The Mizoram Gazette

EXTRA ORDINARY

Published by Authority

RNI No. 27009/1973 Postal Regn. No. NE-313(MZ) 2006-2008

VOL - XLVIII Aizawl, Tuesday 9.7.2019 Ashadha 18, S.E. 1941, Issue No. 435

NOTIFICATION

No. A.17014/1/2015-HFW/362, the 2nd July, 2019. In exercise of the powers conferred by Section 54 of the Clinical Establishments (Registration & Regulation) 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 & Regulation) (Amendment) Rules, 2019.

   (2) It shall have the like extended application as the Principle Rules

   (3) It shall come into force on the date of publication in the Official Gazette.

2. Amendment of rule 3

   1. Clause (e) of sub-rule (2) of rule 3 of the Mizoram Clinical Establishments (Registration & Regulation) Rules, 2014 (hereinafter referred to as the Principal Rules) shall be substituted by the following, namely:-
      e. One representative each to be elected by the executive committee of -
         i) Mizoram State Medical Council
         ii) Mizoram State Dental Council- as and when in force
         iii) Mizoram State Nursing Council
         iv) Mizoram State Pharmacy Council
   2. Clause f of sub-rule (2) of rule 3 of the Principal Rules shall be substituted as follows:-
      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. **(as and when in force)**

3. Amendment of rule 4

   In Clause (d) of sub-rule (3) of rule 4 of the Principal Rules, the word "**quarterly**" shall be substituted by the word "**monthly**".

4. Amendment of rule 6

   1. In sub-rule (4) of rule 6 of the Principal Rules, after the words "**demand draft drawn**" and before the words "**online transactions**", **the words "Banker's Cheque**" shall be inserted.
   2. Sub-rule (5) of rule 6 of the Principal Rules shall be substituted as follows:

(5)(i) 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.

(ii) There shall be constituted a fund called State Clinical Establishment Council Fund and all district authorities shall credit **five**percent of the total amount collected by them by way of fees and penalties.

5. Amendment of rule 11 — In sub-rule (1) of rule 11 of the Principal Rules, the word "six" appearing before the word "monthly" shall be omitted.

6. Amendment of rule 13 — In the Principle Rules, after sub-rule (4) in rule 13, the following sub-rule (5) shall be inserted, namely:-

Clinical Establishment continuing to operate without registration after all monetary penalty has been imposed, shall be liable to closure.

7. Amendment of Form-I — Form – I of the Principal Rules may be substituted with the Application Form for Provisional Registration as framed by the National Council for Clinical Establishments – **Enclosed Annexure A**

8. Amendment of Form-II — Form – II of the Principal Rules may be substituted with the Application Form for Permanent Registration as framed by the National Council for Clinical Establishments – **Enclosed Annexure B**

9. Amendment of Form-IV — Form – IV of the Principal Rules may be substituted with the Certificate for Provisional Registration as framed by the National Council for Clinical Establishments – **Enclosed Annexure C**

10. Amendment of Form-V — Form – V of the Principal Rules may be substituted with the Certificate for Permanent Registration as framed by the National Council for Clinical Establishments – **Enclosed Annexure D**

11. Amendment of Form-VI — Form – VI of the Principal Rules may be substituted with the Duplicate Certificate for Permanent Registration as framed by the National Council for Clinical Establishments – **Enclosed Annexure E**

12. Amendment of Annexure - V — Annexure – V of the Principal Rules may be substituted with the Information & Statistics to be collected monthly from Clinical Establishments as framed by the National Council for Clinical Establishments.
Enclosed Annexure – F

H. Lalengmawia,
Secretary to the Govt. of Mizoram,
Health & Family Welfare Department.

ANNEXURE - A

Form –I

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

Application for Provisional Registration of Clinical Establishment

[Under Section 14 of the Clinical Establishments (Registration and Regulation) Act, 2010]

1. Name of the Clinical Establishment : ____
2. Address: _____________________________ Village/Town/City :________________________
   Block : ________________ District : ____________ State : __________ Pin code _________
   Tel No (with STD code): ______________ Mobile : ____________ Email ID ________________
   Website (if any): ____________________________________
3. Name of the owner : _____________________________ Address : _______________________
   Village/Town/City: ___________________ Block : ________________District:____________
   State: ____________ Pin code _____________ Tel No (with STD code): ________________
   Mobile: ____________________ Email ID: ____
4. Name of the Person In charge _______________________ Qualification(s): ________________
   Registration Number : ___________________________ Name of Central/State Council (with which registered): _________________________ Tel No (with STD code): _______________
   Mobile: _____________________ E-mail ID: ____
5. Ownership a) Government/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):
6. System of Medicine: (please tick whichever is applicable) Allopathy, Ayurveda, Unani Siddha Homoeopathy Yoga Naturopathy Sowa-Rigpa
7. Type of Clinical Services: General Single Specialty Multi Specialty Super Specialty Any other (please specify): ____________________
8. Type of Clinical Establishment: (please tick whichever is applicable)
   a) Inpatient Outpatient Laboratory Imaging Any other (please specify):__________________
   b) i) Inpatient: Hospital Nursing Home Maternity Home Sanatorium Palliative Care __________
   ii) Number of Beds (Inpatient):
   iii) Outpatient: Single practitioner Dispensary Polyclinic Dental Clinic Physiotherapy/Occupational Therapy Clinic Infertility Clinic Dialysis Centre Day Care centre Sub-Centre Mobile Clinic Any other (please specify):
   iv) Laboratory: Pathology Haematology Biochemistry Microbiology Genetics Any other (please specify): _________________________
   v) Imaging Centre: X ray Electro Cardio Graph (ECG) Ultrasound CT Scan Magnetic Resonance Imaging (MRI) Any other (please specify): ________________________
   vi) Any other (please specify): ____________________

I hereby declare that the statements made above are correct and true to the best of my knowledge. I shall abide by all the provisions of the Clinical Establishments (Registration and Regulation) Act, 2010 and the rules made there under. I shall intimate to the District Registering Authority, any change in the particulars given above.

Place: Signature of the Owner/Person in charge

Date: (Name:)

ANNEXURE - B

Form –II

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

Application Form for Permanent Registration of Clinical Establishment

I. ESTABLISHMENT DETAILS

1. **Name of the establishment**: ______________________________
2. **Address** : ____________ Village/Town: ________Block: ________
   District: __________ State: _________ Pin code ________ Tel No (with STD code): _________ Mobile: _________ Fax : __________
   Email ID : ____________ Website (if any): _________________
3. **Month and Year of starting**:____________________________
   (From 4 to 11 mark all whichever are applicable)
4. **Location:**
   Rural Urban Metro Notified/inaccessible areas (including Hilly/tribal areas)
5. **Ownership of Services**
   Government/Public Sector
   Central government State government Local government (Municipality, Zilla parishad, etc) Public Sector Undertaking Other ministries and departments (Railways, Police, etc.) Employee State Insurance Corporation Autonomous organization under Government

   Non-Government/Private Sector
   Individual Proprietorship Partnership Registered companies (registered under central/provincial/ state Act) Society/trust (Registered under central/provincial/state Act)
6. **Name of the owner of Clinical Establishment**: _______________
   Address: _________ Village/Town: ___________ Block: ________
   District: ________ State: _______ Pin code _______ Tel No (with STD code): _______ Mobile: ________ Fax : _______ Email ID: __________
7. **Name, Designation and Qualification of person-in-charge of the clinical establishment**: Qualification(s): ____________ Registration Number : ____________
   Name of Central/State Council (with which registered): _______________
   Tel No (with STD code): ________ Fax: ________ Mobile: ___________
   E-mail ID: _________________________
8. **Systems of Medicine offered: (please tick whichever is applicable)**
   Allopathy Ayurveda Unani Siddha Homoeopathy Yoga Naturopathy Sowa - Rigpa

9. **Type of establishment : (please tick whichever is applicable)**
   (I) **Clinic (Outpatient)**
   - Single practitioner
     (Consultation services only/with diagnostic services/with short stay facility)
   - Poly clinic
     (Consultation services only/with diagnostic services/with short stay facility)
   - Dispensary
   - Health Checkup Centre

   (II) Day Care facility
   Medical Surgical Medical Spa Wellness centers (where qualified medical professionals are available to supervise the services).

   (III) Hospitals including Nursing Home (outpatient and inpatient):
   - Hospital Level 1 a
   - Hospital Level 1 b

- Hospital Level 2
- Hospital Level 3 (Non teaching)
- Hospital Level 4 (Teaching)

(IV) Dental Clinics and Dental Hospital :

a. Dental clinics
   i. Single practitioner
   ii. Poly Clinics (dental)

b. Dental Hospitals (specialties as listed in the IDC Act.)
   i. Oral and maxillofacial surgery
   ii. Oral medicine and radiology
   iii. Orthodontics
   iv. Conservative dentistry and Endodontics
   v. Periodontics
   vi. Pedodontics and preventive dentistry
   vii. Oral pathology and Microbiology
   viii. Prosthodontics and crown bridge
   ix. Public health dentistry

(V) Diagnostic Centre

A. Medical Diagnostic Laboratories:
   Pathology Biochemistry Microbiology Molecular Biology and Genetic Labs Virology

B. Diagnostic Imaging centers
   i. Radiology
   - General radiology
   - Interventional radiology

   ii. Electromagnetic imaging
   - Magnetic Resonance Imaging (MRI),
   - Positron Emission Tomography (PET) Scan

   iii. **Ultrasound**

C. Miscellaneous

ElectroCardioGraphy (ECG)	Echocardiography
Tread Mill Test	Electro MyoGraphy (EMG)
Electro Encephalo Graphy (EEG)	Electrophysiological studies
Mammography	

D. **Collection centers**
   For the clinical labs and diagnostic centres that shall function under registered clinical establishment
   Yes/No
   If Yes, then number of Collection Centre(s): ☐

(VI) Allied Health professions:

- Audiology
- Behavioural health (counseling, marriage and family therapy etc)
- Exercise physiology
- Nuclear medicine technology
- Medical Laboratory Scientist
- Dietetics
- Occupational therapy
- Optometry
- Orthoptics
- Orthotics and prosthetics
- Osteopathy

- Paramedic
- Podiatry
- Health Psychology/ Clinical Psychology
- Physiotherapy
- Radiation therapy
- Radiography / Medical imaging
- Respiratory Therapy
- Sonography
- Speech pathology

(VII) AYUSH

Ayurveda

Ausadh Chikitsa Shalya Chikitsa Shodhan Chikitsa Rasayana Pathya Vyavastha

Yoga

Ashtang Yoga

Unani

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

Siddha

Maruthuvam Sirappu Maruthuvam Varmam Thokknam & Yoga

Homoeopathy

General Homoeopathy

Naturopathy

External Therapies with natural modalities Internal Therapies

II. TYPES OF SERVICE

- TYPE
  - General Practice Services
  - Single Specialty Services
  - Multi Specialty Services (including Palliative care Centre, Trauma Centre, Maternity Home - applicable for hospitals only)
  - Super Specialty Services
- SPECIALITY SPECIFIC

  Medical Specialties – for which candidates must possess recognized PG degree (MD/Diploma/ DNB or its equivalent degree)

  i. Anesthesiology
  ii. Aviation Medicine
  iii. Community Medicine
  iv. Dermatology, Venereology and Leprosy
  v. Family Medicine
  vi. General Medicine
  vii. Geriatrics
  viii. ImmunoHaematology and Blood Transfusion
  ix. Nuclear Medicine
  x. Paediatrics
  xi. Physical Medicine Rehabilitation
  xii. Psychiatry
  xiii. Radio-diagnosis
  xiv. Radio-therapy
  xv. Rheumatology
  xvi. Sports Medicine
  xvii. Tropical Medicine
  xviii. Tuberculosis & Respiratory Medicine or Pulmonary Medicine

Surgical specialties - for which candidates must possess, recognized PG degree (MS/ Diploma/DNB or its equivalent degree)

i. Otorhinolaryngology
ii. General Surgery
iii. Ophthalmology
iv. Orthopedics
v. Obstetrics & Gynecology

Medical Super specialties –

i. Cardiology
ii. Clinical Hematology including Stem Cell Therapy
iii. Clinical Pharmacology
iv. Endocrinology
v. Immunology
vi. Medical Gastroenterology
vii. Medical Genetics
viii. Medical Oncology
ix. Neonatology
x. Nephrology
xi. Neurology
xii. Neuro-radiology

Surgical Super-specialities-

i. Cardiovascular thoracic Surgery
ii. Urology
iii. Neuro-Surgery
iv. Paediatric Surgery
v. Plastic & Reconstructive Surgery
vi. Surgical Gastroenterology
vii. Surgical Oncology
viii. Endocrine Surgery
ix. Gynecological Oncology
x. Vascular Surgery

III INFRASTRUCTURE DETAILS

10. Area of the establishment (in sqft):
a) Total Area: ____________________ b) Constructed area: ____________________

11. **Out Patient Department:**

11.1 Total no. of OPD Clinics: ________________________

11.2 Specialty-wise distribution of OPD Clinic

S.No.	Specialty

12. **In Patient Department:**

12.1. Total number of beds: ____________________

12.2. Specialty-wise distribution of beds, please specify:

S.No.	Specialty	Beds

13. **Biomedical waste Management**

13.1 **Method of treatment and /or disposal of Bio-medical waste**

Through Common Facility Onsite Facility

Any other (please specify): _______

13.2. **Whether authorization from Pollution Control Board/Pollution Control Committee obtained?**

Yes No Applied For __________ Not Applicable

IV HUMAN RESOURCES

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

No. of permanent staff: ____________ No. of temporary staff: _____________

Please furnish the following details:-

Category of staff	Name	Qualification	Registration No	Nature of service Temporary/ Permanent
Doctors				
Nursing staff				
Para-medical staff				
Pharmacists				
Administrative staff				
Others, please specify				

Separate annexure may be attached.

Support Staff

Category	Total no.	Remark

15. **Payment options for Registration Fees:**

Online payment Demand Draft Bank Challan

Amount (in Rs): ______________________________

Details:______________________________________

Receipt No. __________________________________

I,...on behalf of myself and the company/ society/ association/body hereby declare that the statements above are correct and true to the best of my knowledge and I shall abide by all the provisions made under the Clinical Establishments (Registration and Regulation) Act 2010.

I undertake that I shall inform the District Registering Authority of any changes in the particulars given above.

I shall comply with the minimum standards prescribed under Clinical Establishments Act for the services provided by us and also all other conditions of registration as stipulated under the aforesaid Act and Rules there-under.

Place: Signature of the Authorized Signatory

Date: Office Seal

ANNEXURE - C

Form –IV
(See Rule – 5(3), Section 15.17.54 (c) of the Act)

Provisional Registration No.(Computer Generated)

[Symbol of State Govt.]
GOVERNMENT OF *(Name of the State)*
District Registering Authority
(Name of the District)

CERTIFICATE OF PROVISIONAL REGISTRATION

This is to certify that ....*(Name of the Clinical establishment)*.................... located at............*(Full address)*.................... owned by..... *(Name of the owner)*.....has been granted provisional registration as a clinical establishment under Section 15 of The Clinical Establishments (Registration and Regulation) Act, 2010. The Clinical Establishment is registered for providing medical services as a .....*(Type of clinical establishment viz. Hospital, Diagnostic Centre etc.)*.......... under ...(*Allopathic / Homoeopathic / Ayurvedic etc.)*............system of medicine.

This Certificate is valid for a period of one year from the date of issue.

Place *(Computer Generated)*
Date of Issue *(Computer Generated)*

Designation of the Issuing Authority
(Computer Generated)

ANNEXURE - D

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

S. No. (Computer Generated)

Permanent Registration No. (Computer Generated)

[Symbol of State Govt.]
Government of *(Name of the State)*

District Registering Authority
(Name of the District)

CERTIFICATE OF PERMANENT REGISTRATION

This is to certify that .... *(Name of the Clinical establishment)*.................... located at............ *(Full address)*.................... owned by......*(Name of the owner)*.....has been granted permanent registration as a clinical establishment under Section 30 of The Clinical Establishments (Registration and Regulation) Act, 2010. The Clinical Establishment is registered for providing medical services as a .....*(Category of clinical establishment viz. Hospital, Diagnostic Centre etc.)*.......... under ... (Allopathic / *Homoeopathic / Ayurvedic etc.)*............system of medicine.

This Certificate is valid for a period of five years from the date of issue.

Place *(Computer Generated)*
Date of Issue *(Computer Generated)*

Designation of the Issuing Authority
(Computer Generated)

ANNEXURE - E

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

S. No. (Computer Generated) *Permanent Registration No. (Computer Generated)*

[Symbol of State Govt.]
Government of *(Name of the State)*

DUPLICATE

District Registering Authority
(Name of the District)

CERTIFICATE OF PERMANENT REGISTRATION

This is to certify that .... ***(Name of the Clinical establishment)***........... located at.......... ***(Full address)***............... owned by......*(Name of the owner)*.....has been granted permanent registration as a clinical establishment under Section 30 of The Clinical Establishments (Registration and Regulation) Act, 2010. The Clinical Establishment is registered for providing medical services as a .....***(Category of clinical establishment viz. Hospital, Diagnostic Centre etc.)***....... under....... (Allopathic*/Homoeopathic/Ayurvedic etc.)*......system of medicine.

This Certificate is valid for a period of five years from the date of issue.

Place *(Computer Generated)*
Date of Issue *(Computer Generated)*

Designation of the Issuing Authority
(Computer Generated)

ANNEXURE - F

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

Information and Statistics to be collected Monthly from

Clinical Establishments under the Clinical Establishments Act

A. General Information:

1. Name of the Clinical Establishment ____________________________
2. Registration Number of the Clinical Establishment ____________________
3. Address __________ Village/Town/City _____ Block _____ District _____
   State ______ Pincode _____ Tel No (with STD code): ____________
   Mobile : ______ Email ID__________ Website (if any): __________
4. Name of Contact Person ______________
   Contact Details (Cell/Landline/email) __________
5. Clinical establishment Type:
   [ ] General practice [ ] Specialty practice [ ] Super- Specialty practice
   [ ] Psychiatric practice [ ] Obstetrics-Gynaecology Practice [ ] Pediatric practice

B. Category-wise Monthly Reporting forms for following categories (separate form for each category to be filled up)

General Hospitals
Stand Alone Super Specialty Hospital
Multiple Super Specialty Hospital
Stand Alone Specialty Hospital
Multiple Specialty Hospital
One Man Clinic
Polyclinic

Out Patient and In Patient information (as applicable)

i. General Information:

S.No.	Description	Male	Female
1.	Total OPD patients		
2.	Total IPD Patients		
3.	Total Deaths		
4.	Number of Maternal Deaths		
5.	Live Births		
6.	Still Births		
7.	No of Neonatal Deaths (within 24 hours of Birth)		
	No of Deaths of children (0 to 28 days)		
	No of Deaths of children (0 to 1 year)		
	No of Deaths of children under 5 years of age		

ii. Communicable Diseases:

S.No.	Disease	Old patient	New patient
1	Malaria		
2	Pulmonary Tuberculosis		
3	Dengue Hemorrhage fever		
4	Chikungunya		
5	Meningitis		
6	Typhoid		
7	Diphtheria		
8	Whooping cough		
9	Tetanus		
10	Measles		
11	Poliomyelitis		
12	Japanese Encephalitis		
13	Cholera		
14	Syphilis		
15	Gonorrhoea		
16	Leprosy (Multi bacillary)		
17	Leprosy (Pauci bacillary)		
18	Gastroenteritis		
19	Leptospirosis		

20	Hepatitis
21	Conjunctivitis
22	Trachoma
23	Rabies
24	Dog Bite (including Domestic /wild animal)
25	Snake Bite

iii. Non Communicable Diseases:

S.No.	Disease	Old patient	New patient
1	Diabetes* (moderate and above)		
2	Hypertension**		
3	Ischemic Heart Disease		
4	Mental Illness		
5	Osteoarthritis		
6	Stroke		

**Criteria for diagnosing Diabetes*

Diagnosis	Fasting Glucose(mg/dl)	2-hour Post –GlucoseLoad(mg/dl)
Diabetes Mellitus	>=126	>=200
Impaired GlucoseTolerance	<110	>140 to<200
Impaired FastingGlucose	>=110 to <126	

*WHO Definition 1999

**Hypertension
A Blood pressure record of >140/90 mm Hg

iv. Specialty/Department wise Reports : General Information

Name of Specialty	No of OPD Patients	No. of Bed (indicate ICU Beds also)	No. of Admissions (indicate no. admitted in ICUs separately)	Bed Occupancy Rate	No of Deaths	No of Basic Procedure done	No of Advance Procedure done	No. of Malignancy cases (if applicable)
Ophthalmology								
Mental Health								
Orthopaedic								
Gynaecology and Obstetrics								
Pediatrics								
CTVS								
Cardiology								
Neurology								
Gastroenterology								
Endocrinology								
Cancer Hospital								
Urology								
Nephrology								
Trauma Hospital								

v. Specialty/Department wise Reports : Specific Information

Name of Specialty	Name of Disease/Procedure	No of Cases
Ophthalmology	Cataract operations done	
	Glaucoma cases	
	Corneal Transplants done	
Mental Health	No. of Psychosis cases under treatment	
Gynaecology and Obstetrics	No. of deliveries conducted (including Caesarian deliveries)	
	No. of Still Births	
	No. of Maternal Deaths	
Neurology	No. of Strokes	
	Epilepsy	
CTVS		
Cardiology		
Gastroenterology	No. of Cirrhosis cases	
Trauma Hospital	No. of Major Head Injuries	
	Coma cases	
	No. of Brain Stem Death Certified	
Cancer Hospital	Type of Cancers	
Nephrology	Chronic Kidney Diseases (indicateGrade)	
	CRF	
	No. of Patients on Dialysis	

C. Information to be collected Monthly from Diagnostic Medical Laboratory under Clinical Establishments Act Category of Laboratory:

- General
- General with single specialty
- General with multi specialty

1) No of tests performed in the following departments:

S.No.	Department	Tests Number
1	Hematology	
2	Biochemistry	
3	Immunology	
4	Serology	
5	Pathology	
6	Cytology & Histopathology	
7	Molecular Biology	
8	Virology	
9	Genetics	

2) **Number of tests done and reported positive for the following communicable diseases:**

S.No.	Disease & Name of Test	Total No. of Tests performed	Number of positive
1.	HIV		
2.	Tuberculosis		
3.	Malaria falciparum		
4.	Dengue		
5.	Chikungunya		
6.	Japanese Encephalitis		
7.	Others		
(i)	HAV		
(ii)	HBV		
(iii)	HCV		
(iv)	HDV		
(v)	Malaria vivax		
(vi)	Leptospirosis		
(vii)	H1N1/Influenza		
(viii)	Meningococcal Meningitis		
(ix)	Shigella		
(x)	Typhoid		
(xi)	Paratyphoid A		
(xii)	Paratyphoid B		
(xiii)	Plague		
(xiv)	Cholera		
(xv)	Syphilis		
(xvi)	Gonorrhea		

D. Information to be collected Monthly from Diagnostic Imaging Centres under Clinical Establishments Act:

No. of tests performed in the following departments:

S.No	Department	Tests Number
1.	X ray	
2.	USG	
3.	CT Scan	
4.	MRI	
5.	Mammography	
6.	Bone Densitometry	
7.	Doppler	
8.	ECG	
9.	ECHO cardiography	
10.	Holter monitoring	

Published and Issued by Controller, Printing & Stationery Department, Government of Mizoram
Printed at the Mizoram Government Press, Aizawl. C/50