In pursuance of the provision of clause (3) of Article 348 of "the Constitution of India", the Governor is pleased to order the publication of the following English translation of notification No. 233 /XXXVIII-2/04(81)2007, Dehradun, dated March, 2013 for general information.

Government of Uttarakhand Medical Section-2 No. 233(1)/ XXXVIII-2/04(81)2007 Dehradun; dated 2 March, 2013

Notification

MISCELLANEOUS

In exercise of the powers conferred by section 54 of the Clinical Establishments (Registration and Regulation) Act, 2010 and in supersession of all existing rules and orders on the subject, the Governor is pleased to make the following rules for registration and regulation of the established Clinical Establishments in the State of Uttarakhand.

The Uttarakhand Clinical Establishments (Registration and Regulation) Rules, 2013

Chapter-I Preliminary

Short title, extend and commencement

1.

- (1) These rules may be called the Uttarakhand Clinical Establishments (Registration and Regulation) Rules, 2013.
 - (2) It extends to the whole of the State of Uttarakhand.
 - (3) It shall come into force at once:

Provided that different dates may be appointed for different categories of Clinical Establishment and for different recognized systems of medicine.

Definition

- 2. In these rules, unless the contest otherwise requires-
 - (a) 'Act' means •the Clinical Establishments (Registration and Regulation) Act, 2010;
 - (b) 'State Council' means the Uttarakhand State Council for Clinical Establishment;
 - (c) Words and expressions used and not defined in these rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.



Chapter II

Establishment of State Council for Clinical Establishments

Establishment

3.

The State Government shall constitute the State Council for Clinical Establishment by notification with provided manner in the Act.

Functions of the State Council

- 4. 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 in the digits format;
 - (c) Representing the State in the National Clinical Establishment council; •
 - (d) Hearing of appeals against the orders of the authority;
 - (e) Publication of a report on annual basis on the State of implementation of standards within Uttarakhand;
 - (f) Monitor the implementation of the provisions of the Act and rules in the Uttarakhand;
 - (g) Recommend to the Government for 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; and
 - (i) Any other function as may be prescribed by the Central/State Government.

Sub-Committees

- 5. (1) On the direction of the National Council and/or the Central Government for the consideration of particular matters, the State Council may constitute a sub-committee consisting of such numbers amongst of its member, for such period, not exceeding two years.
 - (2) After constitution of the sub-committee its act, number of the members and timeline for completion of tasks shall determined by the State Council. The State Council shall also appoint the



Chairman of the sub-committee on the date of constitution.

(3) Any decisions taken by the sub-committee/s shall be placed before the State Council at its next meeting for its consideration and approval.

Conduct of Business of

State Council

- 6. (1) Every meeting of the State Council shall be presided over by the Chairman.
 - (2) The meetings of the State Council shall ordinarily be held at State Capital on such dates and time as may be fixed by the council. The Council shall meet at least once in 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 before one week of the date of the meeting.
 - (4) One-third of the total number of members of the State council shall form a quorum and all decisions of the council shall be made by a majority of the members present.
 - (5) The proceedings of the meetings of the Council shall be maintained in the form of minutes which shall be authenticated after approval of the Chairman.
 - (6) A copy of the minutes of every meeting of the State Council shall be placed before the Chairman for approval and accordingly approve minutes shall be provide to the each member of the State council.

Resignation and Filling of Casual Vacancles

- 7. (1) A member desiring to resign his/her seat of the State Council shall refer his resignation in writing to the Chairman. Such every resignation shall come into force from the date of application but where no date is mentioned in the application than, the date of received of such resignation received by the Chairman shall be deemed into force.
 - (2) When a casual vacancy occurs by reason of death, resignation or otherwise of a member, than the Chairman shall intimate to the State Government. The State Government may fill the casual vacancy by nomination or election, as the case may be.



Finance and Accounts

8.

The Accounts of the State Council shall be audited annually by an Auditor, who is to be appointed with the prior approval of the Auditor General of Uttarakhand. The expenditure incurred in connection with such audit shall be paid by the State Council.

Chapter-III

District Registering Authority

District
Registering
Authority
Functions of
the District
Registering
Authority

- 9. The State Government by notification shall establish a District Registering Authority for every district for registration of Clinical establishment under section 10 of the Act.
- 10. Functions of the District Registering Authority, as follows; namely-
 - (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 the State Council on a quarterly basis of 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.

Conduct of Business of the District Registering

Authority

- 11. (1) Every meeting of the District Registering Authority shall be presided over by its Chairman.
 - (2) The meetings of the District Registering Authority shall be held at least once in a month at a stipulated date and time.
 - (3) 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.

- (4) One-third of the total number of members of the District Registering Authority shall form a quorum and all decisions of the authority shall be decided by a majority of the members present.
- (5) The proceedings of the meetings of the District Registering Authority shall be maintained in the form of minutes after approval of the Chairman.
- (6) A copy of the minutes of each meeting of the District Registering
 Authority shall be submitted to the Chairman by the convenor and
 accordingly approved minutes shall be provide to the each member
 of the District Registering Authority.

Resignation
and Filling of
casual
vacancies

12.

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 Chairman of the Authority by making a fresh appointment but the said appointment shall be made only for the remaining term of office of such member.

Chapter IV

Registration of Clinical Establishments

Application for 13. (Registration

- (1) The applicant shall apply to the District Registration Authority for provisional registration either in person, or by post or through web based online with the necessary information as per Format-1 prescribed by sub-section (1) and sub-section (3) of section 14 of the Act.
- (2) The applicant shall apply to the District Registration Authority for permanent registration, in person, or by post or through web based online with the necessary information filled and with evidence of having met the requirements of minimum standards and personnel for different categories of Clinical Establishments in a prescribed Format-1.
- (3) If any establishment is offering services in more than one category, than establishment will need to apply for a separate provisional or

permanent registration but if a laboratory or diagnostic center is a part of any establishment providing out patient/inpatient care, no separate registration will be required.

Acknowledge- 14. ment of application

15.

The District 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 Format-2 immediately or the next working day and by online acknowledgement to be generated automatically by the computer system.

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 certificate on Format-3 under section 15 of the Act.

Certificate of Registration

- 16. (1) The District Registering authority shall grant the applicant a certificate of permanent registration as per Format-4 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 under sections 28 and 30 of the Act.
 - (2) In case of permanent registration, under section 29 of the Act, the authority shall pass an order within one month allowing the application for permanent registration or Disallowing the application:

Provided that the authority shall record its justifications and reasons, if it disallows.

Fees to be charged

- 17. (1) The various fees charged for provisional and permaner registration, renewal, late application, duplicate certificate, chang of ownership, management or name of establishment is provided i Format-5 under sub-section (1) of section 14 read with section 19 22, 24, 35 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 for various categories of clinical establishments may be revised by the State Council through a notification issued by the State Government as provided in Format-5.
- (4) The provided fee on Format-5 under sub-section (1) of section 14 and other sections of the Act shall be paid by a demand draft drawn or online transaction to the Registration Authority concerned.
- (5) The provided fee collected by the Authorities for registration of the Clinical establishments shall be deposited by the Authority concerned in 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 Registration Authority.
- (6) The Accounts shall be maintained as per the Financial Code rules and shall be audited by engaging the Auditor. The annual Audit reports shall be submitted to the concerned State Council also.
- (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 the Format-5 for Issue of a revised certificate of Provisional of Permanent registration, as the case may be, incorporating the changes and on surrendering the old certificate under sub-section (3) of section 20 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. The provisional certificate shall be marked Duplicate as per Format-6 under section 19 of the Act.



Renewal of Registration

- 18. (1) The clinical establishment shall apply for the permanent registration before thirty days of the expiry of the validity of the provisional registration, which is twelve months from the date of issuing provisional certificate with fees as provided in the Format-5. In case, the application for renewal is not submitted within the stipulated period, than the Authority shall allow for renewal of registration, on payment of double amount of the renewal fee with a penalty of ₹ 100 per day till the date of application for renewal is accepted under section 22 of the Act.
 - (2) For renewal of permanent registration under sub-section (4) of section 30 of the Act, the clinical establishment shall apply within six months before the expiry of the validity of the permanent registration, which is five years from the date of issuing permanent certificate with the renewal fee as provided in the Format-5.
 - (3) If the application for renewal is not submitted with in the stipulated period, than the double amount of renewal fee and ₹ 100 per day late fee and payment of penalty as provided in the Format-5 to the Authority will allow for renewal of registration.

Registers to be maintained, furnishing of returns and display of information

19.

- (1) Every District Registration Authority shall within a period of two years from its establishment, compile, publish and maintain a register of clinical establishments registered by it in digital format and it shall enter the particulars of the certificate so issued in a register containing particulars as prescribed in Format-7 under sub-section (1) and (2) of section 37 and sub-section (1) and (2) of section 38 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 provide a copy of every entry made in the District register of clinical establishments to the State Council in digital format in such manner as provided in the Act.

Display of Information

20.

- (1) The District registering authority shall, within a period of 45 days from the grant of provisional registration, mandatorily cause 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 Person in charge, system of medicine offered, Type and Nature of services offered and details of the medical Staff (Doctors, Nurses, etc.) as under sub-section (2) of section 16 of the Act.
 - days cause 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 person in charge, system of medicine offered, nature and Type of Services offered and prescribed fees (as per Format-8), 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 of the act.
 - (3) The District registration authority shall cause to be displayed the above information in public domain for a period of thirty days for filling objections before granting permanent registration.
 - (4) 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.
 - (5) The District registering authority shall, within a period of fifteen 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 of the Act.
- Information to be provided by clinical

21.

(1) The Clinical Establishments shall maintain medical records of patients treated by it and health information and statistics in respect of national programmers and furnish the same to the district

establishments

- authorities in form of three monthly reports. The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishments are prescribed in Format-9 as per clause (iii) of sub-section (1) of section 12 of the Act.
- (2) Copies of all records and statistics shall be kept with the clinical establishment concerned for at least 03 years or in accordance with any other relevant act in force at the time under clause (iii) of subsection (1) of section 12 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 State Government may notify from time to time, the nature of information that needs to be furnished by the Clinical Establishment including other disease shall be 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.
- 22. (1) The District Registering Authority or an officer or team duly authorized by it may enter and search of the clinical establishment by such general or special orders as may be made by the authority. Such decision will be required to be taken by majority of the present members of the District Registration Authority.
 - (2) Such entry and search of clinical establishment 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 clinical establishment is being used for purposes other 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 the Act

Power of Enter

- (3) The inspection teath 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 equipment, Furniture and other accessories and enquire into the professional qualifications of the technical staff employed or to be employed and shall the application for registration as grant of license. All persons connected with the running of the clinical establishment shall be bound to supply full and correct information to the inspection team.
- (4) The Authorized Officer and/or inspection team so constituted by the Registering Authority shall submit a inspection report on Format-10 within a week of the inspection to the District Registration Authority and a copy shall send also to the State Council.

Chapter V

Penalties and Appeals

Penalties

- 23. (1) In keeping with the provisions of sub-section (1), (2) and (3) of section 41 and sub-section (1), (2) and (3) of section 42 the Act, whoever carries on a clinical establishment without registration or whoever willfully disobeys and direction, or obstructs any personor 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 to a monetary penalty of fifty thousand which may extend to ₹ two lakh on second contravention and for any subsequent contravention to penalty which may extend to ₹ five lakh.
 - (3) Whoever knowing serves in a clinical establishment which is not duty registered under this Act, shall be liable to a monitory penalty may extend to ₹ twenty five thousand.
 - (4) If the offender has not paid the penal amount under sub-section (2), the said sum shall be recoverable as arrears of land revenue.



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.

Appeals

- 24. (1) In keeping with section 29, 34, 41 and section 42 any person or clinical establishment, if aggrieved by the decision of the Authority may file an appeal to the State Council within three months from the date of receipt of such order with payment of such rate as provided fees in Format-5.
 - (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 fifteen days time for hearing of him case.
 - (3) 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.
 - (4) The State council shall hear all the concerned receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its-decision preferably within 90 days from date of filing 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) The appeal fees collected by the State Council shall be deposited 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 for the activities connected with the implementation of the provisions of the Act as approved by the Council.

(S. Ramaswamy) Principal Secretary.