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NOTIFICATION

No. H. 12018/183/07 LJ D/4, the 23rd April, 2007. The following Act of the Mizoram Legislative Assembly, which received the assent of the Governor of Mizoram is hereby published for general information.

The Mizoram Clinical & Health Establishment (Regulation) Act, 2007
(Act No. 8 of 2007).

[Received the assent of the Governor of Mizoram on 16th April/2007]

AN ACT

To regulate the clinical establishment to provide better provision with respect to medical-health care of the people through these establishments and for matters connected therewith or incidental thereto.

Preamble. Whereas it is expedient to regulate the clinical establishments to provide better provision with respect to medical-health care of the people through these establishments and for matters connected therewith or incidental thereto.

It is enacted in the Fifty Eighth Year of the Republic of India as follows:—

**Short title,
extent and
commence-
ment.**

1. 1) This Act may be called The Mizoram Clinical & Health Establishment (Regulation) Act, 2007.
- 2) It shall extend to the whole of the State of Mizoram.

3) It shall come into force on such date as the State Government may, by Notification in the official Gazette, appoint.

Definitions. 2. In this Act, unless the context otherwise requires-

a) "Clinical Laboratory" means an establishment where tests are carried out for biological, pathological, micro-biological, biochemical, radiological or any other method analogous to any tests carried out for diagnosis of disease and health condition.

b) "Nursing Home" or "Hospital" or "Research Institute" means any premises or establishment used or intended to be used for the reception and admission of persons suffering from illness, injuries or infirmity of body and providing of treatment and nursing for them and includes a Maternity Home or Psychiatric care.

c) "Clinical Establishment" means and includes:-

i) a hospital, nursing home, polyclinic, sanatorium, maternity home, immunization or vaccination clinic, dispensary, dental clinic, special camps where physically or mentally sick, infirm, injured or disabled person is admitted as a patient for treatment, observation or care or seer as out patient.

ii) A place catering to pathological, bacteriological, genetic, radiological, biological investigations or other diagnostic services with the aid and assistance of devices and equipments established as an independent entity or part of an establishment as defined in (i) above.

d) "Health authority" means State Health Authority constituted under Section 4.

e) "Licensing Authority" means State Health Authority or other authority authorised by State Government for issue of License.

f) "Maternity Home" means an establishment" or premises where women are usually received or accomandated or brought for providing ante-natal ar post-natal medical or health care service in connection with pregnancy and childbirth.

g) "Physical Therapy establishment" means an establishment where physical therapy, electro-therapy, hydro-therapy, remedial gymnastics or similar work is usually carried on for the purpose of treatment of disease or infirmity for improvement of health or for the purpose of relaxation or for any other purpose whatsoever, whether or not analogous to the purpose herein before mentioned in this clause;

Central Act
102 of 1956

h) "Qualified Medical Practitioner" means a person who possesses medical qualification as prescribed in the Indian Medical Council Act, 1956, Indian Medicine and Central Council Act, 1970 and the Homeopathic Central Council Act 1973 and who has been registered as a medical Practitioner in the register as provided in the aforementioned Acts.

Central Act
48 of 1970

Central Act
59 of 1973

i) "Qualified Dentist" means a person possessing qualification recognised by the Dental Council Act.

j) "Qualified Nurse" means a nurse possessing any of the qualifications included in the scheduled to Nursing Council Act and registered as such under any law for the time being in force.

k) "Rules" means rules made under this Act.

l) "Prescribed" means prescribed by rules made under this Act.

m) "Government" means the Government of Mizoram.

Clinical Est-
ablishment
not to be es-
tablished
or maintai-
ned without
registration
and licence.

3. No person shall establish or maintain a clinical establishment without registration and a licence granted thereof under this Act.

Provided that clinical establishment already in existence prior to commencement of this Act shall have to be registered and a licence shall be obtained thereafter under this Act within a period of 3 months from the date of promulgation of this Act.

Constitution
of State
Health Au-
thority and
its terms.

4. (i) The Government may, by notification, constitute an authority to be called the STATE HEALTH AUTHORITY. The Health Authority shall be a body corporate having perpetual succession and common seal and may sue and be sued.

(ii) The Health Authority shall consist of eight members including the Chairman and shall be constituted in the following manner:

1. Commissioner/Secretary, Health and Family Welfare-Chairman.

2. Director of Hospital & Medical Education (DHME)-Member Secretary

3. Director of Health Services (DHS)-Member.

4. Medical Superintendent, Aizawl Civil Hospital-Member

5. Representative of Nursing Services not below the rank of Deputy Director-Member

6. Two eminent medical professionals to be nominated by the Government-Members.

7. Representative of Indian Medical Association (IMA)-Member.

(iii) The Health Authority shall be constituted within six months from the date of this Act comes into force and the names of the members shall be published in the official Gazette.

(iv) The Health Authority will be a permanent body.

(v) The term of non-official members will be two years from the date of appointment.

Maintenance of Register of Clinical Establishment.

5. (i) The Health Authority shall, as soon as may be after its constitution and not later than six months from the coming into force of this Act, make orders for maintenance of a Register for the clinical establishment.

(ii) The Register referred to in sub-section (1) shall contain the names of all the clinical establishments and shall be published in the official Gazette.

(iii) The Register shall be maintained in such form as may be prescribed.

Appointment of Registrar and staff.

6. The Government shall appoint or designate a person as Registrar who shall be the Secretary to the Health Authority and also appoint the staff if consider necessary for carrying out the purposes of this Act.

Qualification, function, salary, duties and allowances of the Registrar and staff.

7. The qualification, function, duties, salary and allowances and such other matters relating to the Registrar and the staff shall be such as may be prescribed from time to time.

Establishment and maintenance of clinical establishment.

8. The Health Authority may, in any part of Mizoram within its jurisdiction, allow to establish or maintain clinical establishment for reception, admission, treatment and care of physically ill persons, pregnant woman and carry out laboratory procedure for diagnosis of health and disease at such places as it thinks fit.

Application for registration and licence.

9. (1) Every application for registration in any clinical establishment and for the grant thereof shall be made to Health Authority. The application shall contain such particulars and shall be accompanied by such fees as may be prescribed.

(2) The Health Authority, if satisfied that the applicant and the clinical establishment fulfill conditions specified under Section 10, shall register the applicant in respect of such establishment and shall grant a licence thereof within 45 days from the date of application for registration and licence. The registration and the license shall be valid for a period of three years.

(3) The Health Authority shall reject an application within 45 days from the date of receipt of the application if it is satisfied that-

(a) The applicant or the clinical establishment does not fulfill the conditions specified under section 10.

(b) There are no adequate provisions for maintaining proper biomedical waste management under existing rules.

(c) In the case of nursing home other than a maternity home that such nursing home is not under the charge of a qualified medical practitioner resident therein round the clock and that the nursing of persons received, admitted and accommodated therein is not under the superintendence of a qualified nurse resident therein round the clock; or

(d) In the case of a maternity home that such maternity home is not under the charge of a qualified medical practitioner resident therein round the clock and that the attendance on every woman before at, or after childbirth or on any child born is not under the superintendence of a qualified Midwife resident therein round the clock.

(4) Where the application is rejected under sub section (3), the Health Authority shall be record the reason for such rejection and no application shall be rejected unless the applicant has been given an opportunity of showing cause in support of his application.

Terms and conditions for granting licences. 10. Every license granted under sub-section (2) of section 9 shall be subject to the terms and conditions, namely:

(a) That the clinical establishment shall not be used for immoral purposes.

(b) That adequate measure shall be taken to keep the clinical establishment in perfectly hygienic and sanitary condition.

(c) That adequate measure shall be taken to dispose of the garbages including disposable syringes, needles, etc. conforming to existing Rules and Regulations made by the Government.

(d) That every person keeping or carrying on a clinical establishment shall submit an immediate report to the Health Authority as soon as it comes to his notice that any person who has been admitted as an outdoor or indoor patient in the clinical establishment is suffering from or has been attacked with notifiable diseases as specified by the Government from time to time.

(e) That every clinical establishment records shall be kept in such form and report submitted to the Health Authority in such form, in such manner and at such intervals, as may be prescribed, containing-

(i) The name and other particulars of each person who is received, admitted or accommodated at the clinical establishment as an outdoor or indoor patient.

(ii) The name of any of the prescribed diseases for which such person is treated.

(iii) The name and other particulars of the qualified medical practitioner who attends him.

(iv) The amount paid by each person admitted and treated towards the costs of:-

(a) boarding and lodging, if any, and

(b) treatment;

(c) birth, death and miscarriage, if any, that takes place in the clinical establishment during the period to which the report relates, and

(f) any other terms and conditions which may be prescribed.

Renewal. 11. A license may be renewed from time to time on an application made to the Health Authority in such form and accompanied by such fees as may be prescribed and every such application be made-

(a) in case of nursing home, maternity home or Hospital not less than, ninety days in advance;

(b) in case of clinical laboratory, physiotherapy establishment, thirty days in advance;

(c) in case of any other clinical establishment, not less than sixty days in advance;

Provided that the renewal of a license may be refused if the Health Authority is satisfied that-

(i) the licensee is not in a position to provide the minimum facilities prescribed for the admission, treatment or care and diagnostic services therein of patients, pregnant women; or

(ii) the licensee is not in a position to provide a qualified medical practitioner who is qualified to take charge of the nursing home or Hospital, maternity home, clinical laboratory and physiotherapy establishment; or

(iii) the licensee has contravened any of the provisions of this Act or any rules made thereunder.

"Cancellation or suspension of registration and license.

12. (1) The Health Authority may, suo moto or on complaint for any breach of the provisions of the Act, the rules or the regulations by any clinical establishment, issue notice to it to show cause within fifteen days as to why its registration and license should not be suspended or cancelled for the reasons mentioned in the notice.

(2) On receipt of the show cause and after giving a reasonable opportunity of being heard to the clinical establishment, if the Health Authority is satisfied that there has been a breach of the provisions of the Act, or the rules or the regulations it may, without prejudice to the criminal action that it may take against such clinical establishment, suspend its registration and license for such period as it may think fit, or cancel its registration or license, as the case may be.

Appeal

13. (1) Any person aggrieved by an order of the Health Authority refusing to grant or renew a license or suspending or cancelling a license, may in such manner and within such period as may be prescribed prefer an appeal to the Government:

Provided that the Government may entertain an appeal after the expiry of the prescribed period if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

(2) Every appeal under sub-section (1) shall be made in such form and be accompanied by such fee as may be prescribed.

(3) Any order passed on appeal shall be final and shall not be questioned in any court.

Order for closure of the clinical establishment

14. If the appeal preferred under section 13 is rejected by the Government in respect of any clinical establishment, the Health Authority shall thereafter issue order for closure of the clinical establishment with the approval of the Government and the clinical establishment shall remain closed for such period till the suspension order is withdrawn or a fresh registration and license is granted in respect of that establishment.

Appoint-
ment of
inspecting
officer and
his power
of entry.

15. The Government shall appoint District Medical Superintendent Chief Medical Officer (District concerned) as Inspecting Officer for the purpose of inspecting the clinical establishment.

Penalty for
establishment
or Maintenance
of Clinical Es-
tablishment in
contravention
of the provision
of this Act and
the rules made
there under.

16. (1) Any person who knowingly establishes or maintains a clinical establishment which is not duly registered and licensed under this Act or contravenes the provisions of this Act or rules made thereunder shall, on conviction, be punishable with imprisonment for a term which may extend to one year or with fine with both and in the case of a second or subsequent offences with imprisonment for three years or fine which may extend to fifty thousand rupees or with both.

(2) Whoever after conviction under sub-section (1) continues to maintain a clinical establishment shall on conviction be punishable with fine which may extend to one thousand rupees for which the offence continues after conviction.

General
Provision
for punish-
ment of
other offen-
ces.

17. Any person, who contravenes any of the provision of this Act or of any rule or regulation, made thereunder for the contra-vention of which no penalty is expressly provided in this Act, shall on conviction, be punishable extend to six months and with fine which may extend to ten thousand rupees.

Penalty for
serving in
an unlicen-
ced and un-
registered
clinical
establishment.

18. Any person who knowingly serves in a clinical establishment which is not duly registered and licensed under this act or which is used for immoral purposes shall be guilty of an offence and shall be punishable with fine which may extend to five hundred rupees or with cancellation of his/her registration.

Offence by
Companies.

19. (1) Where an offence under this Act has been committed by a company, every person who, at the time the offence was committed was incharge of, and was responsible to the company, for the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

Provided that nothing contained in this sub-section shall render any such person liable to any punishment if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (I), where an offence under this Act has been committed with consent or connivance of or is attributable to any neglect on the part of any Director, Manager, Secretary or other Officer of the Company, such Director, Manager Secretary or other Officer shall also be deemed to be guilty of the offence and shall be liable to be proceeded against accordingly.

EXPLANATION-

(a) For the purpose of this section, company means body corporate and includes a firm or other association of individual; and

(b) 'Director' in relation to a firm means partner in the firm.

Court com- 20. No Court other than that of a Magistrate of the First Class
petent to shall take cognizance of or try offence under this
try offence
under this
Act and take
cognizance
of offences.

Offence 21. All offence punishable under this Act except Offences under
under this section 17 and 18 shall be cognizable.
Act except
sections 17
and 18 to
be cognizable.

Saving 22. Nothing contained in this Act, rules and regulations framed thereunder shall apply to clinical establishment, established mainly by the State Government, Central Government, Defense, Railways and Public Sector Undertaking.

Indemnity. 23. (1) No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done in pursuance of this Act or any rules, regulations or order made thereunder.

(2) No suit or other legal proceeding shall lie against the Government for any damage caused or likely to be caused for anything which is in good faith done or intended to be done in pursuance of this Act or any rules, regulations or order made thereunder.

Credit of 24. Any fees received or fines paid under this Act and rules
fees and framed thereunder shall be credited to the consolidated Fund of
finer. the State.

- Expenses of the Health Authority.** 25. All expenses incurred by the Health Authority under this Act and rules made thereunder shall be met out of the Consolidated Fund of the State.
- Submission of report to the Health Authority.** 26. (1) Any person in charge of the clinical establishment shall as soon as may be after any disease which is included under the notifiable disease of the Government, cases of burns, poisoning or any other cases suspected to be of medicolegal nature make a report of the cases to the Health Authority.
- (2) Any person in charge of the clinical establishment shall report all death and birth, still birth as per the rules laid down.
- Power to make rules.** 27. (1) The Government may make rules for carrying out purposes of this Act.
- (2) In particular and without prejudice to generality of the foregoing power, such rules may provide for all or any of the following matters, namely:—
- (a) the nature or type of patients or person to whom the clinical establishment shall render services;
- (b) the form in which—
- (i) an application may be made for grant or renewal of a license and a fee payable in respect thereof under section 9 and 11;
- (ii) a license may be granted for the health establishment under section 9.
- (c) the manner in which an order refusing to grant or cancelling a license shall be communicated under section 9 or, as the case may be under section 12;
- (d) the manner in which a report may be made to the Health Authority under clause (e) of section 10;
- (e) the minimum facilities/standard required for treatment of patients in the clinical establishment including:
- (i) Doctor-patient relation;
- (ii) other medical and paramedical staff eligible for rendering services in the clinical establishment;
- (iii) space requirement;
- (iv) treatment facilities; and
- (v) equipments

(f) the manner in which and the condition under which nursing home and Hospital, clinical laboratory, physiotherapy centre shall be maintained;

(g) the form and manner in which and the period within which an aggrieved person can appeal against the refusal to grant licence or renewal of licence or the fee payable in respect of thereof under section 13;

(h) the form and manner in which records shall be maintained under clause (f) of section 10;

(i) the qualification of person who may be appointed as Inspecting Officer and his function salary, etc.

(j) the standards of quality of air, water and pollution control devices;

(k) the procedure and safeguards of handling hazardous substances;

(l) the procedure to conduct tests whether Pathological, Chemical, biological, radiological, bacteriological genetic investigations and others;

(m) any other manner which is required to be or may be prescribed.

**Power to
remove doubts
and difficulties**

28. If any doubt or difficulty arises in giving effect to the provisions of this Act, the Government may as occasions may require, by order to anything not inconsistent with the provision of this Act or the rules made thereunder, which appears necessary for the purpose of removing doubt or difficulty.

Provided that no order shall be issued under this section after the expiry of a period of two years from the date of commencement of this Act.

P.Chakraborty,
Secretary to the Govt. of Mizoram,
Law, Judl. & Par. Affairs,
Aizawl.