MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd May, 2012

G.S.R. 387(E).—In exercise of the powers conferred by section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010), the Central Government hereby makes the following rules, namely:-

1. **Short title and commencement.** - (1) These rules may be called the Clinical Establishments (Central Government) Rules, 2012.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. **Definitions.** - In these rules, unless the context otherwise requires,-

(a) *"Act"* means the Clinical Establishments (Registration and Regulation) Act, 2010;

(b) "Secretary" means the Secretary of the National Council for clinical establishments,

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.

3. **Appointment of Secretary of the National Council by the Central Government-**

(1) The officer of the rank of Joint Secretary dealing with the subject of Clinical Establishments in the Ministry of Health and Family Welfare, Government of India shall be the ex-officio Secretary of the National Council for clinical establishments established under sub-section (1) of section 3 of the Act.

(2) The Secretary of the National Council shall be responsible for the control and management of the secretariat of the National Council and supervision of the other staff of the National Council Secretariat and perform such other duties as may be required of him by the National Council for the purposes of the Act.

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(3) He shall attend the meetings of the National Council for clinical establishments.

(4) The duties and responsibilities of the staff of the National Council shall be such as may be laid down from time to time by the Secretary of the National Council.

4. National Council and its sub - committees.- (1) The National Council shall classify and categorise the clinical establishments of recognised systems of medicine and submit the same to the Central Government for its approval.

(2) For the appointment of each sub-committee the National Council shall define the functions of the sub-committee, number and nature of members to be appointed thereon and timeline for completion of tasks. At the time of formation of each sub-committee, effort should be made to ensure that there is adequate representation from across the country in each committee from experts in the relevant fields across the private sector, public sector and its organizations, non-governmental sector, professional bodies, academia or research institutions amongst others.

(3) The Chairperson of every such sub-committee shall be appointed by the National Council at the time of the appointment of the sub-committee.

(4) The proceedings of the meetings of the sub-committees shall be preserved in the form of minutes.

(5) Any recommendations made by the sub-committees shall be placed before the National Council for its consideration and further necessary action.

(6) The National Council of clinical establishments may request the State Councils or Union territory Councils to provide inputs for its consideration on particular matters. If required, the State Council or Union territory Council shall at the request of the National Council or the Central Government, as the case may be, constitute sub-committee consisting of members of the State and Union territory Council and field experts for such period not exceeding one year, for deliberations and making recommendations on a particular matter or issue.

5. Allowances for the members of the National Council and sub committees.- The official members of the National Council for clinical establishments shall draw their travel and daily allowances as per the Government of India rules from the same source from which their salary is drawn. The non-official members of the Council shall be paid travel allowance and daily allowances in accordance with the Government of India rules as applicable, from time to time for the Group 'A' officers of Junior Administrative Grade.

6. State Council or Union Territory Council representation in the National Council meeting.- The National Council may invite representative(s) from one or more State councils or Union territory councils to participate in its meetings, as may be considered appropriate and the expenses on account of participation by such representatives will be met by the National Council.

7. Common registration form for compilation of the State and National Register.- In order to ensure uniformity in collection of information by the State Governments or Union territory's administration and data flow in connection with the compilation and maintenance of the State Registers and the National Register in digital format for the purpose of sections 38 and 39 of the Act, the National Council shall also develop the standard application form for registration of clinical establishments

8. District Registering Authority

(1) **Qualifications and the terms and conditions for appointment of the members of the authority.**- The district registering authority established by way of notification by the State Government under clause (c) of sub-section (1) of section 10 of the Act shall consist of three other members who shall be nominated by the District Collector or District Magistrate and they shall include the City Police Commissioner or Senior Superintendent of Police or Superintendent of Police, or his nominee, as the case may be, a senior level officer of the Local Self Government at the district level, one representative from a professional medical association or body having presence preferably in the district or within the State, as the case may be, for a tenure of two years.

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(2) **Filling up of casual vacancy.**- If a casual-vacancy occurs whether by reason of death, resignation or inability to discharge functions owing to illness or any other incapacity of a nominated member, such vacancy shall be filled by the District Collector or District Magistrate by making a fresh appointment and the member so appointed shall hold office only for the remaining tenure of the person in whose place he is so appointed.

(3) **Powers of the District Health Officer or Chief Medical Officer for the purposes of provisional registration of clinical establishments.**- The District Health Officer or the Chief Medical Officer (by whatever name called) shall exercise the following powers for the purposes of provisional registration of clinical establishments under sub-section (2) of section 10 of the Act, namely:-

(a) for the purposes of provisional registration of the clinical establishment, an application in the prescribed proforma as adopted by the State government with the requisite fee as the State Government may by rules determine;

(b) the application shall be filed in person or by post or online;

(c) the District Health Officer or Chief Medical Officer shall, within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in such form, particulars and information, as the State Government may by rules determine;

(d) the District Health Officer or Chief Medical Officer shall not conduct any inquiry prior to the grant of provisional registration;

(e) notwithstanding the grant of the provisional certificate of registration, the District Health Officer or Chief Medical Officer shall, within a period of forty-five days from the grant of provisional registration, cause to be published in such manner, as the State Government may by rules determine, all particulars of the clinical establishment so registered provisionally;

(f) where the clinical establishments in respect of which standards have been

notified by the Central Government, provisional registration shall not be granted or renewed beyond.-

(i) the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act;

(ii) the period of two years from the date of notification of the standards for clinical establishments which came into existence after the commencement of this Act but before the notification of the standards; and

(iii) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified;

subject to the conditions as mentioned above, every provisional registration shall be valid till the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable;

(g) the application for renewal of registration shall be made to the District Health Officer or Chief Medical Officer within thirty days before the expiry of the validity of the certificate of provisional registration and, in case the application for renewal is made after the expiry of the provisional registration, the authority shall allow renewal of registration on payment of such enhanced fees, as the State Government may by rules determine;.

(h) in case the certificate is lost, destroyed, mutilated or damaged, the authority shall issue a duplicate certificate on the request of the clinical establishment and on the payment of fees as the State Government may by rules determine.

9. Other conditions for registration and continuation of clinical establishments.- For registration and continuation, every clinical establishment shall fulfill the following conditions, namely :-

(i) every clinical Establishment shall display the rates charged for each type of service provided and facilities available, for the benefit of the patients at a conspicuous place in the local as well as in english language;

(ii) the clinical establishments shall charge the rates for each type of procedures and services within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments;

(iii) the clinical establishments shall ensure compliance of the Standard Treatment Guidelines as may be determined and issued by the Central Government or the State Government as the case may be, from time to time;

(iv) the clinical establishments shall maintain and provide Electronic Medical Records or Electronic Health Records of every patient as may be determined and issued by the Central Government or the State Government as the case may be, from time to time;

(v) every clinical establishment shall maintain information and statistics in accordance with all other applicable laws for the time being in force and the rules made thereunder.

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DR. ARUN K. PANDA, Jt. Secy.

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