medical Termination of Pregnancy Act, 1971 (Act 34 of 1971).

(5) The clinical establishment shall follow the Format and other reporting protocols regarding reports under sub-rule (1) & (2) published by the department which may be posted in the website of the department.

(6) The Proprietor of the clinical establishment shall submit all the reports mentioned in sub-rule (1 to 4) to the Designated Officer and obtain an acknowledgement of the same.

Explanation: Designated Officer means District Statistical Manager attached to the CMOH Office in case of a district other than Kolkata or the District Statistical Manager attached to the DFWO in case of Kolkata or any such officer as may be designated by the Licensing Authority.

(7) The Proprietor of the clinical establishment shall, as soon as possible, generate & submit to the Licensing Authority such reports, other than the mandatory reports under sub-rule (1 to 4), as may be demanded by the Licensing Authority pertaining to the discharge of his duties.

(8) The Proprietor of the clinical establishment shall submit all the reports mentioned in sub-rule (6) & (7) personally, or by messenger, or by registered post or any other effective manner as may be directed by the Licensing authority

31. Report of Vital Events.

(1) Within 48 hours from the occurrence of birth, if any, in any clinical establishment, the Proprietor of that clinical establishment shall give in writing the report of such birth to the appropriate authority.

(2) Within 48 hours from the occurrence of stillbirth, if any, the Proprietor of that clinical establishment shall give in writing the report of such death to the appropriate authority.

(3) Within 48 hours from the occurrence of death, if any, of any patient received or accommodated or both in any clinical establishment, the Proprietor of that clinical establishment shall give in writing the report of such death to the appropriate authority with a copy to the Licensing Authority.

(4) The report under sub-rule (1) to (3) shall contain such particulars as per the Registration of Births and Deaths Act, 1969 and rules made thereunder [ACT NO. 18 OF 1969].

(5) The Proprietor of that clinical establishment shall submit such report under sub-rule (1) to (4) personally, or by messenger, or by registered post or any other effective manner as may be directed by the appropriate authority.

Explanation: ó appropriate authorityô means such authority appointed under the Births and Deaths Act, 1969 and rules made thereunder [Act 18 of 1969] for the area within whose jurisdiction the clinical establishment is situated.

32. Report of Unforeseen Events.

(1) The Proprietor of the clinical establishment shall submit a report regarding any unforeseeable or unanticipated events that has occurred at the clinical establishment to the appropriate authority with a copy to the Licensing Authority by the next working day after the incident occurred or immediately after the Proprietor has reasonable cause to believe that the incident occurred.

(2) The reporting of unforeseeable or unanticipated events shall include, at a minimum, the following information:

(a) deaths of patients of the clinical establishment from unexplained cause or under suspicious circumstances, assault, battery 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

(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 [WB 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

along with any follow up action taken or any other information whichever is relevant to the events.

(3) The Proprietor of the clinical establishment shall retain, for at least such period as specified under any written law pertaining to limitation period, all the information about investigation and findings regarding an unforeseeable or unanticipated events so reported under sub-rule (1).

(4) The Licensing Authority may demand further information of the unforeseeable or unanticipated events from the Proprietor of clinical establishment or any other person if he determines that the information is necessary for further investigation.

(5) The Proprietor or any personnel of a clinical establishment shall not discriminate or retaliate against any person who in good faith provides any information under sub-rule (2) or gives any evidence in any proceedings against any Proprietor or any person related to him.

33. Access to Medical Records.

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

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

Explanation: The Summary Medical Report is a report under sub-section (1) to be provided by the Primary Consultant shall contain such particulars which includes but not limited to ï

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

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

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

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

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

(a) The terminal care given; and

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

(3) Notwithstanding that he may not be able to fulfill his other financial obligation, the patient or patient party is entitled to reproduction, at his expense, the pertinent part or

parts of the medical record and reports pertaining to his healthcare' the purpose or purposes of which he shall indicate in his written demand for reproduction.

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

(5) Every clinical Establishment shall display the charges payable under sub-rule (4) in the Information brochure under sub-rule (5) of rule 29.

(6) On demand of the Licensing Authority in due for copy of any of the Medical records and reports pertaining to discharge of his duties, the Proprietor of the clinical establishment shall, as soon as possible, make available such copy to him at free of cost.

(7) The Proprietor of the clinical Establishment may, for reasons to be recorded in writing, refuse to divulge, or furnish the information, pertaining to the Medical records if he is satisfied that ï

(a) the treatment or test or assessment has been conducted on the direction of Licensing authority and it has the first right to receive the information. or

(b) the report if made available to the patient or the Licensing Authority, is likely to cause injury to the patient or his family members;

after seeking opinion of the Primary Consultant.

34. Notifiable Diseases.

(1) Within 1 hour from the occurrence of such infection or dangerous diseases or other condition as may be notified, if any, of any service recipient received or accommodated or both in any clinical establishment, the Proprietor of that clinical establishment shall give information of such occurrence to the appropriate authority.

(2) The Proprietor of that clinical establishment shall give such information under sub-rule (1) personally, or by messenger over telephone, fax or email followed by submission of a written report personally, or by messenger, or by registered post or any other effective manner as may be directed by the appropriate authority

Explanation: ópappropriate authorityô means such authority as may be notified by the Government for this purpose from time to time.

35. Immediate Emergency Treatment.

(1) The clinical establishment, wherever a Registered Medical Practitioner(s) is engaged, shall provide for and administer the highest possible Emergency medical treatment appropriate for that grade of clinical establishment and necessary first aid to stabilize the emergency medical condition of any person who comes or is brought to such clinical establishment.

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

(2) The Emergency medical treatment as mentioned in sub-rule (1) shall be provided to the individual in all cases, whether medico-legal or not, immediately without any delay or waiting for the arrival of the police or completing legal formalities.

Explanation: ó*Immediately*ô means following the ó*Golden Hour*ô treatment protocol

(3) The Emergency medical treatment as mentioned in sub-rule (1) shall be provided to the person including any indigent person under any circumstances, as per provision of the clause (k) of sub-section (3) of section 7 of the Act.

(4) the Primary Consultant or the RMO or any Registered Medical Practitioner may refer the patient to effect an appropriate transfer under rule 17 to another such appropriate clinical establishment or Registered Medical Practitioner for further medical treatment if in its or his opinion further treatment is medically necessary

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

Provided that where any ambulance van or other transport vehicle is not available with the transferring Clinical Establishment, it shall call for the services of an ambulance or other transport vehicle.

36. Free Treatment & concession.

(1) The clinical establishment who has availed any privilege from a agreed party shall provide for such concession regarding treatment facilities to any deserving person including indigent person as mentioned in the agreement.

Explanation 1: ó*privilege*ô shall include but not limited to ï

(a) full or partial exemption of any tax, duty or fees levied by the Government

(b) procurement of any land, property, equipment or medical supply at a concession rate or free of cost

(c) any kind of gift or donation

Explanation 2: ó*Agreed party*ô means any person who has entered into the agreement with a clinical establishment to offer any privilege under certain conditions and shall include any State Government, Central Government, Union territory, Local self-Government, any local Authority, Armed forces, railways, Employees State Insurance Corporation or any such public sector agencies; or a notified body or corporation

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

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

(4) The clinical establishment shall generate and maintain the records of such patient and submit a yearly report of such patients to the Licensing Authority in the statutory CE FORM VII.

37. Service charges.

(1) The Proprietor of Clinical Establishment shall make available the schedule of rate of charges payable for each type of service, in the form of Information brochures as mentioned under rule 29.

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

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

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

(3) While offering such package rate, the Clinical establishment must ï

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

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

(4) A patient or party shall have the right to obtain a written statement of such estimate under sub-rule (2) on request without any delay.

(5) No clinical Establishment shall collect or try to collect from the patient or his party any amount in excess of the rate of charges printed in the Information brochure under rule 29.

(6) No clinical Establishment shall collect or try to collect from the patient or his party any amount payable against any services, which were not actually rendered by that clinical Establishment.

(7) Proper accounts shall be generated and maintained of all receipts and expenditure.

38. Billing & Payment.

(1) A patient or party shall have the right to be informed by a clinical establishment prior to the initiation of care or treatment of the clinical establishmentôs billing procedures.

(2) The patient or party shall have the right to obtain and examine, on demand, an itemized common bill for all the services rendered by the clinical establishment, at no extra cost, regardless of the manner and source of payment.

(3) He is also entitled to a thorough explanation of such bill.

(4) No clinical Establishment shall collect or try to collect any sum from the service recipient or his party without issuing proper receipt for the amount charged and collected.

(5) The duplicate copy of bill and payment shall be retained by Nursing Home for a period not less than five years which will be liable for inspection by the Licensing Authority.

(6) All payments accepted by the Clinical establishment should be supported by uniquely numbered receipts bearing the name of the clinical establishment.

(7) In the course of his treatment and hospital care, the patient or patient party shall have the right 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.

39. Role in Public Health.

(1) Every clinical establishment shall follow the mandatory therapeutic guidelines for diseases covered under various National Health programmes and as may be notified by the state and central government from time to time.

(2) All the clinical establishments shall actively participate in the implementation of all National and State Health programmes in such manner as may be notified by the State Government from time to time.

(3) In case of any disaster, man-man or natural, and public health exigency, the Proprietor of the Clinical establishment on being requested by the Licensing authority, shall co-operate and provide such reasonable assistance and Medical aid as may be considered essential in course of disaster management by the Licensing authority at the time of natural calamity of disastrous situation

Explanation: ódisasterô and ñdisaster shall be used as defined under The Disaster Management Act, 2005 [Act No. 53 of 2005]

(4) In case of emergence of any infection or dangerous disease, the Proprietor of the Clinical establishment Perform statutory duties in respect of such diseases to prevent the spread and further occurrence of the disease.

40. Capacity Building.

(1) Without the approval from the Authority, no clinical establishment shall confer, grant or issue, or hold itself out as entitled to confer, grant or issue any degree, diploma, license, certificate or any other document stating or implying that the holder, grantee or recipient thereof is qualified to provide any kind of professional service.

Explanation: óAuthorityô means any University or deemed University established by the Central or state law or any other institution recognized by the Central or State Government in this behalf.

(2) 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, certificate or any such document as mentioned in sub-rule (1):

Provided that it may conduct any in-service training or educational programme or any other capacity building programme for the 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.

(3) The Proprietor of the clinical establishment, from time to time, shall organize such capacity building programme for the service providers of the clinical establishment to make them aware about the recent development in public health programme including recent changes of Standard treatment protocol.

(4) The Proprietor of the clinical establishment, from time to time, shall organize orientation programme for them to enable, encourage and motivate them for active participation in various national and state level health programme including implementation of different public health Laws.

(5) The Proprietor of the clinical establishment shall try to build up the capacity of every service provider including nursing personnel and paramedical professionals regarding first Aid & CPR Technique as mentioned in rule 35.

(6) The Department may provide reasonable assistance for organization of such programmes under sub-rule (3) to (5).

(7) The Proprietor of the clinical establishment must read and understand and make all the staff to read and understand the West Bengal Clinical Establishment (Registration and Regulation) Act, 2010 (West Ben. Act XXVI of 2010) and the West Bengal Clinical Establishment (Registration and Regulation) Rules, 2011.

41. Bio-medical Research.

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

(2) The State Government may, by notification ï

(a) designate an officer not below the rank of Joint Secretary, Medical Education as the State Prescribing Authority of Bio-medical research; and

(b) lay down the principles and procedure of approval,

under sub-rule (1).

42. Unethical & Unfair Trade practice.

(1) No service provider or any person associated with the Clinical establishment

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

(b) shall directly 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

Explanation: "fee-splitting" means any form of kickbacks or 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];

(2) The Proprietor of a clinical establishment shall not practice fee-splitting and shall ensure that any service provider or any person associated with the Clinical establishment do not practice fee-splitting

(3) No Service provider or the Proprietor or any person associated with the Clinical establishment shall

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

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

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

(d) carry out or undertake to carry out any form of investigations and procedure which is not medically necessary;

for the sole purpose of financial gain.

43. Responsibilities & Obligation of the patient.

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

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

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

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

(d) He shall ensure that he understands the purpose and cost of any proposed treatment or procedure before deciding to accept the service;

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

(f) He shall insist upon explanations until adequately informed and consult with all relevant persons before reaching a decision;

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

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

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

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

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

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

(2) The patient is expected to first exhaust the grievance mechanism provided in this Act before filing any administrative or legal action.

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

(4) Appropriate action will be taken against any patient found guilty under the West Bengal Medical service persons and Medicare Service Institution (Prevention of Violence and damage to Property Act, 2009 [WB Act XI of 2009].

(5) For the purpose of this rule the term ópatientô shall include ópatient partyô also wherever and whenever applicable.

44. Standard Charter of Patient rights.

(1) A Standard Charter of patient rights based upon various rights provided under this act and rule, shall be adopted, observed and published by the clinical establishment.

(2) The clinical establishment shall orient the staff for the Standard Charter of patient rights under sub-rule (1).

(3) The patient shall be informed about the rights mentioned in sub-rule (1) in a format and language that they can understand.

(4) For the purpose of this rule the term ópatientô shall include ópatient partyô also wherever and whenever applicable.

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

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

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

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

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

45. Regulation of the Clinical Establishment.

(1) Every clinical establishment has got the right to make its own set of Regulation, and standard operating procedures subject to the following terms and conditions:-

(a) Those regulation, and standard operating procedures shall not be contrary to any provision of the Clinical Establishment Act, rules and regulation; and

(b) Those regulation, and standard operating procedures shall not be contrary to the provision of any law of the land; and

(c) Those regulation, and standard operating procedures shall not be violating the fundamental rights or human rights.

(2) Along with the application for license under Rule 52 and application for renewal under rule 58, a draft copy, if any, of those regulation, and standard operating procedure shall be submitted to the Licensing Authority for his information.

(3) It shall be the duty of the Proprietor of the clinical establishment to make all service recipients and service providers aware of the relevant section(s) of those regulation, and standard operating procedures.

(4) The Clinical establishment has the right to recover service charges, or any charges towards the recovery of cost of any damaged property but shall not have the right to impose or realize any fine or penalty from the Patient or party.

46. Grievance redressal System.

(1) Every Clinical establishments, with more than one service provider, shall have an internal redressal system as provided below.

(2) Anyone aggrieved by the denial of assured service is expected to first exhaust the grievance mechanism provided in this Act before filing any administrative or legal action

Explanation: ñDenial of assured servicesò means and includes

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

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

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

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

(e) any other deficiency of service

(3) The Proprietor of the clinical establishment shall a designate a specific member of the staff including himself preferably having experience in public relations to be designated as Grievance Officer as a person in charge of internal Grievance redressal mechanism.

(4) Upon receiving a complaint, oral or written, from the aggrieved party for redressal of grievance, the Grievance Officer shall

(a) register the complaint without any delay in a complaint book mentioning details as specified in the schedule and provide the aggrieved party an acknowledgement number which may be used as reference by the aggrieved party; and

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

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

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

Explanation: ñAggrieved partyò means any person who has submitted a complaint as per sub-rule (4) and includes

(a) Any service recipient including Patient or Patient Party whose individual rights are alleged to be violated; or

(b) Any person(s), as a potential service recipient whose collective community rights are alleged to be violated; or

(c) any organization acting in public interest;

(5) The Grievance Officer under sub-rule (3) shall submit extracts from the register of grievance on grievances made, action taken or not taken, as specified in the schedule, to the respective Licensing Authority at the end of each month/year.

(6) The Proprietor of the clinical establishment shall display the procedure of laying complaints in a manner that is visible for any person entering the establishment and shall communicate the procedure to the service recipient on a regular basis.

(7) If the aggrieved party feels that the grievance is not properly redressed, he has the right to approach the Tribunal under section 40 of the Act.

47. District Register.

(1) The licensing authority shall generate and maintain a register in statutory CE FORM IV to be known as the District register of Clinical establishments for recording the details in respect of clinical establishments of the district.

(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) The registers as mentioned in sub-rule (1) shall have machined-pressed page number and shall be duly authenticated by the licensing authority.

(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, for example, serial number 5 of 1972 and serial number 5 of 1973 shall be mentioned as 5/1972 and 5/1973.

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

48. State Register.

(1) The State Registrar shall generate and maintain a register in statutory CE FORM VIII to be known as the State Register of clinical establishments in respect of clinical establishments of the State based upon the reports received from the District Registrar.

(2) 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 were registered or renewed during the preceding year.

49. Correction or cancellation of entry in the register.

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

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

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

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

he may, subject to such rules as may be made by the State Government with respect to the conditions on which and the circumstances in which such entries may be corrected or cancelled,

50. Name of the Clinical Establishment.

(1) Under of the Act, the naming of a clinical establishment shall conform to the provisions of the Emblems and Names (Prevention of improper use) Act, 1950 [Act No.12 of 1950].

(2) Clinical Establishments having identical names in the jurisdiction of a particular licensing authority shall not be allowed to avoid confusion amongst the service recipient.

(3) Nursing Home(s) having not less than 25 (twenty-five) beds may be named as ñHospitalò or any of its variation:

Provided that it has separate earmarked facilities or department for providing emergency medical services round the clock.

(4) The word ñRESEARCHò or any of its variation may only be used in the name of a clinical establishment if it has obtained the approval under the rule 41 and submit evidence thereof along with the application.

(5) Any clinical establishment shall be considered as óGenetic Counseling Centreô or óGenetic Clinicô or óGenetic Laboratoryô as per the provision of under the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 [Act No. 57 of 1994].

(6) Notwithstanding anything contained in any law for the time being in force, no clinical Establishment shall, except in such cases and under such conditions as may be as may be granted by the Licensing Authority, use, or continue to use any improper Name including the words and abbreviation thereof.

Explanation: óImproper Name means if

(a) it 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) it gives the impression of the patronage of Central Government or State Government; or

(c) it too nearly resembles a name of body corporation or local authority set up by Government under any law for the time being in force; or

(d) it connotes Governmentôs participation or patronage unless circumstances justify it; or

(e) It resembles the name of a healthcare establishment run by the Public sector agencies; or

(f) It does not conform to the clinical establishmentôs function and the facilities available and services offered thereof

(7) If any such name(s) which are prohibited under sub-rule (1) to (6) is being used by any old clinical establishment, the Proprietor of such clinical establishment shall apply in statutory CE FORM II to change such name(s) without any delay.

51. Classification.

(1) The Clinical establishments shall be classified as below depending upon four criteria namely Location; Ownership; System of Medicine Offered and Type of Establishment or any other criteria as may be notified by the Government from time to time.

(2) Depending upon the nature of Location those will be classified into mutually exclusive locations: (1A) Metropolitan: Corporation or Urban Local body having more than 5 lakh population; (1B) Urban: Corporation or Munipality or notified area having equal to or less than 5 lakh population; or (1C) Rural: Panchayat Area

(3) Depending upon the nature of ownership those will be classified into mutually exclusive Proprietorship: (2A) Individual Proprietorship; (2B) Registered Partnership; (2C) Registered Company;(2D) Corporation (including a society) registered under a Central, Provincial or State Act (to be specified); (2E) Trust (including Charitable) registered under a Central, Provincial or State Act (to be specified); (2F) Branch of a Foreign Service provider (to be specified); or (2G) Any other (Private Sector enterprise (to be specified)

(4) Depending upon the nature of System of Medicine Offered those will be classified into mutually exclusive system:

(3A) Allopathy: further sub-classified into mutually exclusive groups: (3A)(i) General; (3A)(ii) Specialty e.g. Medicine, Surgery, Pediatrics etc.; (3A)(iii) Super-specialty e.g. Plastic Surgery, Pediatric Surgery etc.; (3A)(iv) Dental; or (3A)(v) Any other Allopathy (to be specified); or

(3B) Ayurveda: further sub-classified into mutually exclusive groups: (3B)(i) Ausadh Chikitsa; (3B)(ii) Shalya Chikitsa; (3B)(iii) Shodhan Chikitsa; (3B)(iv) Rasayana; (3B)(v) Pathya Vyavastha; or (3B)(vi) Any other Ayurveda (to be specified); or

(3C) Unani: further sub-classified into mutually exclusive groups: (3C)(i) Matab; (3C)(ii) Jarahat; (3C)(iii) Ilaj-bit-Tadbeer; (3C)(iv) Hifzan-e-Sehat; or (3C)(v) Any other Unani (to be specified); or

(3D) Siddha: further sub-classified into mutually exclusive groups: (3D)(i) Maruthuvam; (3D)(ii) Sirappu Maruthuvam; (3D)(iii) Varmam Thokknam & Yoga; or (3D)(iv) Any other Siddha (to be specified); or

(3E) Homeopathy: further sub-classified into mutually exclusive groups: (3E)(i) General Homeopathy; or (3E)(ii) Any other Homeopathy (to be specified); or

(3F) Naturopathy: further sub-classified into mutually exclusive groups: (3F)(i) External Therapies with natural modalities; (3F)(ii) Internal Therapies; or (3F)(iii) Any other Homeopathy (to be specified); or

(3G) Yoga: further sub-classified into mutually exclusive groups: (3G)(i) Ashtang Yoga; or (3G)(ii) Any other Yoga (to be specified); or

(3H) Any other recognized system of Medicine (to be specified)

(5) Depending upon the nature of Service facilities offered by the Clinical establishment those will be classified into mutually exclusive categories:

(4A) providing mainly Outpatient based Service: further sub-classified into mutually exclusive groups: (4A)(i) Solo clinic; (4A)(ii) Polyclinic; (4A)(iii) Dispensary; (4A)(iv) Dental Clinic; (4A)(v) Physiotherapy Clinic; (4A)(vi) Occupational therapy Clinic; (4A)(vii) Infertility Clinic; (4A)(viii) Dialysis Centre; (4A)(ix) MTP clinic; (4A)(x) Day care centre; (4A)(xi) Wellness/Fitness centre/clinic; (4A)(xiii) Integrated Counseling & Testing Centre; or (4A)(xiii) any other clinic (to be specified); or

(4B) providing mainly Inpatient based service: further sub-classified into mutually exclusive groups: (4B)(i) Maternity Home; (4B)(ii) Nursing Home/Hospital; (4B)(iii) Sanatorium or (4B) (iv) Any other IPD centre (to be specified); or

(4C) providing laboratory service further sub-classified into mutually exclusive groups: (4C)(i) Pathology (Biochemistry, Clinical pathology, Morphological pathology, Microbiology and Haematology); (4C)(ii) Genetic Laboratory; (4C)(iii) Electro-cardiography; (4C)(iv) Electro-encephalography; (4C)(v) Electromyography; (4C)(vi) Clinical Physiology or (4C)(vii) any other laboratory (to be specified); or

(4D) providing Diagnostic & Imaging service: further sub-classified into mutually exclusive groups: (4D)(i) X-Ray Centre (Conventional or Digital); (4D)(ii) Mamography centre; (4D)(iii) Bone Densitometry centre; (4D)(iv) Sonography centre; (4D)(v) Colour Doppler Imaging centre; (4D)(vi) CT Scan Centre; (4D)(vii) Magnetic Resonance Imaging (MRI) Centre; (4D)(viii) Positron Emission Tomography (PET) Scan Centre; (4D)(ix) Echo; or (4D)(x) Any other Imaging Centre (to be specified); or

(4E) Any other type (to be specified)

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

Explanation 2: ó"Clinical Pathologyô shall include (i) Estimation of carbohydrate, lipid protein and electrolyte constituents of blood, urine and other body fluids, and their metabolism; (ii) Estimation of carbohydrate, lipid protein and electrolyte constituents of blood, urine and other body fluids, and their metabolism; (iii) Determination of endocrine levels and enzyme reactions; and (iv) Levels of drugs and toxic substances.

Explanation 3: ó"Microbiologyô shall include (i) Bacteriology; (ii) Parasitology; (iii) Mycology; (iv) Virology; and (v) Immunology;

Explanation 4: ó"Haematologyô 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

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

Explanation 6: For the sub-rule (4) and (5), ó"to be specifiedô means ó"to be specified by the applicantô".

(6) Depending upon the bed capacity, the inpatient facilities shall be further sub-categorized in mutually exclusive sub category of: (a) Up to 25 beds; (b) 26-50 beds; (c) 51-100 beds; or (d) More than 100 beds

Explanation: ówinpatient facilitiesô means (i) all types under sub-rule (4B), and Infertility Clinic; Dialysis Centre; MTP clinic; Day care centre under sub-rule (4A) or any other establishment having beds

(7) With the advance of modern medicine, more and more clinical establishment are offering different intensive therapy facilities which can be classified into following mutually exclusive units: (4F)(i) Intensive Therapy unit; (4F)(ii) Intensive Coronary care Unit; (4F)(iii) Intensive Neonatal care Unit; or (4F)(iv) any other therapy unit (to be specified).

(8) All such intensive therapy facilities under sub-rule(7) have to be attached to a Maternity home or Nursing Home or Hospital having inpatient facilities.

(9) Depending upon the complexity of the test and required qualified personnel, the Pathology Laboratory shall be further sub-categorized in mutually exclusive sub category of: (a) Small Laboratory; (b) Medium Laboratory; (c) Large Laboratory; or (d) Collection centre.

(9) The term ówCollection centreô may be defined as a Pathology Laboratory providing services regarding collection of samples or specimen for the purpose of pathological, bacteriological, chemical, biological or other tests, examination, or analysis.

(10) The term ówSmall Laboratoryô may be defined as a Pathology 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.

(11) The term ówMedium Laboratoryô may be defined as a Pathology 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.

(12) The term ówLarge Laboratoryô may be defined as a Pathology Laboratory performing all the Microbiology, and Morphological Pathology tests in addition to tests performed by the medium laboratory.

Explanation 1: ñSampleò means a substance derived from a nonhuman source and collected for the purposes of analysis

Explanation 2: ñSpecimenò means blood, sputum, urine, stool, or other bodily fluids, waste, tissues, and cultures necessary to perform required tests.

Explanation 3: ówTestô or ówexaminationô means any diagnostic or investigative analyses or medical procedures that determine the presence, absence or degree of severity of, or level of exposure to, a condition of health importance, or its precursor, in an individual.

(13) As the tests are not being performed there, every collection centreô as defined under sub-rule (9) must have such arrangement or affiliation with any small, medium or large laboratory to perform those tests who are already registered under this Act and at the time of application for grant or renewal of license, the applicant for collection centre must be able to produce document in support of such arrangement or affiliation with such mother laboratory in the form of a formal written agreement.

52. Application for registration.

(1) An application for registration under sub-section (1) of section 12 of the Act, along with application fees and accompanying documents shall be submitted to the licensing authority on statutory CE FORM II.

Explanation: ôLicensing Authority; means ï

(i) The Chief Medical Officer of Health of that district if the clinical establishment is situated in district other than district of Kolkata; or

(ii) The Assistant Director of Health Services (Clinical establishment) if the clinical establishment is situated in the district of Kolkata; or

(iii) Any such officer as may be notified by the Government from time to time;

who shall be acting as Licensing Authority as per the provision of section 5 of the Act.

(2) The application shall be filled in with the particular name of the applicant and not with the name of a Firm, Company or a Partnership Organization so that the responsibility of the Clinical establishment can be fixed upon a particular individual:

Provided that in case of a Firm, Company or a Partnership Organization, the applicant shall be a representative of Firm, Company or a Partnership Organization after being selected though resolution by that Firm, Company or a Partnership Organization to act as such.

(3) The applicant under sub-rule (3) after being granted a license under the Act shall be registered as the Proprietor of that Clinical Establishment.

(4) The applicant shall submit the application personally, or by messenger, or any other effective manner as may be directed by the Licensing authority.

(5) No Clinical Establishment shall be permitted to operate facilities/services other than those allowed under the License.

53. Application Fee.

(1) The application fee to be submitted along with the application as mentioned in sub-rule (1) of Rule 52 shall be the one-tenth of amount as specified in the schedule VIII and shall be paid in cash to the Reserve Bank of India in Kolkata and to the Treasury elsewhere under the appropriate receipt Head.

(2) The Application fees once credited to the appropriate receipt head will be considered as processing & inspection fee and will not be refunded even in case of rejection of application by the Licensing authority or withdrawal of application by the applicant.

54. Acknowledgement of Application.

(1) The licensing authority shall generate and maintain a register in statutory CE FORM I to be known as the Application register of Clinical establishments to record the relevant information regarding application submitted to him.

(2) Where an application for the grant or renewal of a license is delivered personally, its receipt shall be acknowledged forthwith.

(3) All the acknowledgement of receipt shall bear an unique Acknowledge Number, which can be used for future references.

55. Particulars and the accompanied evidence.

(1) In case of application for grant or renewal of license, the following documents are to be submitted along with the application form under rule 52:

(a) Self declaration as per sub-rule (4)

(b) copy of treasury Challan regarding deposit of License fee;

(c) copy of plan for construction or modification approved by the Appropriate Authority;

(d) Copy of building completion certificate issued by the Appropriate Authority

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

(f) Information Brochure under rule 29;

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

(h) copy of the Regulation of the clinical establishment under rule 45, if any;

(i) copies of Offer letters & Acceptance letters of all the staff empanelled by the clinical establishment;

(j) copies of certificates of Registration and certificate of qualification all Medical, nursing and paramedical Professional empanelled by the clinical establishment under rule 5;

(k) copy of application for ó authorization or consent to establishô under the Bio-Medical Waste (Management and handling) Rules, 1998 submitted to West Bengal Pollution control board in case of application for new license; or copy of ó authorization or consent to establishô under the Bio-Medical Waste (Management and handling) Rules, 1998 issued by West Bengal Pollution control board in case of application for renewal of License;

(l) copy of application for trade license submitted to Local body in case of application for new license or copy of trade license issued by Local body in case of application for renewal of License;

(m) copy of the current rent receipt or rent agreement or any such document if the applicant is a tenant or the current lease-deed if the applicant is a lessee or the current consent letter from the owner if the applicant is granted rent free accommodation by the owner of the premises;

Explanation: ó any such documentô means receipt of rent deposited to rent control or any such appropriate authority;

(n) copy of the óNo objection certificateô from the Owner of the premises if the applicant and the owner is different person in case of application for new license;

(o) copy of treasury Challan regarding deposit of Application fee in case of application for new license.

(p) Copy of acknowledgement of reports under sub-rule (6) of rule 30 and

(q) Any other additional document mentioned elsewhere in the Act or rules.

(2) In case of Companies or Private Limited Companies, the following additional documents are to be submitted along with the application form under rule 52:

(a) copy of Memorandum/Articles of Association in case of Companies / Private Limited Companies; or

(b) copy of the Partnership deed in case of Partnership Firm

(3) Copy of documents mentioned in Sub-rule (1) to (4) means photocopy of such original documents duly attested by a gazetted officer, which shall be produced by the Clinical establishment during the time of inspection under rule 60.

(4) The applicant must submit a self-declaration as per statutory CE FORM VI in the form of an Affidavit on requisite stamp paper sworn by him before the licensing authority

(5) All the supporting documents along with the properly filled in application form shall be submitted under a cover letter/forwarding letter to the Licensing Authority.

(6) Any changes in address or situation of or of staff belonging to, or any other particulars under sub-section (2) of section 12 of the act together with specific mention as to the exact date (s) on which such changes have taken place shall be communicated in statutory CE FORM II by the applicant or Proprietor of the clinical establishment to the licensing authority immediately and in any case not later than thirty days after such change with specific mention as to the exact date under sub-section (3) of section 12 of the act.

56. Role of Licensing Authority.

(1) The Licensing Authority shall be responsible for:

(a) Grant or rejection of License under clause 13;

(b) Suspension of License under clause 23 of the Act

(c) Issuance of Improvement notice under clause 23 of the Act

(d) Issuance of Prohibition order under clause 21 of the Act

(e) Cancellation of License under clause 20 of the Act

(f) Enforcing compliance with the provisions of Clinical establishment Act and Rules

(h) Investigation of complaints of breach to the provisions of Clinical establishment Act and Rules

(g) Generation and maintenance of record of application, registration, renewals, inspections, including records of accounts thereof or any other matters pertaining to act

(i) Preparation and submission of report to the State Registrar; and

(j) Any other duties as may be assigned by the Government from time to time.

(2) While discharging his duties mentioned in Sub-rule (1) the Licensing Authority shall consider the standards of such health care or non-health care related services which come under the purview of the clinical establishment Act and Rules:

Whereas standard of other non-health care related services, which do not come under clinical establishment Act and Rules, shall be regulated by other competent authorities in accordance with the provisions of other relevant Acts and Rules in force at the time.

(3) The Licensing Authority shall pass an order for grant or refusal of application within 90 days of receiving the application.

(4) He shall send the copy of order of refusal to the applicant by registered post, courier service, messenger, e-mail or by any other manner as he deems fit for the purpose.

57. Copy of license.

(1) An application for copy of license under section 12 of the act shall be submitted to the licensing authority on statutory CE FORM II. along with the stipulated fee, the evidence of loss, destruction mutilation or damage and any other documents as may be required by the Licensing Authority.

(2) The stipulated fee under sub-rule (1) shall be Rs.500 and shall be paid in cash to the Reserve Bank of India in Kolkata and to the Treasury elsewhere under the appropriate receipt Head.

58. Renewal of registration and license.

(1) An application for renewal of registration and license shall be submitted to the licensing authority on statutory CE FORM II along with the existing license duplicate.

(2) The applicant, in advance, shall submit the application under sub-rule (1) at least 30 days before the date of expiry of the validity of the license.

(3) If the last date of submitting an application is a gazetted holiday, the application shall be submitted on the immediate next working day.

(4) The applicant shall submit the application personally, or by messenger, or by registered post or any other effective manner as may be directed by the Licensing authority.

(5) In case of renewal of certificate of registration & License, no application fee is to be submitted.

(6) In case the application for renewal is made after the said period but before the date of expiry of the validity of the registration and license, the licensing authority shall allow renewal of registration and license provided that the applicant made an additional payment of 25% of the License fee.

(7) In case the application for renewal is made after expiry of the validity of the registration and license, the licensing authority shall treat it as a fresh application as per rule 52:

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

(8) At the time of submission of application for renewal under sub-rule (1), the applicant shall submit a No objection certificate issued by the Designated Officer under sub-rule (6) of Rule 30 regarding compliance of the submission of routine reports.

59. Order or Notice.

(1) Whenever any order or notice is required to be served under section 21 or section 23 or any other provision of the act, rule, or regulation such order or notice shall be served ï

(a) by giving or tendering the order or notice to such person; or

(b) if such person is not found, by leaving such order or notice at his last known place of abode or business or by giving or tendering the same to some adult member or servant of his family; or

(c) if such person does not reside in the local area and his address elsewhere is known to the executive authority, by sending same to him by post, registered or electronic mail; or

(d) If none of the means aforesaid be available, by affixing same in some conspicuous part of such place of abode or business.

(2) When the person is an owner or occupier of any building or land, it shall not be necessary to name the owner or occupier in the order and in the case of joint owners and occupiers it shall be sufficient to service it on or send it to one of such owners or occupiers.

(3) Notwithstanding anything contained in the sub-rule(1) and (2),regarding the serving of notice, the provision of Civil Procedure Code as amended from time to time shall be followed mutatis mutandis.

(4) 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 and shall be liable to a penalty which may extend to ten thousand rupees.

60. Inspection.

(1) The Licensing Authority shall order a scheduled inspection as soon as possible and as often as may be necessary to

(a) verify the material facts and statement made in the application as per provision of rule 55; and

(b) ascertain the quality of standard of service as per provision rule 4 to 28.

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

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

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

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

(b) that clinical establishment has failed to comply with any provision of this act.

(4) For the purpose of inspection and inquiry as per sub-rule (1), (2) and (3) the Licensing Authority, by general or specific order, will constitute an Enquiring Authority of no less than 1 member of Govt. servant headed by a govt. medical officer.

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

(5) The Enquiring Authority, at any reasonable time, with such assistance as it reasonably require, shall enter the premises of a clinical establishment 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) inspect, make copies of or take extracts from any document;

(e) ask questions of any patient for the purpose of ascertaining whether the patientôs well-being is being adequately cared for

(f) require a Proprietor or any member of staff of the health service establishmentô

(i) to answer a question to the best of that person's knowledge, information and belief;

(ii) to take reasonable steps to produce documents; and

as they deem necessary.

(6) The Enquiring Authority may ask questions and take on the spot or otherwise the statement of any person as he deems necessary:

Provided that, no person shall be required under this sub-rule to answer any question or give any evidence tending to incriminate himself:

(7) While conducting inspection or enquiry, a member of Enquiring Authority -

(a) shall give a prior intimation to the Clinical Establishment, in case of scheduled inspection under sub-rule (1):

Provided that no such prior intimation shall be given to the Clinical Establishment in case of unscheduled or surprise inspection under sub-rule (2) & (3)

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

(c) shall exercise power vested upon him by the act and rules and such other powers as may be necessary, for carrying out the purposes of this Act.

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

(8) Any person who obstructs, hinders or impedes an Enquiring 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

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

(10) Nothing in this rule shall be deemed to deter any such member of Enquiring Authority to inspect any medical record relating to any patient in a clinical establishment maintaining confidentiality and taking care that it doesnôt come into public domain.

61. The Enquiry Report.

(1) The Enquiring Authority shall record the salient points of their observation or inspection in the inspection book to be kept by the CE specified in the schedule with

reference to the availability of minimum standards specified in the schedule and also detailing the specific deficiencies to be corrected, if any.

(2) The Enquiring Authority shall record his observation of inspection and recommendation(s) thereof in the statutory CE FORM III and submit a report to the Licensing Authority along with the form with reference to the availability of minimum standards specified in the schedule and also detailing the specific deficiencies to be corrected, if any.

(3) Where, in the opinion of the Enquiring Authority:

(a) the use of any apparatus, appliance, equipment, instrument, product, goods or item; or

(b) the carrying out of any practice or procedure in a healthcare establishment,

is dangerous or detrimental to any person therein or otherwise unsuitable for the purpose for which it is used or carried out, he shall immediately report, the matter in writing to the Licensing Authority along with the necessary details.

(4) As soon as possible after the receipt of enquiry report, the Licensing Authority shall communicate a copy of the enquiry report pointing out the deficiencies, if any, to the Applicant with a direction to rectify the deficiencies pointed out and inform the Licensing Authority accordingly.

(5) On receipt of enquiry report, the Licensing Authority may issue an Improvement Notice under section 23 of the Act or may take any necessary action according to the procedure notified by the Government from time to time.

(6) Except in the case of a prosecution for a contravention under this Act, a member of the inspection team shall not be bound to give evidence in any proceedings in respect of, or to produce any document containing, any information which has been obtained from any clinical establishment in the course of carrying out any investigation, inspection, enquiry or performing any duty or function under this Act.

(7) A member of the inspection team shall not disclose any information at any forum which is contained in the medical record, or which relates to the condition, treatment or diagnosis, of any person, as may have come to his knowledge in the course of carrying out any investigation, inspection, enquiry or performing any duty or function under this Act unless allowed in writing by the Government.

62. Entry, search, seal & seizer.

(1) An Authorized Officer, preferably in the presence of two or more independent and respectable persons, shall enter any premises specified in the Authorization Notice, including a private dwelling, and-

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

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

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

Explanation 1: óAuthorization Noticeô means the authorization issued by Adjudicating Authority, Tribunal or Court of law or any such appropriate authority as may be notified under section 24(1) of the Act

Explanation 2: óAuthorized Officerô means any officer of the state government authorized by Adjudicating Authority, Tribunal or Court of law or any such appropriate authority as may be notified under section 24(1) of the Act

Explanation 3: ñMaterial objectò means any equipment, sample, article, document, record, register, book, pamphlet, advertisement or any other material object for the purpose.

(2) Upon the request of the Authorized Officer or the Police Officer accompanying him, the occupant and any other person present on the premises must-

(a) make available or accessible or deliver to the Authorized Officer 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 as he or she has with regard to the matter under investigation; and

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

Explanation: óPolice Officerô means the police officer accompanying and assisting the Authorized Officer under section 24(1)(c) of the Act

(3) Before questioning any person at the premises in question, the Authorized Officer or the Police Officer must advise that person of his or her right to be assisted at the time by an advocate or attorney, and allow that person to exercise that right.

(4) The Authorization Notice under sub-rule (1) may impose restrictions on the powers of the Authorized Officer.

(5) The Authorization Notice issued in terms of this rule shall remain in force until-

(a) it is executed;

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

(c) the expiry of one month from the day of its issue; or

(d) the purpose for the issuing of the Authorization Notice has lapsed, whichever occurs first

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

(7) In the case of non-completion of search and seizure operation, the Authorized Officer may make arrangement, by way of mounting a guard or sealing of the premises, for safe keeping, listing and removal of the material object to be seized, and to prevent any tampering with such material object.

63. Compliance of entry, search, seal & seizer.

(1) An Authorized Officer or the Police Officer accompanying him shall immediately before entering the premises in question-

(a) audibly announce that he 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.

(2) The Authorized Officer must-

(a) hand over to the person in control 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 his identity card issued by the Government to that person.

(3) The Authorized Officer 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.

(4) Before using force, the Authorized Officer or the Police Officer must audibly demand admission and must 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.

(5) All Government servants shall render all helps and co-operation whenever they are approached by the Authorized Officer, the Adjudicating Authority, Tribunal or Court of law or any such appropriate authority as may be notified under section 24(1) of the Act for assisting or witnessing the action or in the conduct of enquiry under section 24.

(6) Any reluctance, refusal or non-cooperation noticed on the part of the officer shall be viewed seriously by the government and appropriate penal action may be taken.

(7) Any Police Officer who omits or refuses to perform any duty imposed on him by this Act shall be deemed to have violated the order of a public servant competent to pass such order.

64. Retention of seized Object.

(1) An Authorized Officer shall prepare a list of any material object, seized under sub-rule (1) of Rule 62 at the place of affecting the seizure and get it signed on every page by himself, the witnesses and the Police officer accompanying him:

Provided that the list 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 effecting the seizure.

(2) The Authorized Officer who removes anything from the premises being searched must hand over, under acknowledgement, one copy of the seizer list referred to in sub-rule (1) of Rule 62 to the person from whose custody the material object have been seized:

Provided that a copy of the seizer list may be delivered under acknowledgement, or sent by registered post to the Proprietor 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.

(3) If any material object seized is perishable in nature, the Authorized Officer 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.

(4) The Authorized Officer under sub-rule (2) must return those material objects as soon as practicable after achieving the purpose for which it was removed preferably within 6 weeks:

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 section 24(1) of the Act.

65. License Fees.

(1) A License fee along with application for new or renewal of registration, shall ordinarily be submitted to the LA.

(2) The stipulated License fee for grant of new License shall be the whole amount as specified in the schedule VIII unless otherwise ordered by the Government under section 25 of the Act.

(3) The stipulated License fee for grant of renewal shall be 50% of the amount of license fee as specified in the schedule VIII.

(4) The License fee under sub-rule (2) and (3) shall be paid in cash to the Reserve Bank of India in Kolkata and to the Treasury elsewhere under the appropriate receipt Head.

(5) If necessary, the refund of License fee shall be given from the appropriate refund head

(6) The licensing authority shall keep a record of accounts of the fees so deposited under sub-rule (4), on receipt of the Bank or Treasury Challan to be produce by the applicant.

(7) The existing license in duplicate must be surrendered with the application for every amendment of the clinical establishment license on proper receipt from the licensing authority.

66. The Appeal.

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

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

(3) Any appeal preferred under Sub-rule (1) or (2) shall be accompanied with a non-refundable fee to be deposited in the appropriate receipt head, amount of which shall be equivalent to the same as of the application fee as per rule 53.

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

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

(6) The Appellate Authority, shall hear all the concerned, receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its decision preferably within 90 days from the date of filing the Appeal.

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

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

67. Minor and major deficiencies.

Yet to be prescribed.

68. Cognizance of Contravention.

(1) No Adjudicating Authority shall take cognizance of a contravention under this Act except on a complaint made by-

(a) the Licensing Authority concerned or any officer authorized in this behalf by the State Government; or

(b) a person who has given notice of not, less than sixty days, to the Licensing Authority concerned, of the alleged contravention and of his intention to make a complaint to the Adjudicating Authority.

Explanation: Complaint mentioned in para (b) means a written complaint in plain paper preferably typewritten along with supporting documents if any.

(2) Where a complaint has been made under para (b) of sub- rule (1), the Adjudicating Authority may, on demand by such person, direct the Licensing Authority to make -available copies of the relevant records in its possession to such person.

69. The manner for adjudication.

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

Explanation 1: óAccuserô means the óLicensing Authorityô or any person mentioned under sub-rule 1(b) of Rule 68.

Explanation 2: óAccused Partyô means the person against whom the complaint is made by the Accuser under sub-section (2) of Section 34 of the Act

(2) If after receiving the complaint referred to him under sub-rule (1) the accused party does not appear or omits or fails to take any action to represent his case within the time

given by the Adjudicating Authority, the Adjudicating Authority shall proceed to settle the complaint on the basis of evidence brought to its notice by the Accuser.

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

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

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

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

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

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

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

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

70. The Single Doctor Establishment.

(1) In exercise of the power conferred by section 8 of the act, in case of a Solo clinic, the following terms and conditions has to be fulfilled notwithstanding anything contained in earlier rulesï

(a) The clinic shall have adequate accommodation for the purpose of providing such healthcare appropriate for it.

Explanation: óadequate accommodationô means that the medical clinic has provided -

(i) a space for a Patient examination; sitting arrangement for doctor and patient and one patient party; waiting space for patient;

(ii) access to toilet, and drinking water;

(iii) adequate lighting and ventilation arrangement.

(b) The examination or any health care intervention of a female patient may be carried out in presence of any female member of the family or friend for the purpose of maintaining dignity and privacy of the patient.

(c) If bio-medical waste is generated, submission of an undertaking in the form of a self declaration by the medical clinic to follow the provisions of Bio-Medical Waste (Management and handling) Rules, 1998 may be considered for the purpose of handling bio-medical waste.

(d) The display of following information by the medical clinic may be considered for the purpose of mandatory display ï

(i) The name of the Establishment along with the license Number;

(ii) The system(s) of Medicine practiced, types and availability of health care and other services;

Explanation: As the service provider and the proprietor is the same person in case of solo clinic, the name of such clinic shall be considered as ñClinic of Dré é é é é é . (Name of the Doctor).

(e) Submission of the following reports by the solo clinic may be considered for the purpose of mandatory reporting ï

(i) reports on National or State health programmes such as immunization as per requirement of State or District Programme Officers when applicable;

(ii) reports of Notifiable disease when applicable.

(f) The solo clinic shall actively participate in National & State health programmes.

(2) Notwithstanding anything contained in rule 26, the solo clinic shall generate and maintain adequate records related to patient care.

(3) Notwithstanding anything contained in rule 3, the license for solo clinic may be issued for a validity period up to 5 years in case of new License as well as renewal.

(4) Any act of violence or damage to the property of registered solo clinic shall be dealt with as per provision the West Bengal Medical service persons and Medicare Service Institution (Prevention of Violence and damage to Property Act, 2009 [WB Act XI of 2009].

(5) Notwithstanding anything contained in rule 53, no application fee shall be submitted during application for grant or renewal of license.

(6) Notwithstanding anything contained in Rule 55, the following documents are to be submitted by the Solo clinic along with the application form under rule 52 for grant or renewal of license:

(a) Self declaration as per sub-rule (4) of Rule 55;

(b) copy of treasury Challan regarding deposit of License fee;

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

(d) copies of certificate of Registration and certificate of qualification of the Medical Professional;

(e) copy of the current rent receipt or rent agreement or any such document or if the applicant is a tenant or the current lease-deed if the applicant is a lessee or the current consent letter from the owner if the applicant is granted rent free accommodation by the owner of the premises;

(f) copy of the ôNo objection certificateô from the Owner of the premises if the applicant and the owner is different person in case of application for new license; and

(g) Any other additional document mentioned elsewhere in the Act or rules.