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GOVERNMENT OF PUDUCHERRY HEALTH SECRETARIAT

(G.O. Ms. No. 15, dated 26th February 2014)

NOTIFICATION

In exercise of the powers conferred by sub-section (1) of section 54 of the Clinical Establishments (Registration and Regulation) Act, 2010 (Act No. 23 of 2010), the Lieutenant-Governor, Puducherry hereby makes the following rules, namely:—

- 1. Short title, application and commencement.— (1) These rules may be called the Puducherry Clinical Establishments (Registration and Regulation) Rules, 2014.
- (2) These rules shall be applicable to all the clinical establishments in the Union territory of Puducherry:

Provided that it shall be applicable to various categories of clinical establishments in a phased manner, as may be notified from time to time.

- (3) These rules shall come into force on the date of their publication in the official gazette of Puducherry.
- 2. Definitions.— In these rules, unless the context otherwise requires,—
 - (a) 'Act' means the Clinical Establishments (Registration and Regulation) Act, 2010.
 - (b) 'Rules' means the rules made under the Act.
 - (c) 'Authority' means the District Registering Authority established under section 10 of the Act.
 - (d) 'Certificate' means certificate of permanent registration issued under section 30 of the Act.
 - (e) '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 recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; 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 diagnosis 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 include a clinical establishment owned, controlled or managed by—

- (i) the Government or a department of the Government;
- (ii) a trust, whether public or private;
- (iii) a Corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government:
 - (iv) a local authority, and
- (v) a single doctor, but does not include the clinical establishments owned, controlled or managed by the Armed Forces constituted under the Army Act, 1950, the Air Force Act, 1950 and the Navy Act, 1957.
- (f) 'Emergency Medical Condition' means a medical condition including any illness and/or intentional or accidental injury of any nature that may manifest itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in-
 - (i) placing the life or health of the individual or with respect to a pregnant woman, the life or health of the woman or her unborn child, in serious jeopardy.
 - (ii) serious impairment to bodily functions; or
 - (iii) serious defunction of any organ or part of a body.
 - (g) 'Form' means a Form appended in these rules.
- (h) 'National Council' means the National Council for Clinical Establishments established under section 3(1) of the Act.
- (i) 'Notification' means a notification published in the official gazette.
- (j) 'State Council' means the Puducherry Council for Clinical Establishments established under the section 8 of the Act.
- (k) 'Prescribed' means prescribed by rules made under the Act by the Central Government or Government of Puducherry, as the case may be.
- (1) 'Recognised System of Medicine' means Allopathy, Yoga, Naturopathy, Ayurveda, Homeopathy, Siddha and Unani system of medicines or any other system of medicine as may be recognised by the Central Government from time to time.

- (m) 'Register' means the register maintained by the authority, Government of Puducherry and the Central Government under sections 37, 38 and 39 respectively of the Act containing the number of clinical establishments registered.
- (n) 'Registration' means to register under section 11 and the expression registration or registered shall be construed accordingly;
- (o) 'Standards' means the conditions that the Central Government prescribed under section 12, for the registration of clinical establishments from time to time;
- (p) 'State Government' means, the Administrator thereof appointed by the President under Article 239 of the Constitution; and
- (q) 'To stabilize' means, with respect to an emergency medical condition specified in clause (f), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medial 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.

The words and expressions used herein and not defined but defined in the Act shall have the same meanings respectively assigned to them in the Act.

- 3. The Puducherry Council for Clinical Establishments.— (1) The Government of Puducherry shall by notification constitute a Union Territory Council called "Puducherry Council for Clinical Establishments" under section 8 of the Act.
- (2) Functions of the Puducherry Council for Clinical Establishments:-

The Puducherry Council for Clinical Establishments shall perform the following functions, namely:-

- (a) compiling and updating the Union Territory Registers of clinical establishments;
 - (b) sending monthly returns for updating the National Register;
 - (c) representing the Union Territory in the National Council;
 - (d) hearing of appeals against the orders of the authority;
- (e) publication on annual basis a report on the state of implementation of standards within the Union Territory;

- (f) monitor the implementation of the provisions of the Act and rules in the Union Territory;
- (g) recommend to the Government, any modifications required in the rules in accordance with changes in technology or social conditions;
 - (h) perform any other function as may be outlined by the National Council for Clinical Establishments;
 - (i) any other function as may be prescribed by the Central Government/State Government.
- (3) Disqualification for appointment as member of the State Council:

A person shall be disqualified for being appointed as a member of the Puducherry Council for Clinical Establishments, if he -

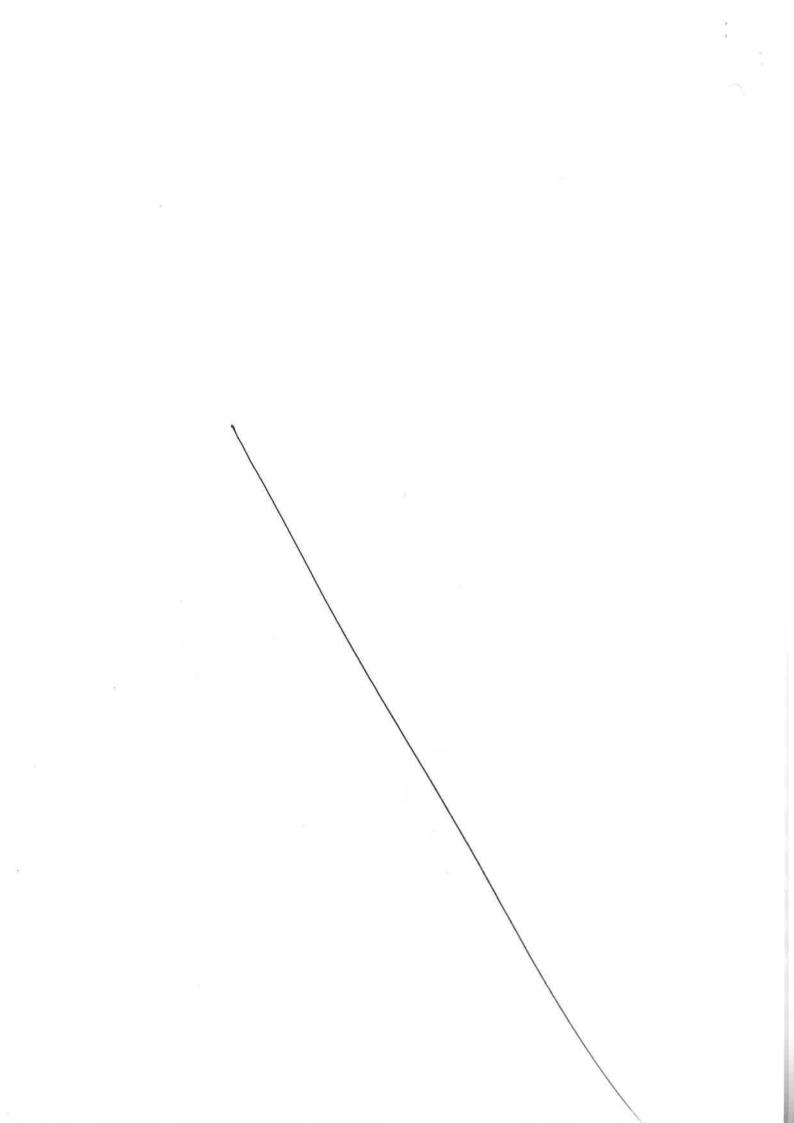
- (a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the State Government involves moral turpitude; or
 - (b) is an undischarged insolvent; or
- (c) is of unsound mind and stands so declared by a competent court; or
- (d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government;
- (e) has, in the opinion of the State Government, such financial or other interest in the Council as is likely to affect prejudicially the discharge by him of his functions as a member.
- (4) Conduct of business: Every meeting of the Union Territory Council shall be presided over by the Chairperson.
- (5) Meeting of the State Council: The meeting of the State Council shall ordinarily be held at Puducherry on such dates as may be fixed by the Council and the State Council shall meet at least once in three months.
- (6) Notice of meeting: Notice of every meeting other than a special meeting shall be issued by the Member-Secretary to each member of the Council not less than one week before the date of the meeting.

- (7) Quorum call for meeting: One-third of the total number of members of the State Council shall form a quorum and all actions of the Council shall be decided by a majority of the members present and voting.
- (8) The notice and agenda of every such meeting of the State Council shall ordinarily be given 7 days before the meeting by the Member-Secretary of the Council.
- (9) The proceedings of the meetings of the Council shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson.
- (10) A copy of the minutes of each meeting of the State Council shall be submitted to the Chairperson within 7 days of the meeting and after having been approved by him/her shall be sent to each member of the Council within 15 days of the meeting. If no objection to their correctness is received within 10 days of their dispatch, any decision therein shall be given effect to, provided that the Chairperson may, where in his opinion it is necessary or expendient so to do, direct that action be taken on the decision of the meeting.
- (11) Resignation and filling of casual vacancies: A member desiring to resign his seat on the State Council shall send his resignation in writing to the Chairperson and every such resignation shall take effect from the date mentioned by him in this behalf or in case no such date is mentioned, from the date of the receipt of his letter by the Chairperson after confirmation from the member concerned about his resignation.
- (12) When a casual vacancy occurs by reason of death, resignation or otherwise of a member, a report shall be made forthwith by the Chairperson to the State Government which shall take step to have the vacancies filled by nomination or election, as the case may be.
- (13) Finance and accounts: The accounts of the State Council shall be audited annually by a registered chartered accountant appointed by the Government. Any expenditure incurred in connection with such audit shall be payable by the Council.
- 4. Establishment of registering authority.— (1) The State Government shall by a notification under section 10 of the Act and in accordance with the rules framed by the Central Government in this behalf set up an authority to be called the District Registering Authority, for registration of clinical establishments in the Union Territory.

- (2) Functions of the registering authority: The registering authority shall perform the following functions, namely:-
 - (a) To grant, renew, suspend or cancel registration of any clinical establishments.
 - (b) To enforce compliance of the provisions of the Clinical Establishments (Registration and Regulation) Act, 2010 and the rules made thereunder.
 - (c) To investigate complaints of breach of the provisions of the Act or the rules made thereunder and take immediate action.
 - (d) To prepare and submit on quarterly basis, report containing details of number and nature of provisional and permanent registration certificates issued; including those cancelled, suspended or rejected, to the State Council.
 - (e) To report to the State Council on a quarterly basis, on the action taken against the functioning of unregistered clinical establishments in violation of the Act and the rules.
 - (f) Perform any other functions as may be prescribed by the Central Government and/or the State Government from time to time.
- (3) Powers of the registering authority: The District Registering Authority shall, for the purposes of discharging its functions under this Act, have the powers in respect of the following matters, namely:-
 - (a) summoning and enforcing the attendance of any person and examining him on oath;
 - (b) requiring the discovery and production of any documents or other electronic records or other material objective produceable as evidence;
 - (c) receiving evidence on affidavits;
 - (d) requisitioning of any public record;
 - (e) issuing commission for the examination of witnesses or documents;
 - (f) reviewing its decision, directions and orders;
 - (g) dismissing an application for default or deciding it ex parte;

- (h) imposing monetary penalty under the provision of the section 41 and 42 of the Act.
 - (i) any other matter which may be prescribed.
- (4) Meetings of registering authority: The meetings of the registering authority shall be held once in a month at a stipulated date and time.
- (5) Conduct of business: Every meeting of the registering authority shall be presided over by the Chairperson.
- (6) Notice of meeting: Notice of every meeting other than a special meeting shall be issued by the convener to each member not less than one week before the date of the meeting.
- (7) Quorum: One-third of the total number of members of the registering authority shall form a quorum and all actions of the authority shall be decided by a majority of the members present and voting.
- (8) The proceedings of the meetings of the registering authority shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson.
- (9) A copy the minutes of each meeting of the registering authority shall be submitted to the Chairperson by the Member-Secretary within 5 days of the meeting and after having been attested by him/her shall be sent to each members of the Council within 15 days of the meeting. If no objection to their correctness is received within 10 days of their dispatch, any decisions therein shall be given effect to, provided that the Chairperson may, where in his opinion it is necessary or expedient so to do, direct that action be taken on the decision taken in the meeting.
- (10) Resignation and filling of casual vacancies: If a casual vacancy occurs in the office, whether by reason of death, resignation or inability to discharge functions owing to illness or any other incapacity, such vacancy shall be filled by the District Collector by making a fresh appointment and the member so appointed shall hold office for the remaining term of office of the person in whose place, in which he is so appointed.

- 5. Registration of clinical establishments.— (1) Application for registration. The applicant shall apply to the concerned registering authority, notified by the Government for provisional registration, either in person, or by post or through web based online facility with the necessary information in a format as per Form-'A'.
- (2) The applicant shall apply to the concerned registering authority notified by the Government for permanent registration, in person, or by post or through web based online facility with the necessary information filled and with evidence of having met the requirements of minimum standards and personnel for different categories of clinical establishments in a form and format as may be specified by the State Government.
- (3) If an establishment is offering services in more than one category, the establishment will need to apply for a separate provisional or permanent registration for each category of establishment under section 14 (1) and section 30 of the Act. However, if a laboratory or diagnostic centre is a part of an establishment providing out-patient/in-patient care, no separate registration will be required.
- (4) Acknowledgment of application: The registering authority or any person in his office authorized in this behalf, shall acknowledge receipt of the application for registration, in the acknowledgment slip in Form-'AA' immediately, if delivered at the office of the authority, or not later than the next working day, if received by post and by online acknowledgment to be generated automatically by the system.
- (5) Grant of registration: The registering authority shall not undertake any enquiry prior to the grant of provisional registration and shall within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration containing particulars and information in Form—'R' either by post or electronically.
- (6) Certificate of permanent registration: The District Registering Authority shall grant the applicant a certificate of permanent registration in form as specified by the State Government either by post or electronically after satisfying itself that the applicant has complied with



all the requirements and criteria, including provisions of minimum standards and personnel required to run the clinical establishment prescribed by the Government and statutory requirements.

- (7) In case of permanent registration, under section 29 of the Act, the authority shall pass an order within the period prescribed hereunder:-
 - (a) allowing the application for permanent registration; or
 - (b) disallowing the application:

Provided that the authority shall record its justifications and reasons, if it disallows an application for permanent registration.

- (8) Fees to be charged: The State Government may charge fees for different categories of clinical establishments.
 - (a) The various fees to be charged for provisional and permanent registration, renewal, late application, duplicate certificate; change of ownership, management or name of establishment shall be as in Form 'AB'.
 - (b) The clinical establishments owned, controlled and managed by the Government (Central, State or local authority) or department of Government shall be exempted from payment of fees for registration.
 - (c) The fees prescribed for registration of various categories of clinical establishments may be revised by the State Council through a notification issued by the State Government.
 - (d) The fee shall be paid by a demand draft/online transaction in favour of the registering authority concerned.
 - (e) The fees collected by the registering authorities for registration of the clinical establishments shall be, deposited by the authority concerned in a nationalised bank account opened in the name of the official designation of the registering authority concerned and shall be utilised by the authority for the activities connected with the implementation of the provisions of the Act and rules as approved by the District Registering Authority.

- (4) The State Council 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.
- (5) If the State Council consider that an interim order is necessary in the matter, it may pass such an order, pending final disposal of the appeal.
- (6) The State Council will have the authority to stay the operation of the order of the district authority till such time as it deems necessary.
 - (7) The decision of the State Council shall be final and binding.
- (8) If no appeal is filed against the decision of the registering authority (i.e.) within 30 days from the date of receipt of the order, the orders of the authority shall be final.
- (9) The penalty fees and appeal fees collected by the authorities shall be deposited by the authority concerned in a nationalised bank account opened in the name of the official designation of the 'Puducherry Council For Clinical Establishments' concerned and shall be utilised by the Council and authority for the activities connected with the implementation of the provisions of the Act as approved by the Council.
- 14. Provision of medical assistance at the time of natural calamity or disaster.— In case of any natural calamity or disaster, all the private clinical establishments shall provide such reasonable assistance and medical aid as may be considered essential at the time of natural calamity or disastrous situation.
- . 15. Implementation of National Health Programmes.— All the private clinical establishments shall implement all the National Health Programmes launched by the Government of India from time to time and shall submit periodical reports to the health authorities concerned in the specified pro forma.

(By order of the Lieutenant-Governor)

V. JEEVA,
Under Secretary to Government (Health).