Tamil Nadu Clinical Establishments (Regulations) Rules, 2018

TAMILNADU India

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Rule

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Tamil Nadu Clinical Establishments (Regulations) Rules, 2018Published vide Notification No. G.O. Ms. No. 206, Health and Family Welfare (Z2), 1st June 2018, Vaikasi 18, Vilambi, Thiruvalluvar Aandu - 2049Last Updated 30th January, 2020No. SRO A-30(b)/2018. - In exercise of the powers conferred by sub-section (1) of section 14 of the Tamil Nadu Clinical Establishments (Regulation) Act, 1997 (Tamil Nadu Act 4 of 1997), the Governor of Tamil Nadu hereby makes the following Rules, namely: -

1. Short title.

- These rules may be called the Tamil Nadu Clinical Establishments (Regulation) Rules, 2018.

2. Definitions.

(1)In these rules, unless the context otherwise requires, -(a)"Act" means the Tamil Nadu Clinical Establishments (Regulation) Act, 1997 (Tamil Nadu Act 4 of 1997);(b)"Advisory Committee" means the Committee constituted at State Level under clause (1) of section 2-A of the Act;(c)"clinic" means a place where treatment for illness is offered without or with injections, minor operations, dressing etc., to the patients for observation. It may include endoscopic clinic, AYUSH Clinic or any other establishment offering treatment for illnesses by use of Medicines or any therapy under Allopathy, Siddha,Unani, Ayurveda, Yoga and Naturopathy or Homeopathy (AYUSH) or any other Government recognised systems of Medicine;(d)"clinical laboratory" means a place where bio-medical or bio-chemical or clinical pathology or biopsy or bacteriological or genetic investigations or any diagnostic tests or investigative services are carried out;(e)"consulting room" means a place where consultation, which includes examination of the patients and issue of prescription is done and

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advice is given;(f)"Dental clinic" means a clinic where treatment for dental ailments is given;(g)"Dental hospital" means a place where patients are treated as inpatient and treatment is given for dental ailments;(h)"District Committee" means the Committee constituted in each district under clause (1) of section 2-D of the Act;(i)"Doctor" means and includes a Registered Medical Practitioner offering consultations or treatment under Allopathy or AYUSH;(j)"Form" means a Form specified in Annexure-II to these rules; (k) "hospital" means and includes a Nursing Home or Health Centre or Treatment Centre or any other place where facilities for admission as in-patients for treatment of illness with or without surgery or conduct of delivery etc., with or without out-patient facilities and diagnostic facilities like laboratory etc., in any recognised system of medicine;(1)"maternity hospital" means a hospital where delivery and other maternity services with or without surgeries and Gynaecological services including surgeries like Hysterectomy, Cesarean operations are undertaken.(m)"patient" means a person who reports himself or brought to any hospital including a dental hospital for treatment or consultation or seeking any other services rendered by the hospital;(n)"polyclinic" means a clinic where more than one doctor offers consultation with or without treatment for illness in any recognised system of medicine;(o)"Registered Medical Practitioner" means a person who possess any of the Government recognised medical qualification and who has been enrolled in the register of the respective Council viz., Medical, Dental, Siddha, Ayurveda, Unani or Homeopathic Councils or the Board of Indian Medicine or any such Council, Board or any other statutory body recognised by the Government of Tamil Nadu;(p)"Staff Nurse" means a person who possess the required qualification from any of the Nursing Teaching Institutions, recognised by the Government of Tamil Nadu and that person must have enrolled in the Tamil Nadu Nurses and Midwives Council under the Indian Nursing Council Act, 1947 (Central Act XLVIII of 1947) or any of the State Nursing Council in India recognised by the Indian Nursing Council and those who have completed the Diploma in Integrated Nursing in Indian System of Medicine Colleges and registered in the Directorate of Indian Medicine for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy establishments.(2)Words and expressions used in these rules and not defined shall have the same meaning assigned to them in the Act.

3. Procedure, Quorum and Minutes of State Level Advisory Committee meeting.

(1)Every notice, calling for meeting of the State Level Advisory Committee shall, -(a)specify the place, date and hour of the meeting;(b)be served upon every member of the State Level Advisory Committee not less than seven clear days before the day appointed for the meeting.(2)The Chairperson shall prepare and circulate to the members along with the notice of the meeting, an agenda for such meeting showing the business to be transacted.(3)The quorum for the meeting shall be not less than four. If within half-an-hour of the time appointed for the meeting, quorum is not present, the meeting shall be adjourned to the same day in the following week at the same time and place and the presiding officer of such meeting shall inform this to the members present, and the notice to the other members shall be communicated by speed post.(4)The minutes of the meeting shall be communicated to the Government.

4. Procedure, Quorum and Minutes of District Committee meeting.

(1)Every notice, calling for meeting of the District Committee shall, -(a)specify the place, date and hour of the meeting.(b)be served upon every member of the District Committee not less than seven clear days before the day appointed for the meeting.(2)The chairperson shall prepare and circulate to the members along with the notice of the meeting, an agenda for such meeting showing the business to be transacted.(3)The quorum for the meeting shall be not less than four. If within half-an-hour of the time appointed for the meeting, quorum is not present, the meeting shall be adjourned to the same day in the following week at the same time and place and the presiding officer of such meeting shall inform this to the members present and the notice to the other members shall be communicated by speed post.(4)The minutes of the meeting shall be communicated to the Government and the Competent Authority.

5. Duties of District Committee.

- In addition to the duties and responsibilities specified in the Act, the District Committee shall also perform the following duties, namely, -(1)scrutinise the applications received as directed by the competent authority;(2)inspect clinical establishment under the direction of the competent authority;(3)examine the complaints, if any received pertaining to the implementation of the Act and refer the same to the Government through the competent authority.(4)any other duties as may be directed by the competent authority or by the Government from time to time.

6. Minimum facilities of a clinical establishment.

- The floor space and other facilities, the minimum number of staff and their minimum qualification, the minimum equipment and other conditions required for a clinical establishment of different systems, for providing different medical services including specialized services shall be in accordance with the norms and conditions specified in Annexure-I to these rules.

7. Application for registration.

(1)Every application for registration of a clinical establishment shall be made, either in person or by Registered Post with acknowledgement due to the competent authority in Form-I, accompanied by a fee for a sum of rupees five thousand in the form of demand draft or treasury challan drawn in favour of the competent authority.(2)If a clinical establishment is offering services in more than one recognised system of medicine separate application shall be made for each such system of medicine.

8. Certificate of registration.

- On receipt of an application for registration of a clinical establishment, the competent authority shall, after satisfying itself that the applicant fulfils all the requirements of the Act and these rules, grant a Certificate in Form-II within one eighty days from the date of receipt of the application. The Certificate of Registration is non-transferable.

9. Time limit for renewal.

- Every application for renewal of Certificate of Registration shall be submitted to the competent authority ninety days before the expiry of its validity.

10. Duplicate certificate.

- An application for issue of a duplicate Certificate of Registration shall be made to the competent authority accompanied by a fee for a sum of rupees three hundred.

11. Duties of clinical establishment.

- In addition to the duties and responsibilities specified in the Act, every clinical establishment shall, -(a)display a copy of the Certificate of Registration in a prominent place of the premises open to the public;(b)maintain records in electronic form showing the names, addresses and the qualifications of its employees and the equipments maintained by it;(c)record and preserve all changes in the employment of the staff and the equipments and intimate the same to the competent authority;(d)maintain clinical records (i.e any paper, film, printout, slide, solution, medium which can be deciphered or used to indicate and diagnose the condition of the human body or a part of it or any material taken out of it and the course of treatment administered to or undergone by the person), of its activities relating to a patient.(e)keep every record open for inspection by the competent authority;(f)surrender the Certificate of Registration and apply for fresh registration on change of ownership of the clinical establishment, on change of system of medicine for treatment;(g)surrender the Certificate of Registration, on ceasing to function as a clinical establishment.

12. Maintenance of medical records.

- Every clinical establishment shall maintain records with particulars relating to the clinical observation, test, investigation, diagnostic opinion advice and treatment given to the person, who has visited the hospital either as an in-patient or out-patient in Form III.

13. Annual Publication of list of clinical establishments.

- The competent authority shall, during the month of January of every year, publish the list of clinical establishments in the Tamil Nadu Government Gazette in Form IV.

14. Appeal.

(1)An appeal against an order of the competent authority rejecting an application for registration under sub-section (2) of section 4 or an order of suspension or cancellation of registration under sub-section (2) of section 5 or any direction of the competent authority under section 6, shall lie to the Director of Medical and Rural Health Services, within thirty days from the date of receipt of that

order or direction.(2) The Director of Medical and Rural Health Services on receipt of such appeal, if he considers that, an interim order is necessary in the matter, he may pass such an order. (3) The Director of Medical and Rural Health Services may within sixty days from the date of receipt of such appeal, after giving a reasonable opportunity of being heard, pass such order, as he deems fit.(4)The decision of the appellate authority shall be communicated to the person concerned within seven days from the date of passing of such order. (5) The decision of the appellate authority shall be final and binding. Annexure-I(see rule 6) A. Allopathy System I. Consulting Room. -(1) Infrastructure. -Consulting room shall have a space of not less than 100 square feet with sufficient light and ventilation. Separate space for the patients waiting for consultation have also to be provided.(2)Staff. - The examination of the patient and prescription of the treatment shall be done only by a registered medical practitioner as required under the Indian Medical Council Act.(3) Equipment. - The following equipment and hospital accessories shall be available in the consulting room, namely: -(a)Examination couch(b)Blood Pressure Apparatus(c)Stethoscope(d)Torch light(e)Tongue depressor(f)Thermometer(g)Weighing Machine for Adult and Paediatrics(h)Knee hammer(i)Measuring tape(j)Special examination trays like proctoscopy, Pelvic Exam Tray(P.V. Tray), Eye testing screen and Ear Nose Throat examination trays as the case may be, and(k)Besides screen or sufficient privacy for examination of the patient;(4)Records. - Every Clinical Establishment shall maintain a register having the details regarding the name, age, sex and address of the patient, date of examination, date of admission. The patient shall be given a slip containing name, age, sex and date of consultation, diagnosis (either provisional or final) and treatment advised, the investigation result shall be entered, if it was undertaken.(5)Prescription slip. - The Doctor shall sign the prescription slip with date and seal.II. Clinic. - In addition to the norms prescribed for a consulting room, the following norms are required to be fulfilled, namely: -(1)Building. - Sufficient space for two cots shall be available for keeping the patient under observation in case of anaphylaxis or for giving intravenous drip or for observation etc.,(2)Staff. - Minimum of a Doctor and a paramedical staff.(3)Equipments. - (a) Steriliser or autoclave; (b) Arrangement for getting autoclaved or sterilised syringes / instruments or shall use only disposable syringes;(c)Sterile Gloves;(d)Cheetles Forceps;(e)Scissors surgical;(f)Adhesive plaster;(g)Suturing trays with equipment;(h)Kidney trays;(i)Surgical equipments for abscess Incision and Drainage etc.; and (j) Drugs.(4)Waste Disposal. - Facilities to segregate the waste, dressings, etc., as per the Government of India and Tamil Nadu Pollution Control Board norms.(5)Dispensation of Medicine. - If the clinic is also engaged in dispensing of medicines to the patients, the same shall be done only by a qualified pharmacist or by the doctor of the clinic or under his direct supervision.(6)Laboratory in a Clinic. - If the clinic is providing laboratory services, the laboratory work shall be done by a qualified Laboratory Technician who holds a Diploma in Medical Lab Technician / Certificate in Medical Lab Technician course approved by the Government or alternately the Medical Officer can get the tests done by trained personnel under his direct supervision. However, urine examination for albumin sugar and blood haemoglobin can be undertaken by a trained person.(7)X-ray (radiograph). - If the clinic is having its own X-ray unit, the X-rays shall be taken by a qualified radiographer who holds a Clinical Research Associate (CRA) certificate recognized by the Government.(8)Minor Surgeries. - In case of minor surgeries like cyst excision, Medical Termination of Pregnancy (MTP), Dilation and Curettage (D&C) are under taken it is advisable to have a clean room for the purpose and facilities available as given for minor Operation Theatre shall be provided. III. Polyclinic. - (1) In addition to the norms prescribed for

clinic and consulting room, separate cubicles shall be made available to each specialities, if they attend simultaneously.(2) Waiting room and provision of safe drinking water shall be made available for the patients. Names of different doctors attending shall be exhibited in the waiting room. IV. Hospital. -(1)Infrastructure. - In addition to the norms prescribed for Clinic, Consulting room and Polyclinic, the waiting room shall be made available for the patients which shall have sufficient space to cater for the number of out patients visiting the hospital.(2)Wards or in-patient rooms clusters. - (a) Space.- (i) Wards or in-patient rooms shall be spacious with good ventilation and light. Electric fan shall be provided to each room and one fan for at least two beds shall be provided for common rooms.(ii)Toilets may be common or separate, but shall be clean and provided with water.(iii)Cleaning arrangements shall be made to swab the wards daily with antiseptic lotion.(iv)A duty room shall be available for every twenty rooms with necessary Equipment like Oxygen, Saline Stand etc.,(b)Staff. - (i) Doctors. - One qualified doctor for every thirty beds- One doctor shall be on call duty up to thirty beds during night and off duty hours.- One duty doctor shall be available in the hospital physically for thirty beds and above in general side for all the 24 hours.- If the hospital is having less than thirty beds, but if an Intensive Care Unit is functioning, then, one doctor shall be available on duty for 24 hours.(ii)Staff Nurses. - One qualified nurse and two trained nursing assistants shall be available for up to thirty beds in a hospital and then for each additional thirty beds one qualified nurse shall be available. The aforesaid human resource is the minimum requirement irrespective of the fact the availability of any number of trained personnel working in the hospital.(iii)Nursing Assistant. - Male and female nursing assistants shall be engaged in sufficient number depending on the bed strength to assist the doctors and nurses in their duties like dressings, enema and preparation of patients for surgery, delivery etc. but they shall not be given the task of giving injections or doing suturing etc. they shall work under the qualified nurse.(iv)Cleaning Services . - Sufficient number of cleaning personnel (sweeper/sanitary worker) shall be available in the nursing home / hospital. At least one sanitary worker per twenty beds is the minimum requirement.(3)Other Services. -(a)Pharmacy. - If a pharmacy is maintained in the hospital for dispensing medicines to the patients, it shall be done by a registered qualified pharmacist only and he should not prescribe any drugs.(b)Laboratory. - If a Laboratory is maintained by the hospital, other than urine albumin, sugar, blood haemoglobin, all other Laboratory Tests shall be performed by a qualified Laboratory Technician only who holds a minimum of Diploma in Medical Lab Technician / Certificate in Medical Lab Technician.(c)X-Ray (Radiograph). - X-Ray department shall confirm to the norms prescribed and X-Rays shall be taken by a qualified radiographer with a Clinical Research Associate (CRA) qualification.(d)Scan. - Ultra sonogram test shall be performed by a Doctor only.(e)Catering and Canteen. - If catering arrangements are available, the Kitchen shall be clean and the cooks shall be periodically medically examined. Clean practices shall be carried out in the canteen and kitchen.(f)Blood Bank. - If a blood bank is maintained by a hospital, it shall confirm to the directions issued by the Government of India from time to time.(g)Ambulance. - It is desirable that, all Hospitals having more than hundred beds shall have an Ambulance with a driver available or alternatively they shall have tie up arrangement with another Hospital having Ambulance or some Ambulance service unit.(h)General facilities. -(i)Waste disposal. - Waste disposal shall be as per the Government of India norms and Guidelines issued by Pollution Control Board. Proper segregation of the waste at the point is to be ensured. (ii) Record Keeping. - (a) A separate record shall be maintained in the form of a register, of all surgical operations, performed in the clinical establishment, which include, among others, the name of the medical practitioner who

performed the operation and the name of the anaesthetist in attendance. All patients either discharged or referred to other Hospitals shall be given a discharge advice card / slip.(b)A medical case record shall be maintained for a period of not less than ten years in the form of a register in the clinical establishment in respect of each patient, which shall include the following particulars, namely: -(i)a detailed daily statement of the patient's health and condition.(ii)details of any investigations made, surgical operations carried out and treatment given and(iii)records of all medical prescriptions, X-Ray reports, laboratory reports or any other report with full name, qualifications of the doctor.(iv)in the case of a maternity home or a maternity case, the said person shall keep a case record of each child born to a patient. Full and detail record of pregnancy must be maintained for at least a period of ten years.(iii)Medico Legal Cases. - Every Hospital which treats medico legal cases in accordance with Government Order, all such records and registers pertaining to such cases shall be preserved as per the Government orders from time to time and police shall be intimated regarding their admission, discharge, death etc.,(4)Mortuary room. - An hospital having more than hundred beds shall have a mortuary room or room with freezer box facilities for the dead bodies.(5)Water Supply. - Potable water supply shall be made available. Hot water supply also to be provided.(6)Clothing and Linen. - Bed sheets and other linen used for the patients shall be changed daily.(7)Fire Fighting. - Fire fighting equipments shall be installed as per rules in force. Only ISI marked equipments to be provided. Adequate precautions against the risk of fire, including provisions for fire escape, fire extinguishers and system of giving warnings and for evacuation of all persons in nursing home or clinic or hospital shall be taken in the event of fire.(8)Quality Assurance. - The names of the doctors working in the hospital and the facilities made available in the hospital shall be written and exhibited in the hospital. The Hospital shall strive to maintain quality in each of it with the patients.(9)Communication. - Telephone shall be made available for the communication of the patients with the relative and for referrals. (10) Security. - Due protective measures shall be under taken by the Hospital to ensure safety of the patients, their properties and to prevent child lifting etc., Every Clinical establishment must exhibit relevant provisions of the Tamil Nadu Medicare Service Persons and Medicare Service Institutions (Prevention of Violence and Damage or Loss to Property) Act, 2008 (Tamil Nadu Act 48 of 2008) in conspicuous places.(11)Hospital accessories. - Sufficient number of wheel chairs, trolleys, and stretchers shall be made available in the hospital.(12)Generator. - A generator shall be provided to maintain essential services during power failure.(13)Labour Room. - If the Hospital is maintaining a labour room and is conducting deliveries it shall have the following norms, namely:-(a)Building. - There shall be a room for preparation of the patient for delivery, giving enema etc., with sufficient water supply. The Labour room shall be not less than 120 square feet well ventilated with sufficient light. Space for keeping the newborn baby and for its resuscitation is essential.(b)Staff. - Labour shall be conducted by a qualified Doctor, Staff Nurse, Auxiliary Nurse Midwife or a trained dais. Untrained persons shall not be entrusted with the Job. Even if a Staff Nurse / Auxillary Nurse Midwife conduct the delivery, a doctor shall be on call for any emergency or newborn resuscitation. If the labour ward is in a maternity hospital and deliveries are taking place regularly, a duty doctor shall be available for all the 24 hours. It is desirable to have a Paediatrician on call, wherever possible.(c)Equipment. - The following equipments and hospital accessories shall be made available, namely:-(i)Labour Board with lithotomic stand(ii)Saline Stand(iii)Oxygen Cylinder with Vent mask(iv)P.V. Tray with equipment(v)Dilation & Curettage (C & A) Set(vi)Focus Lamp(vii Trolleys for instrument and to receive the baby(viii)Vaccine extractor / Forceps delivery set(ix)Sterile core clamp(x)Antiseptic

lotions(xi)Suction apparatus(xii)Baby resuscitation set(xiii)Baby Warmer (a light may also do)(xiv)Baby mucus sucker (disposable)(xv)Paediatric ambu bag(xvi)Suturing tray for episiotomy and suturing.(d)Drugs. -

Injection Methergin
 Injection Pitocin
 Injection Carboprost
 adenosine monophosphate
 adenosine monophosphate

- I.V. Fluids 5% dextrose 2 bottles.

- 5% dextrose or Saline

- Ringer lactate.

- Inj.Diazepam 2 amp- 2% Lignocane Vial - 1

- Disposable Syringe 10 Numbers

- Injection Vitamin K

- Injection Eptoin

(e)Records. -(i)Birth Register(ii)Birth intimation slip(iii)Case sheets and notes to be recorded(iv)Register for babies and mothers to prevent child changing.(14)Operation Theatre. -(a)Minor Operation Theatre. - Where septic cases and minor surgeries like abscess, Incision and Drainage (I&D) and septic cases like amputations etc., are carried out.(i)Space. - Sufficient space not less than 100 square feet with adequate lighting and ventilation.(ii)Staff. - All surgeries in minor operation theatre shall be carried out by qualified doctor only. However dressings can be done by a Nurse or a Nursing Assistant.(iii) Equipments. - Operation table.- Focus light- Sterilizer- Auto clave-Bins- Saline Stand- Minor surgical equipments- Regional Anaesthesia equipment- Sterile gloves-Sterile syringes- Drugs as required- Drugs for emergency tray- Boyle's apparatus with Oxygen cylinder, Nitrous Oxide Cylinder (Desirable)- Suction apparatus- Baby resuscitation set(iv)Records. - Records of all surgeries done in minor operation theatre shall be entered in a register.(b)Main Operation Theatre. -(i)Space. - Shall have sufficient space with a minimum of 150 square feet is essential, well lit preferably air-conditioned. Other than the operating room, there shall be provision for patient waiting and a cot provided for postoperative recovery. Sufficient space shall be available for autoclave and sterilization and for scrubbing. Running water from the tap shall be available in the scrub room. Ultra violet lamps shall be fitted in the operation theatre. Sufficient arrangements for formalisation of operation theatre. Swab for culture to be taken from operation theatre at least once a month.(ii)Staff. - A qualified nurse shall be the head of nursing staff in the Operation Theatre. Anaesthesia to be provided by a qualified Anaesthetist or by a doctor only who is trained in anaesthesia. Surgeries shall be performed by qualified doctors only. (iii) Equipments. - Operating table- Focus Light preferably wall mounted- Boyle's apparatus with sufficient cylinders- Monitoring devices like(a)Cardiac monitor - must(b)Pulse Oximeters - must- Suction apparatus preferably two-Sterilizer, Autoclave-Surgical equipments for surgery-Sterile bin-Stretcher for shifting of patient-Anaesthesia Kit.(iv)Records. - Record of all surgeries performed shall be available in a register duly with name, age, sex, address of patient, Surgeon, Anaesthetist and Staff Nurse also to be entered. Biopsy reports also shall be entered. (15) Intensive Care Unit. - An Intensive Care Unit may be maintained in all Nursing Homes / Hospital having more than hundred beds. The following norms

are to be maintained, namely:-(a)Space. - A well ventilated preferably air conditioned room with sufficient lighting is essential. If four Cots are there, a minimum space of 240 square feet is needed. Sufficient space for keeping ventilators and monitors to be available. Space for duty doctor and nurse shall also be available. There shall be provision for attendants outside the Intensive Care Unit.(b)Staff. - One doctor for every ten beds for day time. If there are more than ten beds, one additional doctor for every additional five beds. Similar provision shall be made for night time.(c)Nurse. - One qualified nurse for up to six beds for day time. An another qualified nurse for every additional three beds. This similar arrangement shall be made for night time. (d) Equipments. -- Intensive Care Unit Cots- Saline Stands- Ventilators- Cardiac Monitor- Pulse Oximeter-Defibrillator- Suction apparatus- Oxygen supply (either Cylinder or central supply)- Incubation equipments- Drugs- Generator(e)Records. - A record of in-patients in Intensive Care Unit shall be available in a register as to their illness, treatment offered, specialists visited - Out come etc.,(16)Medical Record Maintenance in a Hospital. - The following records shall be maintained, namely:-(i)Admission and Discharge Register.(ii)Case sheets(iii)Referrals(iv)Infectious and Communicable disease Register.(v)Immunisation particulars(vi)Family Welfare Services(vii)Medico Legal Records(viii)Maternal Death Record(ix)Infant Death record(x)1 to 5 years Child Death records(xi)any other record as may be required by the Government, from time to time.V. Maternity Hospitals. - In addition to facilities/ Norms specified for Nursing Homes / Hospitals, a labour room and an operation theatre is preferable facilities for transport of patients like an Ambulance or tie up arrangement with a Central Ambulance Service is desirable. VI. Dental Clinic. - (1) Building. - The consulting room if it accommodates the Dental Chair also shall be having sufficient space not less than 100 square feet. The room shall be well ventilated and shall have sufficient lighting arrangements. Space for keeping the Sterilizer and Trays to be provided. Sufficient space for patient waiting to be provided outside the consulting room. (2) Staff. - Dental Surgery, Consultation and prescription shall be performed by a qualified Dental Surgeon only as per the Indian Dentist Act, 1948 (Central Act XVI of 1948). Injections and administration of anaesthesia shall be done by the dental surgeon himself. X-Ray shall be taken by a qualified Radiographer or by the Dentist.(3) Equipments. - (a) Dental Chair(b) Provision of water for surgery(c) Steriliser(d) Bin for sterile cotton gauze etc.(e)Trays with instruments(f)Dental instruments(g)X-Ray (desirable)(h)Disposable (optional) / autoclaved syringes.(4)Records. - A record of the patients treated along with name, age, sex, disease and treatment given shall be available. A slip shall be given to the patient with all the above particulars. VII. Dental Hospitals. - Out-patient department. -The outpatient department of a dental hospital shall confirm to the norms prescribed to a Dental Clinic. In addition, sufficient waiting room shall be provided to the patients. Wards, Operation Theatre and other aspects shall be as per the norms prescribed to the nursing homes and hospitals.VIII. Clinical Laboratories. - They shall include clinical laboratories, pathological laboratories, genetic laboratories etc.(1)Building. - A minimum of space for sample collection, First Aid Room, Processing, Report preparation etc., 500 Square feet in Rural, 700-1500 Square feet in Urban should be available. There shall be lavatories for the patients use at least one shall be available with sufficient water. There shall be sufficient space for Microscopy and for Biochemical tests. The room shall be well ventilated with sufficient light. Space for keeping a cot for the use of patient shall be available. If x ray is also functioning norms as for an X ray centre shall be followed. The laboratories shall ensure adequate space in relation to the following:-(a)Patient's reception(b)Sample collection(c)Isolation for Bio hazardous materials(d)Radioisotope related work

as per the regulatory agency Atomic Energy Regulatory Board (AERB) requirement. The Laboratories shall ensure standards prescribed by the National Accreditation Board for Testing and Calibration of Laboratories for the personal, qualification etc., Quality assurance in Lab Service, Internal Quality and External Quality should be ensured.(2)Staff. - (a) The Biopsy examination and reporting shall be done by a Pathologist or by a Trained Doctor. When culture and sensitivity tests are carried out, a Microbiologist either Medical or non-Medical shall be available, Cytology reports shall be given by a Pathologist only.(b)Qualification for technical staff. - The staff performing the technical tests shall have the following qualifications, namely:-(i)Graduate in Medical laboratory Technology; or(ii)Two years Diploma course in Medical Laboratory Technology; or(iii)One year Certificate course in Medical Laboratory Technology with two years experience; or(iv)Graduate in science with one year experience in Medical Laboratory; or(v)Diploma in medical radiation and radioisotope technology (DMRIT); or(vi)Certificate in Cytotechnology by Indian Academy of Cytology for screening of ex-follative cytology in addition to the above qualification for Cytotechnologist.(c)In a genetic laboratory, all tests shall be carried out and reporting done by a qualified Genetist or qualified doctor only. If amniocentesis is done as permitted by law it shall be done only in a Minor Operation Theatre and all facilities as needed for a Minor Operation Theatre shall be available and it shall be done by a qualified doctor under sterile conditions only.(3)Equipments. -(a)Microscopes(b)Calorimeter(c)Centrifuge(d)Test Tubes(e)Slides(f)Reagent as needed(g)Semi Auto Analyser or Auto Analyser (Optional)(h)Cell Counter (Optional)(i)Haemoglobin meter(j)Counting Chambers etc.(k)Refrigerator(l)Hot Air oven(m)Physical Balance(n)Micro Puppets fixed and variable volume.(4)Records. - All tests carried out on the Laboratory shall be recorded in a Register along with name, age, sex, investigation done report, date, etc., The following minimum Records to be maintained: -(a)Daily Results Register(b)Internal Quality Control Register(c)Sample Collection Register(d)Participation in External Quality Assessment Schemes Programmes.IX. X-Ray (Radiograph) Centres. - This Centre shall include all centres of Imaging, Sciences namely, Ultra Sonogram Scan Centres, Computed Tomography (C.T.) Scan Centres, Magnetic resonance imaging (MRI) Scan Centres, X-Rays (Radiograph) as well as Electro Cardiogram (ECG), Electroencephalography (EEG) and Treadmill Echocardiography.

- 1. Buildings. Sufficient space as the equipment in use demands. Sufficient space shall be provided for patient waiting and resuscitation of the patient in case of any anaphylaxis occurring, during contrast injection or after a treadmill test patient feels like resting. X ray and imaging centres shall fulfil the "Atomic Energy Regulatory Board" (AERB) norms
- 2. Staff. All tests shall be carried out by qualified technical persons only as follows:-

X-Ray - Radiographer with Clinical Research Associate(CRA) Qualification

Ultra Sonogram - by a qualified Doctor or by a Radiologist orConcerned Specialist as per

the provisions of the Pre-ConceptionAnd Pre-Natal Diagnostic

Tamil Nadu Clinical Establishments (Regulations) Rules, 2018

Techniques (Prohibition of SexSelection) Act, 1994

Electro Cardiogram (ECG) by an Electro Cardiogram (ECG) Techniciantrained in Electro

Cardiogram (ECG) taking

Electroencephalography (EEG) Technician trainedin

(EEG) Electroencephalography (EEG) taking

Computed Tomography by a Radiographer and report by a Radiologist orby the concerned

(CT) scan specialist.

Treadmill Concerned Technician. A doctor shall be presentduring the Test.

Echo Cardiograph by a Qualified Doctor preferably a Cardiologist Contrast Studies Radiologist or by the Concerned Specialist

Magnetic resonance

imaging (MRI)

Radiologist or by the Concerned Specialist

3. Equipments. - Equipments according to the concerned machine.

4. Records. - Name, age, sex, address of patient, the nature of investigation done referral doctor, and result of the investigation shall be available in a register. Number of cases treated free of charges shall also be available along with name, age, sex, address and result etc.

B. Indian System Of Medicine And HomoeopathyI. Consulting Room / Clinic / Polyclinics

- 1. Building. The Consulting room shall be spacious, well ventilated and having sufficient light. The space shall be not less than 100 square feet. There shall be sufficient space for waiting of the patients etc., If it is a polyclinic, different cubicles shall be available for each doctor. The names of visiting doctors and their system of medicine shall be exhibited in front of the clinic.
- 2. Staff. The clinics namely, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoepathy Clinics shall be manned by the registered Medical practitioner. If the pharmacy attached with the clinic, dispensing of medicines shall be done by a Pharmacist qualified under the respective system or by the doctor himself.
- 3. Equipment. (a) Diagnostic equipments ordinarily needed for all AYUSH, Indian System of Medicine and Homeopathy and Yoga and Naturopathy Clinics:

(i)Thermometer(ii)Sphygmomanometer(iii)Stethescope(iv)Knee hammer(v)Tongue Depressor(vi)Torch(vii)Weighing machine

- 4. Drugs. The drugs dispensed to the patients shall contain a label indicating the name of medicine and the name of patient to whom it is given and quantity to be given etc., the date of expiry shall be specified in the label, if the drug has an expiry date. The drug to be given internally and the drug to be used externally shall be indicated and white and red labels to be provided respectively with clear writing as "For Internal use" or " For External Use" in vernacular.,
- 5. Records. A record of all patients seen as to their name, age, sex, diagnosis and treatment shall be available. The patient shall be provided with a slip with name, age, sex, diagnosis of treatment given.
- II. Nursing Homes And Hospitals. -
- 1. Building. The norms prescribed for consulting room or outpatient in the Allopathy system of medicine shall be fulfilled. It shall also have sufficient space for patient waiting separate cubicles for each doctors to work. The names of the doctors and then Specialists and different facilities available in the hospital shall be put up in a board.
- 2. Wards or inpatient rooms. Inpatient wards shall be spacious with ventilation and lighting. Electric fan shall be provided to each room and in common rooms one fan for at least four beds shall be provided. Toilets be common or separate but shall be clean and provided with water from tap. Cleaning arrangements shall be made to swab daily the wards with antiseptic lotion.
- 3. Staff. (a) Doctors. The hospital shall employ only registered medical practitioner to treat the patients. The doctor shall also be registered in the Council under his respective system of medicine or in the Council/Board for Indian System of Medicine.
- (b)Nurse. A qualified nurse shall be available at the ratio of one nurse and two Nursing Assistant for upto thirty beds.(c)Pharmacist/Therapist. Pharmacist/Therapist qualified in the respective system of medicine shall be employed for dispensing of medicines. If the hospital has more than thirty beds, for less than thirty beds the doctor himself can dispense the medicines or employ a

qualified pharmacist/Therapist.(d)Other Staff. - Other staff like Mazdoor etc. shall be employed as per need. Sufficient number of cleaning staff shall be available at least one for every thirty beds.

4. Equipment. -(a) The following Exercise Therapy equipments shall ordinarily needed for all Siddha Hospitals, namely: -

(i)Traction Kit(ii)Walker(iii)IR light(iv)TFT and Ultrasound Therapy Instrument(v)Vibrator (Manual and Electronic)(b) The following equipments ordinarily required for all Siddha Hospitals, namely:-(i)Thokkanam table(ii)Vedhu Chamber(iii)Wax bath machine(iv)Karanool(v)Kazhichal endhiram(vi)Vaanathi maruthuvam Chair(vii)Nasiyam Chair(viii)Peetchu endiram-Disposal Packs(ix)Kidney Tray(x)Motion tray(xi)Nebuliser Set(xii)Moving Stretcher(xiii)Disposable Syringes(xiv)Surgical instruments for common procedures, First Aid(xv)Parenteral drugs and infusion related equipments(xvi)Equipments needed for specific Aga maruthuvam, puramaruthuvam procedures.(c)Equipments for Yoga and Naturopathy. -Yoga Therapy. -(i)Carpets /coir mats(ii)Jala neti pot(iii)Eye wash cup(iv)Yoga charts(v)Sutra neti rubber catheter Hvdrotherapv.-(i)Enema can(ii)Steam bath cabin with Automatic steam generator(iii)Facial sauna(iv)Fomentation bag(v)Ice bag(vi)Packs - Chest, Leg, Arm, Knee, Abdomen, GH Pack, Renal, Full wet sheet pack(vii)Linen cloth for compress(viii)Epsom salt-packets(ix)Hip bath tub(x)Spinal bath tub(xi)Spinal Spray(xii)Foot and arm bath tub(xiii)Small and Big towelsMud Therapy. -(i)Mud storer-100 lts barrel-2(ii)Linen cloth- for preparing mudpacks(iii)Mud trays(iv)Bucket and mug-2Magneto Therapy. -(i)High, Medium, Low power magnets with keepers(ii)Magnetic belt -Neck, Abdomen, Knee, Wrist Massage Therapy. -(i) Massage table-cushioned and covered with rexin(ii)Foot stepper(iii)Vibratory massager(iv)Roller massagerChromotherapy. -(i)Colour lamps(ii)Colour glass bottles(iii)Color ThermoleumElectrotherapy. -Infra red lamp (IRR)Acupuncture/Acupressure. -(i)Moxa stick(ii)Electronic Acu - stimulator(iii)Reflexology chart(iv)Acu-Roller-Spinal,Spinal,Palm,Soles,Legs,Fingers(v)Acupuncture needlescopper-(0.25x25)

5. Physical fitness

(i)Static cycle(ii)Manual Treadmill(iii)Rowing machine(iv)Overhead pulleys

6. Infrastructure. - Clinic shall have the consultation items and minimum equipments to give out patient treatments. Hospital shall have all the equipments along with diet centre to prepare bland diet, natural diet, herbal juice and other special diet therapy for various diseases. In addition to above, first aid and emergency management need to be provided. Sufficient number of Wheel Chairs, Stretchers shall be available at least one per every thirty beds.

- 7. Records. (1) A record of all patients admitted / treated shall be available along with the investigations diagnosis and treatment. The patient shall be provided with a discharge slip containing the details of investigation, diagnosis, treatment and follow up etc.,
- (2)The following register shall be maintained. It is the duty of the clinical establishment to give all the relevant particulars to the patients on demands.(i)Admission and Discharge Register(ii)Contagious and infectious disease register.(iii)Medico legal cases register (in case medico legal cases are brought there for treatment at any stage) Records with full address shall be kept ready for verification by the District Committee.C. General Conditions To Be Fulfilled By The Hospitals Under Allopathy And Ayush.
- 1. Communication. A telephone connection shall be available for use by patients (on payment)
- 2. Security. Sufficient security shall be provided for the safety of inmates and to prevent theft.
- 3. Fire Fighting. Fire fighting equipment with I.S.I. mark shall be provided as per rules in the hospital.
- 4. Kitchen. If food is provided to inmates, the kitchen shall be clean and the cook(s) shall be periodically, medically examined for any infection or contagious diseases.
- 5. Clothing and Linen. It shall be clean and changed daily.
- 6. Water Supply. The potable water shall be provided to the patient.
- 7. Waste Disposal. It shall be as per the Government of India norms and shall follow the guidelines of Tamil Nadu Pollution Control Board.
- 8. Record Maintenance. (a) Every Clinical Establishment shall maintain the permanent records pertaining to details of the employees as well as the clinical records pertaining to the patients. The records shall be kept open for inspection by the competent authority or any other officer authorized in this behalf.
- (b)Every Private Clinical Establishment shall make available a copy of list of observation, treatment etc., pertaining to the patient on payment of necessary charges within the reasonable time. Every

Clinical Establishment shall display at a prominent place the charges for obtaining such information.(c)Every Clinical Establishment may refuse to furnish such information, if such information is likely to cause injury to the person or his family members or if the treatment has been conducted on the direction of a public authority. Annexure - IIForm I(see rule 7(1))Application Form For Registration / Renewal Of Registration Of Clinical EstablishmentEstablishment Details

4 Name of the Olimical Esta		1. Registration					
1 Name of the Clinical Esta	abiisnment:				No:		
2. Address:							
Village/Town:				Taluk			
District:			State: Pincode		Pincode		
Telephone No.(with STD o	eode)			Mobile:			Fax
Email ID:				Website (if			
Eman ID.				any)			
3. Year of starting:(From 4 applicable)	to 11, Mark all	whichever is					
4. Location:							
Metro		State Capital	City	7	To	own	
Notified Area		Village	Any	other (Please s	pecify):		
5. Ownership of Services	-Public Sector						
Central Government	State Governm	ent		Local Governm	ent (please	specify)	
Public Sector Undertaking	Railways			Employees Star Corporation	te Insuranc	e	
Autonomous organization	Society/Not for profit			Any other (plea	ase specify)		
Private Sector							
Individual Proprietorship				Registere		Register	
			_	Partnersh	nip	Compan	ıy
Corporation (including a s Provincial or State Act (Ple	•	edunder a Cen	ıtral,				
Trust (including Charitable		der aCentral,					
Provincial or State Act (ple							
Branch of a Foreign Service	e provider (plea	asespecify)					
Any other (please specify)							
6. Name of the owner	r of Clinical	Establishm	nent	t:			
Address:							

Taluk

State:

Pincode

Village/Town:

District:

Telephone No. (with STD code)Email ID: Mobile: Fax:

7. Name, Designation and Qualification of person-in-charge of the clinical establishment

Designation: Qualification:

Address:

Village/Town: Taluk

District: State: Pincode
Telephone No.(with STD code)Email ID: Mobile: Fax:

8. Any other (please specify)

9. Type of clinical establishment :(Please tick whichever is applicable)

Clinic

Single Practitioner Consulting Room Polyclinic

Dental

Any other(Please specify)

Centre

Primary Health Community Health

Centre Centre

Dispensary Day Care Centre Counselling centre

Physiotherapy

Centre Yoga Cen

Yoga Centre In Vitro Fertilization (IVF) Centre

Urban Health Centre

Dialysis Hospice Centre Any other (like Audiometry, Prosthetic & or-thotic etc.,

(please specify)

Hospital

General Practice Services Maternity Home

Single speciality Services Multi Speciality Services

Super speciality Services Operation Theatre
Emergency Causality Intensive Care Unit
Any other please specify

10. Whether the clinical establishment,-

(a) is attached with Laboratory (if so, please tick whichever is applicable)

Pathology Haematology Histopathology

Cytology Genetics Samples Collection Centre

Any other (Please specify)

Biochemistry Microbiology Any other (please specify)

If answer to (a) above is yes, the following details may be furnished, namely: - Tests that it proposes to carry out -- List of equipments available-- A list of technical staff (both technical and supervisory)-- List of personnel who are going to sign test reports.(b) is attached with Imaging

Centre (if so, please tick whichever is applicable)

Portable X ray Conventional X Ray Digital X Ray

X Ray with computed Radiography Ultrasound Ultrasound

system Color Doppler

Mammography Orthopentogram(OPG) CT Scan

Magnetic Resonance Imaging (MRI)

Positron Emission Tomography (PET)

Bone

Scan Densitometry

Uro -flowmetry Any other (Please specify)

(c)is attached with Blood Banks (if so, please tick whichever is applicable)

(A) Based on Location

Stand alone Hospital Based Any other (please specify)

(B)Based on Facilities

Blood bank/Centre having whole blood facilityonly

Blood bank/Centre having whole blood and component facility

Blood bank/Centre having whole blood and/orcomponent facility with any other additional facility (pleasespecify):

11. Details of the equipments maintained with :-

System of Medicine

12. Services offered (please tick whichever is applicable)

(a) Allopathic Speciality

Medical Surgical Obstetrics and Gynecology Paediatrics

Any other please specify

(b)Ayurveda

Anusadh Chikitsa Shalya Chikitsa Shodhan Chikitsa Rasayana

Pathya Vyavastha Any other please specify

(c)Unani

Matab Jarahat Ilaj-bit-Tadbeer Hifzan-e-Sehat

Any other please specify

(d)Siddha

Maruthuvam Sirappu Maruthuvam Varmam Thokknam & Yoga

Any other please specify

(e)Homeopathy

General HomeopathyAny other please specify

(f)Naturopathy

External Therapies with natural modalities Internal Therapies

Any other please specify

(g)Yoga

Ashtang Yoga Any other please specify

13. Area of the establishment (in square metres)

(a) Total area: (b) Constructed Area:

14. Out-Patient Department

Total number of Out Patient Department Clinics

Sl.No. Speciality Number of Rooms

15. In-Patient Department

(a)Total number of beds:(b)Specialty-wise distribution of beds, please specify:

Sl.No. Speciality Number of beds

16. Biomedical Waste Management

(a)Method of treatment and/or disposal of bio-medical waste

Through Common FacilityAny other (please specify) Onsite Facility (b)Whether authorization from Pollution Control Board/Pollution Control Committee obtained? Yes No Applied for Not applicable

17. Total number of Staff (as on date of application):

Number of permanent staff: Number of temporary staff:

Category of Staff

Name Qualification

Registration

Nature of Service

Number

Temporary/Permanent

Doctors

Nursing Staff

Para-medical Staff
Pharmacists
Support Staff
Others, Please
specify

Separate annexure may be attached

18. Payment options for Registration Fees:
Demand Draft Treasury receiptAmount (in Rs.)Details:I / We hereby declare that the statement stated above are true and correct to the best of my/our knowledge and I/We shall abide by the Tamil Nadu Clinical Establishments (Regulation) Act, 1997 and the Rules made thereunder.Place:Date:Signature of the Authorised person of the clinical establishment
1.
(Name of the clinical establishment) operating from(Complete Address) as
(Type of clinical establishment) is hereby registered under the provisions of the Tamil Nadu Clinical Establishments (Regulation) Act, 1997 to provide services undersystem of Medicine with(bed strength)
2. The Certificate of Registration shall be subject to the conditions laid down in the Tamil Nadu Clinical Establishments (Regulation) Act, 1997 and the Tamil Nadu Clinical Establishments (Regulation) Rules, 2018.
Competent AuthorityPlaceDate:Seal:Form III(see rule 12)
Part A – . {
- System of Medicine Clinical Laboratory: Tamil Nadu Clinical Establishment RegulationAct Registration no. : }Register of Laboratory Test ConductedDate
S.No Name of the Patient and address Mobile No. Age Sex ID No. Referring Doctor (1) (2) (3) (4) (5) (6) (7)

1. 2. 3. 4. 5. Method of Additional Initial of Provisional Investigation Investigation Investigation and Result information if the Medical performe Diagnosis Specimen Equipment Officer any (8)(10)(11) (14)(9) (12)(13)

Note: If electronic records are maintained and / or existing registers capture this information, a monthly print outs / copy shall be taken and signed by the authorities concerned.

Part B - {|

|-| System of Medicine| Clinical Laboratory:| Tamil Nadu Clinical Establishment RegulationAct Registration no.:|}Date

S.No Name of the Patient and address Mobile No. Age Sex ID No. Referring Doctor

- (1)
 (2)

 (3)
 (4)
 (5)
 (6)
 (7)

 1.

 2.
- 2.3.4.5.

Duorisional	Investigations	Investigation	Method of		Additional	Initial of
	Investigations		Investigation and	Result	information if	the Medical
Diagnosis	Specimen	performe	Equipment		any	Officer
(8)	(9)	(10)	(11)	(12)	(13)	(14)

Note: If electronic records are maintained, and / or existing registers capture this information, a monthly print outs / copy shall be taken and signed by the Medical Officer.

Part C – System of Medicine____Hospital / Nursing Home

Tamil Nadu Clinical Establishment Regulation Act Registration no. :Admission and Discharge Register of Patients

S. No	Name of address	the Patient a	nd Mobi No.	ile A	ge S	lex	Hospital IP No.		te of mission		ovisional agnosis
(1)	(2)		(3)	(2	4) (5	5)	(6)	(7)		(8))
1.											
2.											
3.											
4.											
Investif any	tigations	Final diagnosis	Treatmen	Date nt Discl	of harge		Result Cured / Same condition Referred /Expi	,		f	Initial of the medical officer
(9)		(10)	(11)	(12)			(13)		(14)		(15)

Note: If electronic records are maintained and / or existing registers capture this information, a monthly print outs / copy shall be taken and signed by the Hospital authorities.

2. The hospital shall maintain individual case sheets for the patients

Part D - {|

|-| System of Medicine| Clinic / Consulting Room| Tamil Nadu Clinical Establishment Regulation ActRegistration no.:|-| Name of the Doctor:| xxxxxx||}Register of PatientsDate

Serial No	Name of the Patient and address	Mobile No./ Contact No. if available	Age Sex Provisional Diagnosis
(1)	(2)	(3)	(4) (5) (6)
1.			
2.			
3.			

4.

Investigations i		Treatmen	Result Cured / Same t condition / Referred	Additional	Initial of the	
any	diagnosis	Troutinon	/Expired	information if any	Medical officer	
(7)	(8)	(9)	(10)	(11)	(12)	

Note: If electronic records are maintained and / or existing registers capture this information, a monthly print outs / copy shall be taken authenticated by the Hospital authoritiesPart-E {||-| System of Medicine| Hospital / Nursing Home| Tamil Nadu Clinical Establishment Regulation ActRegistration no.:|}Operation RegisterOperation Theatre (Please specify the OT either Maternity / General/ Ortho etc., as the case may be)

Name of the No Patient and address	Mobile No.	$\begin{array}{c} \text{Age Sex} \\ \text{Admission} \end{array}$	Hospital II No.	P Provisional Diagnosis	Investi gations if any
(1) (2)	(3)	(4) (5) (6)	(7)	(8)	(9)

Operation	Operating Surgeon	•	Staff	Operation-	Opration	Transferred		Initial of the
performed	_	Anaethetist	Tuise	Time (From to)	Notes	to willen	information if any	Medical officer
(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)

Note: If electronic records are maintained, and / or existing registers capture this information, a monthly print outs / copy shall be taken and it shall be authenticated by the Hospital authorities.Form IV(see rule 13)List of Clinical EstablishmentsPeriod - 1st January, to 31st December,

Serial No.	Name and Address of Clinical Establishment	TNCERA No. and Date	District	Type of Establishment	Validity Period (6) From	То
(1)	(2)	(3)	(4)	(5)		

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.