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TRIPURA LEGISLATIVE ASSEMBLY
SECRETARIAT
NEW CAPITAL COMPLEX
AGARTALA, TRIPURA, PIN - 799 010
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No.F.7(12-25)-LA/2018.

Dated, Agartala the 24th November, 2018.

NOTIFICATION

“ As required under Rule 117 of the Rules of Procedure and Conduct of Business in the Tripura Legislative Assembly. “ **The Tripura Clinical Establishment (Registration and Regulation) Bill, 2018 (The Tripura Bill No. 17 of 2018)** ” as introduced in the Assembly on the 23rd November, 2018 is published in the Tripura Gazette.”

(**S. Sikdar**)
Secretary
Tripura Legislative Assembly

The Tripura Bill No.17

**THE TRIPURA CLINICAL ESTABLISHMENT
(REGISTRATION AND REGULATION) BILL, 2018.**

A

BILL

to provide for the registration and regulation of clinical establishments in the Tripura and for matters connected therewith or incidental thereto.

WHEREAS, it is considered expedient to provide for the registration and regulation of clinical establishments with a view to prescribe minimum standards of facilities and services which may be provided by them, so that mandate of article 47 of the Constitution for improvement in public health may be achieved;

BE it enacted by the Tripura Legislative Assembly in the Sixty ninth year of the Republic of India as follows:

CHAPTER I

Preliminary

1. Short title and commencement –

1. This may be called the ‘Tripura Clinical Establishment (Registration and Regulation) Act, 2018’;
2. It shall come into force on the date of its publication in the Tripura Gazette.
3. It excludes the facility of Defense Forces.

2. Definitions –

In this Act, unless the context otherwise requires:-

(a) “Clinical establishment” means-

- (i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not, and or
- (ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall also include an establishment, established, administered or maintained by-
 - (a) the Government or a department of the Government,
 - (b) a trust, whether public or private,

- (c) a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government,
- (d) a local authority, and
- (e) a practicing doctor,

but does not include the clinical establishments owned, controlled or managed by the Armed Forces.

Explanation.—For the purpose of this clause “Armed Forces” means the forces constituted under the Army Act, 1950 (46 of 1950), the Air Force Act, 1950 (45 of 1950) and the Navy Act, 1957 (62 of 1957) or any other law for the time being in force;

- (b) “Clinical laboratory” means an establishment where –
 - i. Biological, pathological, bacteriological, radiological, virological, chemical or other tests, examinations or analysis. or
 - ii. The preparation of cultures, vaccines serums or other biological or bacteriological products. In connection with the diagnosis or treatment of diseases, are of is usually carried on:
- (c) “Maternity home” means an establishment where women are usually received or accommodated or both for the purpose of confinement and antenatal and post-natal care in connections with child – birth :
- (d) “Nursing home” means an establishment where persons suffering from illness. injury or infirmity whether of body or mind are usually received or accommodated or both for the purpose of nursing and treatment and includes it maternity home ;
- (e) “Collection centre” means an establishment where biological samples are usually collected or stored for analysis from other laboratory or its own laboratory in another area.
- (f) “Physical therapy establishment” means an establishment where persons are usually treated by physical means such as message, electrotherapy, hydrotherapy, remedial gymnastics or the like ;
- (g) “Prescribed” means prescribed by rules made under this Act ;
- (h) “Qualified medical practitioner” means a medical practitioner registered in Tripura Medical Council or MCI under a law for the registration of medical practitioner;
- (i) “Qualified midwife” means a midwife registered in an state in India under a law for the registration of midwives;
- (j) “Qualified nurse” means a nurse registered in a state in India under a law for the registration of nurse.
- (k) “Qualified pathologist” means a medical practitioner with required qualification in pathology registered in any state in India under a law for the registration of medical practitioner.
- (l) “Qualified radiologist” means a medical practitioner with required qualification in Radiologist register in a State in India under a law for the registration of medical practitioner.
- (m) “Qualified Microbiologist” means a medical practitioner with required qualification in Microbiology register in a State in India under a law for the registration of medical practitioner.
- (n) “Qualified Biochemist” means a medical practitioner with required qualification in Biochemistry register in a State in India under a law for the registration of medical practitioner.

- (o) "Register" means to register under section 8 of this Act and the expression "registered and "registration" shall be construed accordingly.
- (p) "Rules" means rules made under this Act ;
- (q) "Supervising authority" means the person of authority appointed by the state Government by notification in the Official Gazette, to perform all or any of the functions of the supervising authority under this Act.
- (r) "Practicing Doctor" in any system of Medicine,

CHAPTER II

The State Council for Clinical Establishment

3. Establishment of State Council

(1) State Government shall by notification constitute a State Council for the purposes of this Act, with effect from such date, as may be appointed by the State Government in such notification;

(2) The State Council, shall consist of the following members, namely:—

| | | | |
|-----|--------------------------------------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------|
| (a) | Secretary, Health | — | <i>Ex officio</i> , who shall be the Chairman; |
| (b) | Director of Family Welfare & Preventive Medicine | — | <i>Ex officio</i> Member-Secretary; |
| (c) | An officer, not below the rank of a Joint Director of Family Welfare & Preventive Medicine | — | <i>Ex officio</i> members & State Nodal Officer |
| (d) | Registrar-cum-Secretary | State Medical Council of Tripura | <i>Member</i> |
| (e) | Registrar | State Nursing Council of Tripura | <i>Member</i> |
| (f) | Registrar | State Pharmacy Council of Tripura | <i>Member</i> |
| (g) | One Branch Officer from each | Ayurvedic, Homeopathic and Dental Branch of the Directorate | <i>Members</i> |
| (h) | District Nodal Officers | Of each District | <i>Member</i> |
| (i) | Secretary | Indian Medical Association, Tripura State Branch | <i>Permanent Invitee</i> |

4. Duration of Sate Council

- (i) The duration of the State council will be for a term of three years;
- (ii) If any vacancy arises due to the expiry or absence of any member, then Director, Family Welfare & Preventive Medicine, with the prior approval of the state Government may, nominate any other officer of the Directorate to fill the vacancy.

5. Function of State Council

The State council shall perform the following functions, namely –

- (a) compiling and updating the State Registers of clinical establishment,
- (b) sending monthly returns for updating the National Register,
- (c) representing the State in the National Council,
- (d) hearing of appeals against the orders of the Licensing/Registration authority, and

(e) publication on annual basis a report on the state of implementation of standards within their respective States.

CHAPTER III

The District Council for Clinical Establishment.

6. District Council for Clinical Establishment

The State Government shall, by notification, set-up an authority to be called the district registering authority for each district for registration and supervising of clinical establishments, with the following members, namely:—

- (a) District Magistrate & Collector of the District or any other officer, nominated by him, not below the rank of Addl. D.M — Chairperson;
- (b) Chief Medical Officer — Co-Chairperson;
- (c) District Health Officer — District Nodal Officer;
- (d) District Quality Assurance Officer — Member.

7. Function of District Council

The District Council shall perform the following functions, namely ----

- (a) compiling and updating the District Registers of clinical establishment;
- (b) sending monthly returns for updating the State Register;
- (c) representing the District in the State Council;
- (d) publication on annual basis a report on the District of implementation of standards within their respective District.
- (e) compilation and maintenance of the information and statistics collected from the clinical establishments under clinical establishment Act. every month.

8. Authority for Registration.

(1) The State Government shall, by notification, set-up an authority to be called the District Registering Authority, for each district for registration of clinical establishments, with the following members, namely:—

- (a) Chief Medical Officer — Chairperson;
- (b) District Health Officer — Member;

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under Section 12, the Chief Medical Officer shall exercise the powers of the authority as per procedure, as may be prescribed.

9. District Supervising Team.

(1) The State Government shall, by notification, set-up an authority to be called the District Supervising Team for each district, for supervision of clinical establishments, with the following members, namely:—

- (a) District Health Officer — Chairman
- (b) District Family Welfare Officer — Member
- (c) District Quality Assurance Officer — Member
- (d) Any officer, as time to time Nominated by the CMO ----Member

CHAPTER IV
Registration and Standards for Clinical Establishment.

10. Registration for Clinical Establishment.

No person shall establish, maintain, manage or carry on any clinical establishment, without being registered under this Act and except under and in accordance with the terms of registration issued.

11. Condition for Registration.

- (1) For registration or carrying on the clinical establishment, the following conditions shall be full filled, namely:
- i) The minimum standards of facilities and services, as may be prescribed,
 - ii) The minimum number required personnel, technical or non-technical, as may be prescribed,
 - iii) Provision for maintenance of records and reporting, as may be prescribed,
 - iv) Policy for providing first aid treatment to emergency medical conditions, sexually assaulted, acid victims and Road Traffic Accident cases, and
 - v) Any other matter, as may be prescribed.

12. Application for Registration.

- (1) Every person intending to establish a new clinical establishment shall make an application for provisional registration, in such manner and form and with such fee, as may be prescribed, to the District Registering Authority, who on being satisfied about the information contained in such application, may issue a provisional registration which will remain valid for Six months, within which period the District Registering Authority shall require the District Supervising Team to make an inspection, who will then after necessary inspection, in such manner, as may be prescribed, submit its report, to the District Registering Authority;
- (2) If the District Registering Authority is satisfied that all the required standards and conditions are fulfilled, it may take further action according the procedure prescribed for registration under this chapter;
- (3) But if the District Registering Authority, on the basis of the report of the District Supervising Team, is satisfied that all the required standards and conditions are not fulfilled, he may by order extend the period of validity of such provisional registration for a further period of Six months and direct the applicant to take necessary corrective measures within such date and time, as may be specified in that order;
- (4) If an applicant fails to make necessary corrections, within the extended period also, the applicant shall be treated as a defaulter for making any application for

registration for a subsequent period of one year, which shall be communicated in writing to the applicant;

- (5) An applicant, who holds a valid provisional registration and is not declared as a defaulter according to sub-section (4), may make an application for registration, in such manner, form and shall be accompanied by such fee, as may be prescribed;
- (6) Registration of Clinical establishment issued once shall be valid for five years in respect of Hospitals and three years in respect of all other categories of Clinical Establishment on receipt of an application for registration or renewal of the same, the District Registering Authority may require the District Supervising Team to make an inspection, who will then after necessary inspection, in such manner, as may be prescribed, submit its report, to the District Registering Authority and the District Registering Authority, if satisfied that all the required standards and conditions are fulfilled, shall forward the same to the Director, Family Welfare & Preventive Medicine for approval;
- (7) After the approval of the Director, Family Welfare & Preventive Medicine, the District Registering Authority shall issue the registration;
- (8) If any application fails to fulfil the criteria during the time of inspection by the District Supervising Team, then the establishment may be given three months more time to fulfil the latches, after which the supervising team will inspect or examine the latches detected during the previous inspection and if any applicant fails in the subsequent inspection also, then his application will be treated as cancelled, but such cancellation will not be a bar for applying for a new provisional registration, with prescribed fee.
- (9) Notwithstanding anything contained in this chapter, a clinical establishment already holding a valid registration under the Tripura Clinical Establishment Act, 1976, hereby repealed, shall make an application for registration under this Act, on the due date of renewal of his registration under the Act, so repealed.

13. Display of Certificate of Registration.

The registration certificate shall be kept affixed in a conspicuous place in the clinical establishment in such manner so as to be visible to everyone visiting such establishment.

14. Display of District Registration no.

The registration number, provided to the establishment by the District Registering Authority shall be displayed in the signboard, advertisement, OPD tickets, IPD tickets, reports, bills and private prescriptions and any other paper, document or display, by whatever style or manner.

15. Duplicate Certificate.

In case the certificate is lost, destroyed, mutilated or damaged, the authority shall issue a duplicate certificate on the request of the clinical establishment and on the payment of such fees as may be prescribed.

16. Renewal of Registration.

The application for renewal of registration shall be reached to the District Registering Authority ninety days before the date of expiry of the validity of the registration.

Provided that, if the application is submitted after the stipulated time, not later than three months after the expiry of the registration, the application may be considered by the District Registering Authority, subject to the showing of satisfactory reasons for such delay and on the payment of such fine, as may be prescribed.

17. Cancellation of Registration.

(1) If, at any time after any clinical establishment has been registered, the authority is satisfied that,—

- (a) the conditions of the registration are not being complied with; or
- (b) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act, it may issue a notice to the clinical establishment to show cause within three months' time as to why its registration under this Act should not be cancelled for the reasons to be mentioned in the notice; or
- (c) if any government doctors doing private practice in two or more districts; or
- (d) if monthly information & statistics as per if not submitted on due time to the Supervising Authority.

(2) If after giving a reasonable opportunity to the clinical establishment, the authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, by an order, without prejudice to any other action that it may take against such clinical establishment, cancel its registration.

(3) Every order made under sub-section (2) shall take effect—

- (a) where no appeal has been preferred against such order immediately on the expiry of the period prescribed for such appeal; and
- (b) where such appeal has been preferred and it has been dismissed from the date of the order of such dismissal:

Provided that the authority, after cancellation of registration for reasons to be recorded in writing, may restrain immediately the clinical establishment from carrying on if there is imminent danger to the health and safety of patients.

18. Inspection of Registered Clinical Establishments.

(1) The supervising authority or any officer empowered by it in this empowered by it in this behalf may, subject to sub-general or special orders as may be made by the State Government enter and inspect any premises which are used or which the supervising authority or the officer empowered by it has reasonable cause believe to be used for the

purpose of clinical establishment and inspect records required to be kept in accordance with the provisions of this Act.

(2) If any person refuses to allow the supervising authority or the officer empowered by it to enter or inspect any such premises as aforesaid, or to inspect any such records as aforesaid or obstructs the supervising authority or the officers empowered by it in the execution of the powers under this section, he shall be guilty of an offence under this Act.

(3) Nodal Officer of the State (TCE Act) along with the supervising authority of the District or any officer empowered by the supervising authority may randomly inspect the clinical establishment registered under this Act.

19. Levy of fee by state government.

The State Government may charge fees for different categories of clinical establishments, as may be prescribed. Any fees received or fines paid under this shall be credited to the Consolidated Fund of the District through Bank Challan.

CHAPTER V

Register of Clinical Establishment.

20. Maintenance of State Register.

State Council shall maintain a State Register, containing district-wise monthly updated status, within 20th day of the next month, on the basis of the reports of the districts, in such format, as may be prescribed.

21. Maintenance of District Register.

Every District Registering Authority shall maintain a district register containing the updated records of all clinical establishments under their respective jurisdiction, including the information and statistics, which should be sent to the State Council within 15th day of the next month, in such manner and format, as may be prescribed.

22. Maintenance of Clinical Establishment Register.

Every clinical establishment will maintain the updated records of clinical establishments, including such information and statistics, in such manner and format, as may be prescribed, which shall be submitted to the District Registering Authority, within the 07th day of the subsequent month.

CHAPTER VI

Penalties.

23. Penalty for Non Registration.

(1)Whoever contravenes any provision of this Act shall, if no penalty is provided elsewhere, be punishable for the first offence with fine which may extend to ten

thousand rupees, for any second offence with fine which may extend to fifty thousand rupees and for each subsequent offence with fine which may extend to five lakh rupees or six months imprisonment or both;

- (2) No court inferior to that of a Magistrate of the first class shall try any offence punishable under this Act.

24. Penalty for Disobedience, Obstruction and Refusal of Information.

- (1) The District Registering Authority or any other person duly authorized by such authority, within its respective jurisdiction, is empowered to make inspection of any establishment, at all reasonable time and the Clinical Establishments are liable to show cause for disobedience, obstruction and refusal of information for the first instance;
- (2) If no reply is received in stipulated time or the reply is not satisfactory, the District Registering Authority, on recording of the reasons of his findings in writing, shall have the power to impose and realize fine, which may extend to Rs 10,000/-, with the prior approval of the Director, Family Welfare & Preventive Medicine;
- (3) If any clinical establishment, doesn't reply to the show cause or fails to pay the fine, within 30 days, the registration of the establishment may be cancelled, with the prior approval of the Director, Family Welfare & Preventive Medicine.

25. Offences by Government Departments.

Where an offence under this Act has been committed by a Department of Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer or official, other than the Head of the Department, such officer or official shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

26. Recovery of Fine.

Whoever fails to pay the fine, the State Council of clinical establishment may prepare a certificate signed by an officer authorised by it specifying the fine due from such person and send it to the Collector of the District in which such person owns any property or resides or carries on his business and the said Collector, on receipt of such certificate, shall proceed to recover from such person the amount specified thereunder, as if it were an arrear of land revenue.

CHAPTER VII

Miscellaneous

27. Protection of action taken in good faith.

- (1) No suit, prosecution or other legal proceedings shall lie against any authority or any member of the National Council or State Council or any officer 15 under clause (iv) of sub-section (1) of section 12;

- (j) Classification authorized in this behalf in respect of anything, which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder;
- (2) No suit or other legal proceedings shall lie against a State Government or the Central Government in respect of any loss or damage caused or likely to be caused by anything which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder;
- (3) If any objection or grievance is received by the District Registering Authority, against any establishment, such objections shall be communicated to the clinical establishment, seeking explanation within a period of fifteen days from the date of receipt;
- (4) If no explanation is received within stipulated time or the explanation is not satisfactory, the District Registering Authority, on recording of the reasons of his findings in writing, shall have the power to make an enquiry and to take action against such establishment according to the procedures prescribed in this Act and the rules made thereunder.

28. Repeal and Savings

- (1) The existing Act entitled “ Tripura Clinical Establishment Act, 1976 “ (Act No. 12 of 1976) in its application to the State of Tripura , is hereby repealed;
- (2) Notwithstanding such repeal, anything done or any action taken or any proceeding instituted or any order made or any notification issued under the Act, so repealed, shall be deemed to have been done, taken, instituted, made or issued under the corresponding provisions of this Act;
- (3) All reference in any other enactment to any of the provisions of the Act so repealed shall be construed as a reference to the corresponding provisions of this Act.

29. Power to remove difficulties

- (1) If any difficulty arises in giving effect to the provisions of this Act, after its commencement, the State Government may, by order, published in the official gazette, make such provisions not inconsistent with the provisions of this Act. as may appear to be necessary for removing the difficulty ;
Provided that, no such order shall be made under this section after the expiry of two years from the date of commencement of this Act.
- (2) Every order made under this section, shall be laid, as soon as may be after it is made, before the state legislature.

STATEMENT OF OBJECTS AND REASONS

The Clinical Establishments (Registration and Regulation) Bill, 2018 has been prepared to provide for registration and regulation of all clinical establishments in the State with a view to prescribing the minimum standards of facilities and services provided by them.

2. The existing Act entitled “The Tripura Clinical Establishment Act 1976 “(Act No. 12 of 1976) was designed to provide for the registration of clinical establishments and the matter connected therewith. The said Act has no provision for inclusion of Single doctor Chamber, AYUSH Centre, Collection Centre etc. In the State of Tripura with the time, number of Health care services delivery of point also increases which included in The Clinical Establishments (Registration and Regulation) Bill, 2018.

3. There is increase in the number of private hospitals, private Nursing Homes, private laboratories, radiological centres, collection centres etc in the every district of the State. For providing quality standard in the services and proper supervision of these centres this Clinical Establishments (Registration and Regulation) Bill, 2018 is absolutely necessary for the benefit of the community.

4. In order to deal with them effectively and to consolidate the Law on Clinical Establishment throughout the State, this legislation is being proposed. The main features as contained in the Bill are as follows:

- i) Proposing of 7 nos. of Chapter in Tripura Clinical Establishment (Registration and Regulation) Bill/Act. 2018.
- ii) Proposing of 29 nos. of Sections in Tripura Clinical Establishment (Registration and Regulation) Bill/Act. 2018.
- iii) Proposing of Chapters namely Preliminary, The State Council for Clinical Establishment and The District Council for Clinical Establishment, Registration and Standards for Clinical Establishment, Procedure for Registration, Register for Clinical Establishment, Penalties and Miscellaneous.
- iv). a provision is being made for temporary registration in this proposed Bill as during the period of provision a supervising team will check the necessary standards and as per report the permanent registration will be given.
- v). the main purpose of the Clinical Establishments (Registration and Regulation) Bill, 2018 is to protect the public morals of the people.

The Bill seeks to repeal and re-enact the existing Act entitled “The Tripura Clinical Establishment Act 1976 “(Act No. 12 of 1976) with a view to achieving the above objects.

[Minister, Health & Family Welfare]

TECHNICAL REPORT

The subject – matter of the Bill is related to Entry 6 of List II (State chapter) in the Seventh Schedule to the Constitution of India .The legislature of the State is ,therefore , competent to make a law on this subject. The provisions of the Bill are not repugnant to any provision of the Constitution of India or any Existing Central Law. The Bill does not attract the proviso to clause (b) of Article 304 of the Constitution of India and, therefore, previous sanction n of the President is not necessary for introduction of the Bill. It is not a money bill within the meaning of Article 199, or a “Financial Bill” within the meaning of Article 207(3) of the Constitution of India, therefore, recommendation of the Governor for introduction and consideration of the Bill shall not be necessary.

FINANCIAL MEMORANDUM

The provision of the Tripura Clinical Establishment (Registration and Regulation) Bill 2018 will be enforced by the existing machinery of the State. It is not envisaged to create any new post at any level. Therefore, no expenditure is involved from the consolidated fund of the State.