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NOTIFICATION

No. A.17014/23/2011-HFW/Pt., the 27th May, 2014. In exercise of the powers conferred by Section 54 of the Clinical Establishment Act, 2010, the Governor of Mizoram hereby makes the following rules, namely:-

1. **Short title, application and commencement:**

- (1) These rules may be called the Mizoram Clinical Establishments (Registration and Regulation) Rules, 2014
- (2) These rules extend to the whole State of Mizoram and are applicable to all the Clinical Establishments in the State of Mizoram.
- (3) These Rules shall come into force on the date of their publication in the government of Mizoram Official Gazette.
- (4) The Rules shall be applicable to various categories of clinical establishments in a phased manner, as may be notified from time to time.

2. **Definitions:**

In these rules, unless the context otherwise requires:

- (a) '*Act*' means the Clinical Establishments (Registration and Regulation) Act 2010 (Central Act 23, 2010)
- (b) '*Authority*' means the district registering authority set up under Section 10 of the Act.
- (c) '*Certificate*' means certificate of permanent registration issued under section 30 of the Act;
- (d) '*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 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 include a clinical establishment owned, controlled or managed 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,
 - (d) Provincial or State Act, whether or not owned by the Government;
 - (e) a local authority; and
 - (f) 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.
- (e) '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 women, the life or health of the woman or her unborn child, in serious jeopardy;
 - (ii) serious impairment to bodily functions; or
 - (iii) serious dysfunction of any organ or part of a body
- (f) '*National Council*' means the National Council for clinical establishments established under section 3 of the Act
- (g) '*Prescribed*' means prescribed by rules made under the Act by the Central Government or, as the case may be, the State Government;
- (h) '*Recognised System of Medicine*' means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognised by the Central Government from time to time;
- (i) '*Register*' means the register maintained by the authority, State Government and the Central Government under sections 37, 38 and 39 respectively of the Act containing the number of clinical establishments registered;
- (j) '*Registration*' means to register under section 11 and the expression registration or registered shall be construed accordingly;
- (k) '*Standards*' means the conditions that the Central Government prescribes under section 12, for the registration of clinical establishments from time to time;
- (l) '*State Government, in relation to a Union Territory without Legislature*' means the Administrator thereof appointed under article 239 of the Constitution; and
- (m) '*To stabilise*' (with its grammatical variations and cognate expressions) 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 medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

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.

THE STATE COUNCIL FOR CLINICAL ESTABLISHMENTS

3. Establishment of state council for clinical establishments:

- (1) The State Government shall by notification constitute a State Council for clinical establishments, as the case may be.
- (2) The State Council shall consist of the following members, namely :-
 - (a) Secretary, Health & Family Welfare Department – Ex Officio, who shall be the Chairman
 - (b) Principal Director, Health & Family Welfare Department – Vice Chairman
 - (c) Director, Hospital & Medical Education – Ex Officio member Secretary

- (d) Director of Health Services/Directors of different streams of Indian Systems of Medicine – Ex Officio member
 - (e) One representative each to be elected by the executive committee of –
 - (i) State Medical Council of India
 - (ii) State Dental Council of India
 - (iii) State Nursing Council of India
 - (iv) State Pharmacy Council of India
 - (f) Three representatives to be elected by the Executive of the State Council or the Union territory Council, as the case may be, of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicine.
 - (g) One representative to be elected by the State Council of Indian Medical Association.
 - (h) One representative from the line of paramedical systems.
 - (i) Two representative from State level consumer groups or reputed non-Governmental organizations working in the field of health.
- (3) The nominated member of the State Council shall hold office for a term of three years, but shall be eligible for re-nomination for maximum of one more term of three years.
- (4) The elected members of the State Council shall hold office for three years, but shall be eligible for re-election.
Provided that the person nominated or elected, as the case may be, shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the State Council.

(5) ***Functions of the 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 (including in the digital format);
- (c) representing the State 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 their respective States.
- (f) monitor the implementation of the provisions of the Act and rules in the State;
- (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 of Clinical Establishments
- (i) Any other function as may be prescribed by the Central Government.

(6) ***Disqualification for appointment as member***

A person shall be disqualified for being appointed as a member of the State Council 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; or
- (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.

(7) ***Conduct of Business :***

Every meeting of the State Council shall be presided over by the Chairperson

(8) Time & Place for Meetings of the State Council:

The meetings of the State Council shall ordinarily be held at State Capital on such dates as may be fixed by the Council. The State Council shall meet at least once in three months.

(9) 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.

(10) Quorum, Call for Meeting, Minutes :

- (a) 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.
- (b) The notice and agenda of every such meeting of the State Council shall ordinarily be given 7-10 days before the meeting by the Member Secretary of the Council.
- (c) 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.
- (d) A copy of the minutes of each meeting of the State Council shall be submitted to the Chairperson within 5-7 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 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 of the meeting.

(11) Resignation and Filling of Casual Vacancies:

- (a) 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.
- (b) 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 steps to have the vacancies filled by nomination or election, as the case may be.

(12) Finance and Accounts:

The Accounts of the Council shall be audited annually by a Chartered Accountant, who is to be appointed from a panel approved by the Comptroller and Auditor General of India. Any expenditure incurred in connection with such audit shall be payable by the Council.

THE DISTRICT REGISTERING AUTHORITY

4. Establishment of district registering authority:

- (1) The State Government shall, by notification under Section 10 of the Act and in accordance with the rules framed by Central Government in this behalf 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) District Collector – Chairperson
 - (b) Chief Medical Officer – Convener
 - (c) Three members with such qualifications and on such terms and conditions as may be prescribed by the Central Government.

- (j) City Police Commissioner or Sr. Superintendent of Police or Superintendent of Police.
 - (ii) Senior level Officer of the Local Self Government at district level.
 - (iii) One representative from a professional medical association or body.
- (2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under section 14, the District Health Officer of the Chief Medical Officer (by whatever name called) shall exercise the powers of the authority as per procedure that may be prescribed.
- (3) ***Functions of the District Registering Authority:***
- (a) to grant, renew, suspend or cancel registration of any clinical establishments
 - (b) to enforce compliance of the provisions and rules of the Clinical Establishments (Registration and Regulation) Act 2010
 - (c) to investigate complaints of breach of the provisions of this Act or the rules made there under and take immediate action;
 - (d) to prepare and submit on quarterly basis report containing details of related to number and nature of provisional and permanent registration certificates issued; included those cancelled, suspended or rejected to the State Council.
 - (e) to report to the State Council on a quarterly basis on action taken against non-registered clinical establishments operation in violation of the Act
 - (f) perform any other function as may be prescribed by the central government and / or the state government from time to time.
- (4) ***Powers of the District Authority:***
The district authority shall, for the purposes of discharging its functions under this Act, have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, 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 document or other electronic records or other material objective producible 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 decisions, directions and orders;
 - (g) dismissing an application for default or deciding it exparte;
 - (h) any other matter which may be prescribed.
- (5) ***Time and Place of and Preparation of Business for Meetings of the District Registering Authority:***
The meetings of the District Registering Authority shall be held at least once in a month at a stipulated date and time.
- (6) ***Conduct of Business:***
Every meeting of the District Registering Authority shall be presided over by the Chairperson.
- (7) ***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.

(8) ***Quorum, Minutes:***

- (a) One - third of the total number of members of the District Registering Authority shall form a quorum and all actions of the Authority shall be decided by a majority of the members present and voting.
- (b) The proceedings of the meetings of the District Registering Authority shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson.
- (c) A copy of the minutes of each meeting of the District Registering Authority shall be submitted to the Chairperson by the Member Secretary within 5-7 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 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.

(9) ***Resignation and filling of casual vacancies:***

If a casual-vacancy occurs in the office of any other members, 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 he/she is so appointed.

5. **Registration Of Clinical Establishments**

(1) ***Application for Registration:***

- (a) The applicant shall apply to the District Registration Authority for provisional registration, either in person, or by post or through web based online facility with the necessary information in **Form-I** under Section 14 (1) and 14 (3) of the Act.
- (b) The applicant shall apply to the District Registration Authority 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 **Form-II** under Section 24 and 25 of the Act .
- (c) If an establishment is offering services in more than one category as specified under the Mizoram Clinical Establishments (Registration and Regulation) Rules ,2014, the establishment will need to apply for a separate provisional or permanent registration for each category of establishment under Section 14 (I) and Section 30 of the Act. However, if a laboratory or diagnostic center is a part of an establishment providing out patient / inpatient care, no separate registration will be required.

(2) ***Acknowledgement of Application:***

The Registration Authority, or any person in his office authorized in this behalf, shall, acknowledge receipt of the application for registration, in the acknowledgment slip provided as per **Form-III** immediately, if delivered at the office of the authority, or not later than the next working day if received by post and by online acknowledgement to be generated automatically by the system.

(3) ***Grant of Registration:***

The 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 as per **Form-IV** either by post or electronically under Section 15, read with Section 17 of the Act.

(4) ***Certificate of registration:***

- (a) The District Registering Authority shall grant the applicant a certificate of permanent registration as per **as per Form-V** either by post or electronically after satisfying itself that the applicant has complied with all the requirements and criteria, including provision of minimum standards and personnel required to run the clinical establishment
- (b) In case of permanent registration, under Section 29 of the Act, the authority shall pass an order within 31/2 months –
 - (i) allowing the application for permanent registration; or
 - (ii) disallowing the application:
Provided that the authority shall record its justifications and reasons, if it disallows an application, for permanent registration.

6. **Fees to be charged:**

- (1) The various fees charged for provisional and permanent registration, renewal, late application, duplicate certificate, change of ownership, management or name of establishment is prescribed in **Annexure-I** under Section 14 (I) read with Section 19, Section 20 (2), Section 22; Section 24, Section 35, Section 54(a)(e)(h)(i)(p)(r) of the Act.
- (2) Clinical establishments owned, controlled and managed by the government (Central, State or local authority) or department of government, shall be exempt from payment of fees for registration.
- (3) The fees prescribed for various categories of clinical establishments may be revised by the State Council through a notification issued by the State Government
- (4) The fee shall be paid by a demand draft drawn / online transaction in favour of the Registration Authority concerned as specified under Section 14 (I) and Section 30 of the Act.
- (5) The fees collected by the Authorities for registration of the Clinical Establishments shall be, deposited by the Authority concerned in a Nationalized scheduled bank account opened in the name of the official designation of the Registration Authority concerned and shall be utilized by the Authority for the activities connected with the implementation of the provisions of the Act and these rules as approved by the District Registration Authority.
There shall be constituted a fund called State Clinical Establishment Council Fund and all district authorities shall credit two percent of the total amount collected by them by way of fees and penalties.
- (6) The Accounts shall be maintained as per the Financial Code and shall be audited by a qualified Chartered Accountant empanelled by CAG. The annual Audit reports shall be submitted to the concerned State Council.
- (7) In the event of any change of ownership or management, the establishment shall intimate to the District Registration in writing within one month of such change along with the fee prescribed in **Annexure-I** for issue of a revised certificate of Provisional or Permanent registration, as the case maybe, incorporating the changes and on surrendering the old certificate under Section 20 (2) and Section 30 of the Act.
- (8) In the event of certificate of registration (Provisional or Permanent) being lost or destroyed, the owner shall apply to the District Registration Authority to issue a duplicate certificate upon payment of the fee prescribed in **Annexure-I** under Section 19 and Section 30 of the Act.

7. **Ownership change & lost of certificate:**

- (1) In the event of any change of ownership of management, the establishment shall intimate to the District Registration in writing within one month of such change along with the prescribed fee, for issue of a revised certificate of provisional or permanent registration, as the case maybe, incorporating the changes and on surrendering the old certificate as under Section 20(2), Section 30, Section 54(f).

- (2) In the event of certificate of registration (provisional or permanent) being lost or destroyed, the owner shall apply to the District registration authority to issue a duplicate certificate upon payment of the fee prescribed, and the provisional certificate shall be marked "Duplicated" as per **FORM-VI** as under Section 19, Section 54(e).

8. Renewal of registration:

- (1) The clinical establishment shall apply for renewal of provisional registration thirty days before the expiry of the validity of the certificate of provisional registration. In case the application for renewal is not submitted within the stipulated period, the authority shall allow for renewal of registration on payment of the renewal amount as prescribed in **Annexure-I** and penalty of Rs. 100 per day till the date of application for renewal under section 22 of the Act.
- (2) For renewal of permanent registration, the clinical establishment shall apply three (3) months before expiry of the registration period of five (5) years. The renewal will be granted by the Authority within 3 months of receipt of the application failing which it will be deemed to have been renewed. If the clinical establishment does not apply within one month of expiry of registration period, the registration will be deemed to have been suspended.
- (3) Under Section 30 (4) of the Act the clinical establishment shall apply for renewal of permanent registration six months before the expiry of the validity of the certificate of permanent registration. In case the application for renewal is not submitted within the stipulated period, the authority will allow for renewal of registration on payment of the renewal amount as prescribed in **Annexure-I** and penalty of Rs. 100 per day till the date of application for renewal is accepted.

REGISTERS TO BE MAINTAINED, FURNISHING OF RETURNS AND DISPLAY OF INFORMATION

9. Registers to be maintained:

- (1) Every District Registration Authority shall within a period of two years from its establishment, compile, publish and maintain in digital format a register of Clinical Establishments registered by it and it shall enter the particulars of the certificate so issued in a register containing particulars as prescribed by the State under Section 37(1), Section 54(s) of the Act.
- (2) Every District Registration Authority including any other authority set up for the registration of clinical establishments under the law for the time being in force shall supply in digital format to the State Council of Clinical Establishments a copy of every entry made in the District register of clinical establishments for a particular month by the 15th day of the following month in keeping with Section 37 (2), Section 54(t) of the Act.

10. Display of information:

- (1) The District Registering Authority shall, within a period of forty-five days from the grant of provisional registration, mandatorily cause to be published in the public domain either through two local newspapers or any other public forums and on the website, which the District Registering Authority will launch, the name of the Clinical establishment, Address, Ownership, Name of Person in Charge, System of Medicine offered, Type and Nature of Services offered and details of the Medical Staff (Doctors, Nurses, etc.) as under Section 16 (2), Section 54(d) of the Act.
- (2) The State council could make changes in the nature of information to be provided in the Public Domain through a notification, except in the case of the mandatory information to be provided under Section 16 (2)of the Act.
- (3) The District Registering Authority shall, within a period of 7 days cause to be published in the public domain either through two local newspapers or any other public forums and on the website, which the District Registering Authority will launch, the name of the Clinical establishment, Address, Ownership, Name of Person in Charge, System of Medicine offered,

Type and Nature of Services offered, details of the Medical Staff (Doctors, Nurses, etc) and the details and information related to having complied with the minimum standards and personnel prescribed for the particular category of clinical establishment as under Section 26, Section 54(k) of the Act.

- (4) The District Registration Authority shall cause to be displayed the above information in public domain for a period of 30 days for filing objections before granting permanent registration as prescribed in **(Annexure-II)** under Section 26 of the Act.
- (5) If any person has any objection to the information published regarding the clinical establishment they shall give in writing the reasons and evidence of objection or non-compliance to the District Registration Authority as under Section 27 of the Act.
- (6) The District Registering Authority shall, within a period of 15 days cause to be published in the public domain the name of the Clinical Establishment whose (Provisional or Permanent) registration has expired as under Section 21 and Section 30 of the Act.

11. Information to be provided by clinical establishments:

- (1) The Clinical Establishments shall maintain medical records of patients treated by it and health information and statistics in respect of national programmes and furnish the same to the district authorities in form of six monthly reports. The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishments will be as in **Annexure IV & V** under Section 48 of the Act.
- (2) Copies of all records and statistics shall be kept with the clinical establishment concerned for at least 3 years or in accordance with any other relevant act in force at the time under Section 12 (1) (iii) of the Act. All clinical establishments shall be responsible for submission of information and statistics in the time of emergency or disaster or epidemic situation.
- (3) The government may notify from time to time, the nature of information that needs to be furnished by the Clinical Establishments including other disease notified for this purpose along with the prescribed interval.
- (4) In addition to the specific provisions of the Clinical Establishments (Registration & Regulation) Act 2010, all establishments shall comply and maintain information and statistics in keeping with other applicable Acts and Rules which are in force in the country.

12. Power to enter:

- (1) Entry and search of the clinical establishment can be done by the District Registering Authority or an officer or team duly authorized by it or subject to such general or special orders as may be made by the authority. Such a decision will be required to be taken by majority of members of the District Registration Authority.
- (2) Such entry and search of clinical establishments can be conducted if anyone is carrying on a clinical establishment without registration or does not adhere to the prescribed minimum standards or has reasonable cause to believe the CE is being used for purposes other than that it is registered or contravenes any of the provisions of this Act & Rules, shall at all reasonable times enter and inspect any record, register, document, equipment and articles as deemed necessary under the provisions of Section 34, Section 54(o) of the Act.
- (3) The inspection team shall intimate the establishment in writing about the date of visit and reasons for the inspection. The team shall examine all portions of the premises used or proposed to be used for the clinical establishment and inspect the equipments, furniture and other accessories and enquire into the professional qualifications of the technical staff employed or to be employed and shall make any such other enquires as they consider necessary to verify the statements made in the application for registration and grant of license. All persons connected with the running of the establishment shall be bound to supply full and correct information to the inspection team.

- (4) The officer and / or inspection team so constituted by the Registering Authority shall submit a report as per **Annexure-III** within a week of the inspection to the District Registration Authority with a copy to the State Council.
- (5) 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.
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 there under, it may, by an order, without prejudice to any other action that it may take against such clinical establishment, cancel its registration.
- (6) 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.

PENALTIES & APPEALS

13. Penalties:

- (1) In keeping with the provisions of Section 41 (1) (2) (3) and Section 42 (1) (2) (3), Section 54(u) of the Act, whoever carries on a clinical establishment without registration or whoever willfully disobeys any direction, or obstructs any person or authority or withholds any such information or provides false information shall be liable for a monetary penalty.
- (2) Whoever carried on a clinical establishment without registration, shall, on first contravention be liable to a monetary penalty upto fifty thousand rupees, for second contribution to a monetary penalty which may extend to two lakh rupees and for any subsequent contravention to penalty which may extend to five lakh rupees.
- (3) Whoever knowingly serves in a clinical establishment which is not duly registered under this Act, shall be liable to a monetary penalty which may extend to twenty five thousand rupees.
- (4) The penalty fees collected by the authorities for shall be, deposited by the Authority concerned in a Nationalized bank account opened in the name of the official designation of the State Council concerned and shall be utilized by the Council and authority for the activities connected with the implementation of the provisions of the Act and approved by the Council.

14. Appeals:

- (1) In keeping with Section 36, 41 (4) (5) (6) (7) and Section 42 (4) (5) (6) (7), any person or clinical establishment, if aggrieved by the decision of the Authority under Sections 29 and 34 of the Act, may file an appeal in the **Form-V** to the State Council within thirty (30) days from the date of receipt of such order along with a fee of Rs.5000/-
- (2) The appeal against a public healthcare establishment shall be filed in **Form-V** and shall be sent to the state council by registered post or in person.
- (3) Every appeal shall be accompanied by a fee of rupees one thousand.

- (4) After receipt of the appeal, the State Council shall fix the time and date for hearing and inform the same to the appellant and others concerned by a registered letter giving at least 15 days time for hearing of the case.
- (5) The appellant may represent by himself or authorized person or a Legal practitioner and submit the relevant documentary material if any in support of the appeal
- (6) The 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
- (7) If the State Council considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal.
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.
The decisions of State Council shall be final and binding.
- (8) If no appeal is filed against the decision of the Registering Authority in the prescribed period (i.e.) within 30 days from the date of receipt of the order, the orders of the Authority shall be final.
- (9) The appeal fees collected by the authorities shall be deposited by the Authority concerned in a Nationalized bank account opened in the name of the official designation of the State Council concerned and shall be utilized by the Council and authority for the activities connected with the implementation of the provisions of the Act as approved by the Council.

Form – I

(See Rule – 5(1) (a), Section 14(1)(3), Section 54(a)(b) of the Act)

Application Form for Provisional Registration of Clinical Establishments

- e) **Name of the Establishment:** / Doctor (in case of single practitioner) _____
2. **Address:** _____
 Village/Town: _____ Taluka: _____
 District: _____ State: _____ Pin code _____
 Tel No (with STD code): _____ Mobile: _____ Website (if any): _____
3. **Name of the owner:** _____
Address: _____
 Village/Town: _____ Taluka: _____
 District: _____ State: _____ Pin code _____
 Tel No (with STD code): _____ Mobile: _____ Email ID : _____
- 3a) Name of Person in charge and Qualifications:** _____
4. **Ownership**
 a) Public Sector : ↑Central government ↑State government ↑Local government ↑Public Sector Under taking ↑Any other (please specify) : _____
 b) Private Sector ↑Individual Proprietorship ↑Registered Partnership ↑Registered Company ↑Co-operative Society ↑Trust/Charitable ↑Any other (please specify): _____
5. **Systems of Medicine offered: (please tick whichever is applicable)**
 ↑Allopathy ↑Ayurveda ↑Unani ↑Siddha ↑Homeopathy ↑Yoga & Naturopathy
6. **Services Provided: (please tick whichever is applicable)**
 ↑Inpatient ↑Outpatient ↑Laboratory/Imaging Centre ↑Any other (please specify): _____
 a) **Category of Clinical Services:** ↑General ↑Single Specialty ↑Multi Specialty ↑Super Specialty
7. **Type of Establishment (please tick whichever is applicable)**
 a) Inpatient: ↑ Hospital ↑ Nursing Home ↑Maternity Home ↑Primary Health Centre
 ↑Community Health Centre ↑Sanatorium ↑Day Care centre
 b) **Number of Beds:** _____
 c) Outpatient: ↑Single practitioner ↑Polyclinic ↑Sub-Centre ↑Physiotherapy Clinic ↑Occupational Therapy ↑Infertility clinic ↑Dental clinic ↑Dispensary ↑Dialysis Centre ↑Any other (please specify): _____
 d) Laboratory: ↑Pathology ↑Haematology ↑Biochemistry ↑Microbiology ↑Genetics
 ↑Collection Centre ↑Any other (please specify): _____
 e) Imaging Centre: please specify: _____
 Special diagnostics: Please specify: _____

I hereby declare that the statements above are correct and true to the best my knowledge and shall abide by all the rules and declarations under the Clinical Establishment (Registration and Regulation) Act 2010. I undertake that I shall intimate to the appropriate registering authority any change in the particulars given above.

Date:

Signature of the Authorized Signatory

Form – II

(See Rule – 5(1) (b), Section 24, Section 25 of the Act)

Application Form for Permanent Registration of Clinical Establishments

- e) **Name of the Establishment:** / Doctor (in case of single practitioner) _____
2. **Address:** _____
Village/Town: _____ Taluka: _____
District: _____ State: _____ Pin code _____
Tel No (with STD code): _____ Mobile: _____ Website (if any): _____
3. **Name of the owner:** _____
Address: _____
Village/Town: _____ Taluka: _____
District: _____ State: _____ Pin code _____
Tel No (with STD code): _____ Mobile: _____ Email ID : _____
- 3a) Name of Person in charge and Qualifications:** _____
4. **Ownership**
a) Public Sector: ↑Central government ↑State government ↑Local government ↑Public Sector Undertaking ↑Any other (please specify): _____
b) Private Sector ↑Individual Proprietorship ↑Registered Partnership ↑Registered Company ↑Co-operative Society ↑Trust / Charitable ↑Any other (please specify): _____
5. **Systems of Medicine offered: (please tick whichever is applicable)**
↑Allopathy ↑Ayurveda ↑Unani ↑Siddha ↑Homeopathy ↑Yoga & Naturopathy
6. **Services Provided: (please tick whichever is applicable)**
↑Inpatient ↑Outpatient ↑Laboratory/Imaging Centre ↑Any other (please specify): _____
a) Category of Clinical Services: ↑General ↑Single Specialty ↑Multi Specialty ↑Super Specialty
7. **Type of Establishment (please tick whichever is applicable)**
a) Inpatient: ↑Hospital ↑Nursing Home ↑Maternity Home ↑Primary Health Centre ↑Community Health Centre ↑Sanatorium ↑Day Care centre
b) **Number of Beds:** _____
c) Outpatient: ↑Single practitioner ↑Polyclinic ↑Sub-Centre ↑Physiotherapy Clinic ↑Occupational Therapy ↑Infertility clinic ↑Dental clinic ↑Dispensary ↑Dialysis Centre ↑Any other (please specify): _____
d) Laboratory: ↑Pathology ↑Haematology ↑Biochemistry ↑Microbiology ↑Genetics ↑Collection Centre ↑Any other (please specify): _____
e) Imaging Centre: please specify: _____
Special diagnostics: Please specify: _____

I hereby declare that the statements above are correct and true to the best my knowledge and shall abide by all the rules and declarations under the Clinical Establishment (Registration and Regulation) Act 2010. I undertake that I shall intimate to the appropriate registering authority any change in the particulars given above.

Date:

Signature of the Authorized Signatory

FORM - III
(See Rule - 5(2))

ACKNOWLEDGEMENT
REGISTRATION OF CLINICAL ESTABLISHMENT

The application in Form ___ for Grant / Renewal of Provisional / Permanent registration of the Clinical Establishment submitted by _____ (Name and address of Owner) has been received by the District Registration Authority on _____ (date) and found to be

Complete
Or
Incomplete

This acknowledgement does not confer any rights on the applicant for grant or renewal of registration.

Signature and Designation of Registration Authority or authorized person in the Office of the Appropriate Authority.

SEAL

Designation of the Issuing Authority *(Computer Generated)*
Place & Date: *(Computer Generated)*

FORM - IV
(See Rule 5(3), Section 15, 17, 54(c) of the Act)

PROVISIONAL CERTIFICATE
FOR REGISTRATION OF CLINICAL ESTABLISHMENT

Provisional registration No: *(Computer Generated)*

Date of issue: *(Computer Generated)*

Valid up to: *(Computer Generated)*

1. Name of the Clinical Establishment: _____
2. Address: _____
3. Owner of the Clinical Establishment: _____
4. Name of Person in Charge: _____
5. System of Medicine : _____
6. Type of Establishment: _____

Is hereby provisionally registered under the provisions of Clinical Establishments (Registration and Regulation) Act 2010 and the Mizoram Clinical Establishment (Registration & Regulation) Rules 2014 made there under. This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act 2010 and the Mizoram Clinical Establishment (Registration & Regulation) Rules 2014 made there under.

Designation of the Issuing Authority *(Computer Generated)*
Place & Date: *(Computer Generated)*

District Registration Authority
Address:

Phone number in case of Grievances

FORM – V
(See Rule 5(4), Section 30, 54(m) of the Act)

**PERMANENT CERTIFICATE
FOR REGISTRATION OF CLINICAL ESTABLISHMENT**

Permanent registration No: *(Computer Generated)*

Date of issue: *(Computer Generated)*

Valid up to: *(Computer Generated)*

- 7. Name of the Clinical Establishment: _____
- 8. Address: _____
- 9. Owner of the Clinical Establishment: _____
- 10. Name of Person in Charge: _____
- 11. System of Medicine : _____
- 12. Type of Establishment: _____

Is hereby provisionally registered under the provisions of Clinical Establishments (Registration and Regulation) Act 2010 and the Mizoram Clinical Establishment (Registration & Regulation) Rules 2014 made there under. This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act 2010 and the Mizoram Clinical Establishment (Registration & Regulation) Rules 2014 made there under.

Designation of the Issuing Authority *(Computer Generated)*
Place & Date: *(Computer Generated)*

District Registration Authority
Address:

Phone number in case of Grievances

FORM – VI
(See Rule 7(2), Section 19, 54(e) of the Act)

**DUPLICATE CERTIFICATE
FOR REGISTRATION OF CLINICAL ESTABLISHMENT**

Duplicate registration No: *(Computer Generated)*

Date of issue: *(Computer Generated)*

Valid up to: *(Computer Generated)*

- 13. Name of the Clinical Establishment: _____
- 14. Address: _____
- 15. Owner of the Clinical Establishment: _____
- 16. Name of Person in Charge: _____
- 17. System of Medicine : _____
- 18. Type of Establishment: _____

Is hereby provisionally registered under the provisions of Clinical Establishments (Registration and Regulation) Act 2010 and the Mizoram Clinical Establishment (Registration & Regulation) Rules 2014 made there under.

This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act 2010 and the Mizoram Clinical Establishment (Registration & Regulation) Rules 2014 made there under.

Designation of the Issuing Authority *(Computer Generated)*
Place & Date: *(Computer Generated)*

District Registration Authority
Address:

Phone number in case of Grievances

FORM – VII
(See Rule 14(1), 36(2), 54(n)(q)(v) of the Act)

(see S.36 (2))

Application for Appeal

To

The State Council,
Government of

Sir,

I, Dr....., of had applied for registration / is a valid license holder with registration number under clinical establishments act, 2010 for my located at.....

I was communicated by the district authority as per letter no. dated..... that either;

- i) That my application was rejected
- ii) That my registration is cancelled
- iii) That I am restrained from carrying on with the running of clinical establishment
- iv) That I am charged with a penalty for an offence under the act
- v) Any other

The above decision of the district authority appears to be not valid. I request you to consider my application as per the justifications mentioned below;

- i)
- ii)
- iii)

I am willing to appear before you for a personal hearing, if necessary. I am enclosing herewith a draft of Rs. 1000/-

Thanking you,

Place:
Date:

Signature:
Name:

Annexure - I
(See Rule 6(1), Section 19, 20(2), 22, 24, 35, 54(a)(e)(h)(i)(p)(r) of the Act)

Fees to be Charged

Description	Urban		Rural		Metro	
	Provisional	Permanent	Provisional	Permanent	Provisional	Permanent
Out Patient Care	100	500	50	250	200	1000
In Patient Care						
1 to 30beds	100	500	50	250	200	1000
30 to 100 beds	200	1000	100	500	400	2000
Above 100 beds	300	1500	150	650	600	3000
Testing& Diagnostic Laboratories	200	1000	100	500	400	2000
Diagnostic & Imaging Centre	300					
Other Fees						
<ul style="list-style-type: none"> · For Renewal half the amount of registration fee (Provisional/Permanent) · For Late Application the amount would be double of the registration fee (Provisional/Permanent) · For Duplicate Certificate the amount would be Rs. 200 · For change of ownership, management or name of establishment would be Rs 100 · For any appeal the amount would be Rs. 100 <p>* If a laboratory or diagnostic center is a part of a establishment providing out patient/Inpatient care no separate registration is required.</p>						

Annexure - II
(See Rule 10(4), Section 26,54(k) of the Act)
(Sec. 26)

Display of registration status for filing objections

I,being the authority under the Clinical Establishments Act, 2010 after considering the applications received during the period; from..... to under Sec.24 satisfying the provisions of the clinical establishments act, 2010 and the Mizoram Clinical Establishments Rules, 2014 made theirunder, hereby publish the list of Clinical Establishments; within the jurisdiction ofdistrict.

Serial No.	Name of Clinical Establishment with address	Ownership/In charge	System of medicine	Date on which application was submitted	Category & standards complied with

Objections if any, in writing to the published list may be addressed in duplicate to (address of the authority) within 30 days, from the date of this notification, as required under section 26 of the Act.

Place:
Date:

Signature:
Name:

(Seal of the authority)

Annexure - III
(See Rule 12(4), Section 33, 34, 54(o) of the Act)

Suggested Format for Submission of Inspection Report

Number of visits made with dates

Names and details of members of the inspection team

Name of clinical establishment visited

Address and contact details of clinical establishment visited

Process followed for inspection (e.g. kindly outline who was met with, what records were examined, etc)

Salient Observations / Findings

Conclusions

Specific Recommendations:

(1) To the Clinical Establishment

(2) To the District Registering Authority

**In case of lack of consensus amongst members of the inspection team, the same may be kindly indicated*

Signature (of all members of the inspection team)

Date

Place

Annexure – IV
(See Rule 11(1), Section 48, 54(w) of the Act)

RECORDS TO BE MAINTAINED BY CLINICAL ESTABLISHMENT

- Outpatient register
- Inpatient register
- Operation Theater register
- Labor room register
- MTP register (if registered under the MTP Act)
- Case sheets
- Medico-legal register
- Laboratory register
- Radiology and Imaging register
- Discharge summary
- Medical certificate in duplicate
- Complaint register
- Birth register (Notified to such medical officer as authorized)
- Death register by Government in such format as prescribed by Government/State level authority)
- Information in terms of government programmes/areas of work (eg. maternal health, child health, immunization, family planning, Vector borne disease, NLEP, RNTCP, IDSP, NRHM initiatives-ASHA, JSY)
- Number of beds system-wise and speciality-wise in Clinical Establishments providing in patient care (e.g. General Med/Surg Beds; Special Care Beds)
- Total Discharge:

FURNISHING OF RETURNS (See Rule 11(1) Section 48, 54(w) of the Act)
HALF YEARLY RETURNS

Sl.No.	Item	Month												Year ending Achievement								
		April		May		June		July		Aug		Sept			Mid-Year Achievement	Oct	Nov	Dec	Jan	Feb	March	
		M	F	M	F	M	F	M	F	M	F	M	F									
1	Out patient register																					
2	Inpatient register																					
3	Operation Theater register																					
4	Labor room register																					
5	MTP register																					
6	Medico-legal register																					
7	Laboratory register																					
8	Radiology and Imaging register																					
9	Medical certificate in duplicate																					
10	Complaint register																					
11	Birth register (Notified to such medical officer as authorized)																					
12	Death register by Govt. in such format as prescribed by Govt./State level authority)	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	<48hr adm	>48 hrs adm	
13	Information in terms of govt. programmes/areas of work (eg. No. of ANC, immunization of children, family planning-IUD, OCP, Tubectomy Vector borne disease, NLEP, RNITCP, IDSP, NRHM initiatives-ASHA, JSY)																					
14	No. of beds system-wise and speciality-wise in Clinical Establishments providing in patient care (e.g. General Med/Surg Beds; Special Care Beds)																					
15	Total Discharge																					

**GOVERNMENT OF MIZORAM
HEALTH & FAMILY WELFARE DEPARTMENT
MIZORAM SECRETARIAT, MINECO, AIZAWL-796001**

NOTIFICATION

Aizawl, the 10th October, 2022

No.A.17014/2/2022-HFW(CEM)/23-24 : In supersession of this Department's Notification No.A.17014/23/2011-HFW/Pt. dt.02.05.2018 and in pursuant to the enactment of the State Clinical Establishments (Registration and Regulation) Act 2010 under Section 8(3) & (4) read with rules 3(3) & (4) of the Mizoram Clinical Establishment (Registration and Regulation) Rules, 2014, the Governor of Mizoram is pleased to re-constitute the **State Council for Clinical Establishments** comprising of the following members with immediate effect for a period of 3 (three) years:-

Chairman - Principal Secretary, Health & Family Welfare Department (**Ex-officio**)
Vice-Chairman - Principal Director, Health & Family Welfare Department
Member Secretary - Director, Hospital & Medical Education (**Ex-officio**)
Member - Director, Health Services (**Ex-officio**)

Elected Members:

1. Vice-Chairman, Mizoram State Medical Council
2. Asst. Secretary, Indian Medical Association, Mizoram State Branch
3. Vice-President, Mizoram State Pharmacy Council
4. President, Mizoram Nursing Council
5. President, Indian Dental Association, Mizoram State Branch
6. General Secretary, Mizoram Ayush Doctors' Association

Nominated Members:

1. President, Mizoram Consumer Union
2. Secretary, Health & Sanitation Sub-Committee, Central YMA
3. Secretary, Mizoram Health Technical Staff Union

Power and Functions of the state Council for Clinical Establishments:-

The State Council shall perform the following functions, namely:-

1. Compiling and updating the State Registers of Clinical Establishment;
2. Sending monthly returns for updating the National Register (including in the digital format)
3. Representing the state in the National Council
4. Hearing of appeals against the orders of the authority
5. Publication on annual basis a report on the state of implementation of standards within their respective States
6. Monitoring the implementation of the provisions of the Act and rules in the State
7. Recommend to the Government, any modifications required in the rules in accordance with changes in technology or social conditions
8. Perform any other function as may be outlined by the National Council of Clinical Establishments
9. Any other functions as may be prescribed by the Central Government

Sd/-ESTHER LAL RUATKIMI
Principal Secretary to the Govt. of Mizoram
Health & Family Welfare Department

Memo.No.A.17014/2/2022-HFW(CEM)/23-24 : Aizawl the 10th October, 2022

Copy to:

1. Secretary to the Governor, Mizoram
2. P.S to Minister, Health & Family Welfare Department, Mizoram
3. P.A to MLA & Vice Chairman, Health & Family Welfare Board, Mizoram
4. PPS to Principal Secretary, Health & Family Welfare Department, Mizoram
5. Principal Director, Health & Family Welfare Department, Mizoram
6. Director, Health Services, Mizoram.
7. Director, Hospital & Medical Education, Mizoram.
8. Director, Zoram Medical College (ZMC), Falkawn.
9. SNO, Clinical Establishment Act, DHME
10. President, Mizoram State Medical Council
11. President, Indian Medical Association, Mizoram State Branch
12. President, Mizoram State Pharmacy Council
13. President, Mizoram Nursing Council
14. President, Indian Dental Association, Mizoram Branch
15. President, Mizoram AYUSH Doctors' Association
16. President, Mizoram Health Technical Staff Association
17. All Chief Medical Officers, Mizoram
18. All Medical Superintendent, Mizoram
19. President, Central Young Mizo Association, Aizawl
20. President, Mizoram Consumer Union, Aizawl
21. Persons concerned
22. Web Manager, Directorate of Health Services
23. Guard File


(JOSEPHINE ZONUNSANGI)

Under Secretary to the Govt. of Mizoram
Health & Family Welfare Department