

SIKKIM



GOVERNMENT **GAZETTE**

EXTRAORDINARY
PUBLISHED BY AUTHORITY

Gangtok

Wednesday 1st August, 2012

No. 383

GOVERNMENT OF SIKKIM
HEALTH CARE HUMAN SERVICES AND FAMILY
WELFARE DEPARTMENT

No.266/HC,HS&FW

Date:-31/07/2012

NOTIFICATION

In exercise of the powers conferred by section 54 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010), the State Government hereby makes the following rules, namely:-

1. Short title, extent, commencement and Application--

- (1) These Rules, may be called the Sikkim Clinical Establishment, (Registration and Regulation) Rules, 2012
- (2) They shall extend to the whole of Sikkim.
- (3) They shall come into force on the date of their publication in the Official Gazette.
- (4) These rules shall be applicable to the various categories of clinical establishments in a phased manner, as may be notified from time to time.

2. Definitions. – (1) In these Rules, unless the context otherwise require:-

- (a) "Act" means Clinical Establishment (Registration and Regulation) Act, 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 and includes:-
 - (i) a hospital, maternity home nursing home, dispensary, polyclinic, sanatorium, maternity home, immunization or vaccination clinic, single practitioner clinic, 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 seen as outpatient or an institute by whatever

name called that offer services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person, whether incorporated or not, or

- (ii) a place established as an independent entity or part of an establishment referred to in sub clause (i) above, in connection with the diagnosis or treatment of disease 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, provincial or state Act, whether or not owned by the Government;
 - (d) a local authority; and
 - (e) a single doctor,

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

Explanation.-For the purpose of this clause "Armed Forces" means the forces constituted under the Army Act, 1950, the Air Forces Act, 1950 and Navy Act, 1957.

- (e) "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.
- (f) "Government" means the State Government of Sikkim;
- (g) "Maternity Home" means an establishment or premises where Women are usually received or accommodated or brought for providing ante-natal or post-natal medical or health care service in connection with pregnancy and childbirth;
- (h) "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;

Maternity Home or Psychiatric care.

- i) "Nurse" means a nurse possessing any of the qualifications included in the Schedule to Nursing Council Act 1947 and registered as such under any law for the time being in force.
- (j) "prescribed" means prescribed by rules made under the Act by the Central Government or as the case may be the State Government.
- (k) "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.

- (2) Words and expression used in these rules and not defined in the rules but defined in the Act, shall have the same meaning respectively assigned to them in the Act.
3. **Constitution of State Council:-**The State Government shall by notification constitute the State Council as required under section 8 of the Act.
4. **Function of the State Council.-**(1) The State Council shall perform following functions, namely.-
- compiling and updating the State Registers of the Clinical Establishment;
 - sending monthly returns in digital format for updating the National Register;
 - representing the State in the National Council;
 - hearing of appeals against the orders of the authority;
 - publishing report on the state of implementation of standards on annual basis;
 - monitoring the implementation of the provisions of the Act and rules in the state;
 - to recommend to the Government, any modification required in the rules in accordance with changes in technology or social conditions;
 - to perform any other function as may be outlined by the National Council of Clinical Establishment;
 - any other function as may be prescribed by the Central Government.
5. **Sub-Committees.**
- (1) The State Council may at any time constitute a sub-committee consisting of any number of its member, for such period not exceeding 2(two) years, for the consideration of particular matters, at the request of the National Council and/or as determined by the Central Government.
 - (2) A motion for the appointment of the sub-committee shall define the function of the sub-committee, number of the member to be appointed thereon and timeline for completion of task. The Chairman of every such committee shall be appointed by the State Council at the time of the appointment of the committee.
 - (3) Any decision taken by the Sub-Committee shall be placed before the State Council at its next meeting for its consideration and approval.
6. **Meetings.**
- (1) Every meeting of the State Council shall be presided over by the Chairman.
 - (2) The meeting of the State Council shall ordinarily be held at State capital on such date as may be fixed by the Council. The State Council shall meet at least once in 3(three) months.
 - (3) 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.
 - (4) 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.
 - (5) 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.
 - (6) 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 Chairman.

- (3) Space Accommodation for patients etc.
 - a) the floor space for clinical establishment shall be 120 square feet for one bed to additional 80 square feet for every additional bed in the room;
 - b) labor rooms or operation theater shall be provided with minimum floor space of 180 square feet;
 - c) adequate space for storage of medicine, food article, equipment's etc, shall be provided;
 - d) there shall be facilities for blood transfusion services.

13. Water Supply.-

- (1) The water used in the clinical establishment shall be pure and drinkable quality.

14. Health, Clothing and sanitary requirements of Staff.-

- (1) The staff shall be free from contagious diseases and shall be provided with clean uniform suitable to the nature of their duties.

15. Equipment's and linens etc.-

- (1) The clinical establishment shall provide and maintain;
 - a) adequate number of commodes, bed pans and slop sinks with flushing arrangements;
 - b) high pressure sterilizer and Instrument sterilizer;
 - c) Oxygen cylinder and necessary attachment for giving oxygen.

16. Admission and provision of diet.

- (a) Admission shall be restricted to the number of beds to be maintained.
- (b) The scale of diet should not be below the standard norms in the clinical establishment providing diet to the patients. The diet should be served and prepared in hygienic conditions

17. Nursing Staff.-

- (1) One nurse shall be on duty at all times for every ten beds or a fraction thereof in the clinical establishment:

Provided that part of nursing staff may be substituted with prior approval of the Authority by other trained staff like midwife, pharmacist, dresser etc. according to the specific needs of the clinical establishment.

18. Records.

- (1) Separate stock register shall be maintained by the clinical establishment for , -
 - a) equipment;
 - b) instruments;
 - c) linens.

19. Radiological facilities

- (1) An establishment with radiological facilities shall comply with the following conditions, namely:-
 - (a) The X -ray machine shall be operated by qualified X -ray technicians.
 - (b) X -ray shall have adequate dimensions with proper airtime to prevent stirring up of the dust.
 - (c) Sitting room for the patients and attendants shall be away from X -ray room and at the time of X -raying , patients attendants shall not be normally allowed inside the X - ray room. In case of children being X -rayed the attendant shall however be allowed to stay.
 - (d) Each X -ray clinic (Diagnostic) shall have the following protective accessories.-

- (i) Protection Screen,
- (ii) Lead apron 1-1.5 mm thickness up to 75 kilo voltage,
- (iii) Protective gloves,
- (iv) Protective goggles,
- (v) Lead blocker for protection of generative organ of patients and
- (vi) Cones

(e) X ray equipment and protective clothing shall be checked from time to time. For this purpose florescent screen shall be used.

(f) While taking X ray of teeth, films shall be held by the patients themselves and not by X-ray technicians.

(g) All records maintaining to X- ray shall be properly maintained.

(h) The operator of the X-ray equipment shall comply with anti-accident regulations

(i) Monitoring (Films badges services) shall be introduced.

(2) Establishments having /doing X- ray and imaging, radiology, ultrasonography shall comply with Safety Manual Rules prepared by Atomic Energy Regulatory Board Government of India or prescribed by Authority from time to time.
Establishment having the facilities of Ultrasonography via portable machine should have license under Pre-natal Diagnostic Techniques Act.

(3) Technical Qualification: - The technical person performing the X-Ray test should have the following qualifications:

(a) Bachelor in Medical Imaging Technology.

(b) 1(one) or 2(two) years Diploma in X-Ray technology awarded by the Recognized University or Institution or Central Technical Board.

(c) Supervisory Personnel:- The large and super specialty X-Ray Unit shall be supervised by a person with Master Degree in (Radiology), or Diploma in Medical Radio diagnosis. The small and medium X-Ray Unit may be manned by MBBS, Diploma in Medical Radio diagnosis or BSc in Medical Imaging Technology with at least 5(five) years of experience in X-Ray unit.

20. Bio Medical Waste (Management and Handling Rules) 1998. -

Every Clinical Establishment shall comply with Bio –Medical Waste(Management and Handling) Rules 1998, or rules as may be prescribed from time to time.

21. (1) Physicaltherapy establishment. -

(1) Physical therapy establishment shall have establishment providing therapy to patients suffering from crippling diseases and disabilities. Accommodations should be provided in forms of booths. A long room with curtains, which could be drawn to form cubicles in form of adequate privacy.

(2) The treatment varies from physical, hydro therapy, occupational therapy and exercise. Such establishment shall be under direct supervision of qualified expert on particular type of treatment.

(3) The employees and the persons giving the actual treatment shall have proper qualifications approved by the appropriate authority for imparting such treatment.

(4) Male or female employees providing such therapy shall be under direct supervision of qualified persons. He or she should possess a minimum qualification of secondary education or equivalent from recognized board of secondary education and must possess practical experiences for a period of 5(five) years as trainer or work as Assistant under physiotherapist in Physiotherapy Department of Government hospital or hospital recognized for such purpose by appropriate authority to achieve a satisfactory knowledge on,-

- a) basic anatomy specially on bones, joints and muscles;
- b) basic physiology with rudimentary knowledge of diseases in which massage is indicated or contraindicated;
- c) mechanism and use of remedial apparatus;
- d) physical and application on of electrical appliances used in modern physiotherapy.

22. Technical person for Diagnostic Laboratory Establishment. -

(1) the technical person performing the tests should have the following qualification:-

(a) Graduate in Medical Laboratory Technology, or

(b) 1(one) or 2(two) years Diploma in Medical Laboratory Technology awarded by a Recognized University or Institution or Central Technical Board.

(2) The Laboratory shall have a system of imparting training to technical staff at various levels. There shall be a system so that a technical person receives adequate training in the operation of new analytical equipments and performances of new test before he or she is assigned to such work.

(3) The minimum space required to run a diagnostic laboratory should be 200 square feet. Separate space should be available for sample collection and to store chemicals. For medium and large laboratories and super specialty laboratory the minimum space should be 300 square feet. Separate space should be available for various branches of laboratory medicine.

(4) The diagnostic laboratory can be a hazardous work place unless proper precautions are taken. The laboratory safety programme should include establishment of a safety policy and proper disposal of waste and related material as per guidelines implemented by the State Government from time to time. All steps will be taken to ensure that such waste is handled without any adverse effect to human health and environment.

23. Supervisory Personnel:-

The large and superspeciality laboratory shall be supervised by a person with post-graduate qualification MD in pathology or microbiology or biochemistry, or Ph. D. in the respective discipline. The small and medium laboratory may be manned by an DCP or a M.Sc; or Bachelor in Medical Laboratory Technology with atleast (five) years of experience in laboratory medicine.

24. Procedure for Registration.-

No person shall run a Clinical Establishment unless it has been duly registered in accordance with the provisions of these rules

25. Application for registration.-

(1) The applicant shall apply to the District Registration Authority for provisional registration, either in person or by post or web based online facility with the necessary information.

(2) The applicant shall apply to the District Registering Authority for permanent registration either in person or by post or 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 establishment in Form I.

26. Acknowledgement of Application.-

The Authority or any person in his office authorized in this behalf, shall acknowledge receipt of the application for registration in Form II or, in the acknowledgement slip 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.

27. Grant of Provisional Registration.-

the Authority shall not undertake any inquiry prior to the grant of provisional registration and shall within a period of 10 (ten) days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in Form III containing particulars and information, either by post or electronically.

28. Certificate of registration.-

(1) The District Registering Authority shall grant the applicant a certificate of permanent registration in Form IV, 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.

(2) In case of permanent registration, the authority shall pass an order within 3 ½ months-
a) allowing the application for permanent registration; or
b) disallowing the application.

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

29. Levy of fees:-

- (1) The fees payable for provisional and Permanent registration under the Act shall be as specified in the Schedule.
- (2) If a laboratory or diagnostic centre is a part of a establishment providing outpatient or inpatient care no separate registration is required.
- (3) Clinical Establishment 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.
- (4) The fees prescribed for various categories of Clinical Establishment shall be revised by the State Council through a notification issued by the State Government.
- (5) The fee shall be paid by a demand draft drawn in State bank of India. The fees collected by the Authorities for registration of the Clinical Establishment shall be deposited by the Authority concerned in a Nationalized 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 Registering Authority.
- (6) The account shall be maintained as per the Financial rules for the time being in force in Sikkim and shall be audited by engaging a qualified Chartered Accountant. 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 Registering Authority in writing within one month of such change along with the fee prescribed in the Schedule for issue of a revised certificate of Provisional or Permanent Registration, as the case may be, incorporating the changes and on surrendering the old Certificate under sub-section (2) of section 20 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 Registering Authority to issue a Duplicate Certificate upon payment of the fee prescribed in the Schedule and the Certificate of registration shall be marked as "Duplicate" Form V.

30. Renewal of Provisional Registration.-

The clinical establishment shall apply for renewal of provisional registration 30(thirty) days before the expiry of the validity of the certificate of the 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 and penalty of rupees ten per day till the date of application for renewal.

31. Renewal of Permanent Registration.-

For renewal of permanent registration, the clinical establishment shall apply 6 (six) months before expiry of the registration period of 5 (five) years. The renewal shall be granted by the Authority within three months of receipt of the application failing which it shall be deemed to have been renewed. If the clinical establishment does not apply within one month of expiry of registration period, the registration shall be deemed to have been suspended or the authority shall allow for renewal of registration on payment of the renewal amount as prescribed and penalty of Rs 100 rupees (one hundred) per day till the date of application for renewal is accepted.

32. Register to be maintained.-

(1) Every District Registration Authority shall within a period of 2(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.

(2) Every District Registration Authority including any other 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 the clinical establishments a copy of every entry made in the District register of clinical establishments.

33. Display of information. -

(1) The District Registering Authority shall, within a period of 40(forty-five) days from the grant of provisional registration, mandatory causes to be published in the public domain through two local dailies and on the website, which the District Registering Authority will launch, the name of the Clinical Establishment, Address, Ownership, Name of the Person in charge, System of Medicine offered, type and nature of services offered and details of the Medical Staff (Doctors, Nurse, etc.)

(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.

(3) The District Registering Authority shall, within a period of 7(seven) days cause to be published in the public domain through two local dailies and on the website, which the District Registering Authority shall launch, the name of the Clinical Establishment, Address, Ownership, Name of the Person in charge, System of Medicine offered, type and nature of services offered and details of the Medical Staff (Doctors, Nurse, etc.) and the details and information related to having complied with the minimum standards and personnel prescribed for the particular category of Clinical Establishment.

(4) The District Registering Authority shall cause to be displayed the above information in public domain for a period of 30(thirty) days for filing objections before granting permanent registration.

(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 Registering Authority.

(6) The District Registering Authority shall, within a period of 15(fifteen) days cause to be published in the public domain the name of the Clinical Establishment whose (provisional and permanent) registration has expired.

34. 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 three monthly reports as prescribed.

(2) Copies of all records and statistics shall be kept with the clinical establishment concerned for at least 3 (three) years. 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 and 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.

35. Entry and search.-

(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 shall be required to be taken unanimously by all members of the District Registering Authority.

(2) Such entry and search of clinical establishment can be conducted if anyone is carrying on a clinical establishments without registration or does not adhere to the prescribed minimum standards or has reasonable cause to believe the Clinical Establishment is being used for purpose other than that it is registered or contravenes any of the provisions of this Act and Rules, shall at all reasonable times enter and inspect any record, register, document, equipment and articles as deemed necessary under the provisions.

(3) The inspection team shall intimate the establishment in writing about the date of visit. 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 or inspection team so constituted by the Registering Authority shall submit a report in Form VI within a week of the inspection to District Registering Authority with a copy to the State Council.

36. Penalties.-

(1) Whoever contravenes any provision of these rules shall, if no penalty is provided elsewhere, be punishable for the first offence with fine which may extend to ten thousand rupees, for any second offence with fine which may extend to fifty thousand rupees and for any subsequent offence with fine which may extend to five lakhrupees.

37. Monetary penalty for non-registration. -

(1) Whoever carries on a clinical establishment without registration shall, on first contravention, be liable to a monetary penalty up to fifty thousand rupees; for second contravention with a monetary penalty which may extend to two lakh rupees and for any subsequent contravention with a monetary penalty which may extend to five lakh rupees.

(2) 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.

(3) For the purpose of adjudging under sub-rule (1) and(2), the authority shall hold an inquiry after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty:

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstances of the case to give evidence or to produce any document which in the opinion of the authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-rule (1) and (2), it may by order impose the monetary penalty specified in those sub rules to be deposited within 30 (thirty) days.

(5) The 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 and approved by the Council.

(6) While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(7) Any person aggrieved by the decision of the authority may prefer an appeal to the State Council within a period of three months from the date of the said decision.

38. Appeal.-

(1) If any person or clinical establishment, if aggrieved by the decision of the authority, may file an appeal to the State Council within 30 (thirty) days from the date of receipt of such order along with prescribed fees.

(2) 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 (fifteen) days time for hearing of the case.

(3) The appellant may represent by himself or authorized person or legal practitioner and submit the relevant documentary material if any in support of the appeal.

(4) The State Council shall hear all the concerned, receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its decision preferably within 90 (ninety) days from the date of filling the appeal.

(5) 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 decision of State Council shall be final and binding.

(6) If no appeal is filed against the decision of the Registering Authority in the prescribed period within 30(thirty) days from the date of receipt of the order, the order of the authority shall be final.

(7) 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.

Sd/-

Dr K. Bhandari, MD,DM
Director General cum secretary
HC,HS& FW Department
Government of Sikkim

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