

Minutes of Meeting

The first meeting of **National Council for Clinical Establishments** was held under the Chairmanship of Dr. Jagdish Prasad, Director General of Health Services (DGHS) on 01-06-12 in the second floor Committee Room at Nirman Bhawan, New Delhi.

The list of participants is annexed.

The agenda of the meeting and the issues discussed are as follows

1. Background & progress of Clinical Establishment Act
2. Overview & salient features of Clinical Establishment Act
3. Functions & Powers of the National Council and preliminary work done till date
4. Quorum and Procedure of Conduct of Meetings of National Council
5. Application form for Provisional Registration
6. Certificate of Provisional Registration
7. Broad Template of Minimum Standards
8. Information to be displayed by Clinical Establishments
9. Subcommittees under National Council
10. The Project for development of Web based portal for Online Registration of Clinical Establishments
11. The Project on Survey of Clinical Establishments and drafting of Minimum Standards

The agenda papers along with copy of the Act, rules and notifications in relation to the Act and National Council were distributed to all the participants.

At the outset, the Chairman, Dr. Jagdish Prasad welcomed the participants to the first meeting of the National Council. After the introduction, he briefed the participants about the Clinical Establishments Act (CEA) 2010 which has come into force in the states of Sikkim, Mizoram, Arunachal Pradesh & Himachal Pradesh and all the 7 Union Territories (UTs) with effect from 1st March, 2012. He stated that it is an important Act and needs to be implemented urgently and there should be no delay in implementation. He added that in every parliamentary session, issues related to Clinical Establishments, let it be regulation, pricing or standards, are discussed. For implementation of this Act, minimum standards are required, drafts of which the Quality Council of India (QCI) is going to develop based on a survey of Clinical Establishments in the 61 districts of the aforesaid 4 States & UTs. The survey is being carried out by the Indian Medical Association (IMA) through its state and district level branches.

Mr. Sunil Nandraj, Advisor Clinical Establishments Act made a presentation on the background and progress on the implementation of the Act so far. He emphasized that this is a historical Act which is required for registration and regulation of Clinical Establishments in both public and private sector. National Council for Clinical Establishments has been notified by the Centre on 19th March, 2012. Rules under the Act have been notified on 23rd May, 2012. Two meetings (in April 2011 and March 2012) were organized for orientation of State representatives and way forward for implementation of the Act. National Informatics Centre is presently developing web based software for implementation of the Act. An Advisor has been engaged for assisting in the implementation of the Act. The Ministry of Health and family Welfare (MOHFW) is presently providing technical assistance to the states for the implementation of the Act. Central Government has appointed the Joint

Secretary (Regulation) in the MOHFW as the Secretary of the National Council under Section 3 (10) of the Act.

The Secretary of the National Council, Dr. Arun K. Panda made a presentation on the Clinical Establishments Act and its salient features. He informed that implementation of the Act has been identified as a major governance reform by the Government and is directly being monitored by the Hon'ble Prime Minister's office. He emphasized the importance of the Act which will help in better regulation and better data collection which is required for proper Health Planning. As on date, other than the 4 states and UTs as stated by the Chairman, UP, Rajasthan and Jharkhand have also adopted the Act. He stated that as on date, we do not have information about the various types of Clinical Establishments in the country and their capacities to handle the disease burden of the country and any disaster(s) that may happen. He requested the members to advocate this legislation and spread awareness about this and dispel any doubts/misconceptions in the minds of Doctors and other stakeholders.

Dr. Anil Kumar made a presentation on the functions and powers of the National Council for Clinical Establishments. He informed about various provisions in the Act that are related to the functioning of National Council. He emphasized on the time line as defined in the Act for publishing the National Register of clinical establishments and determining the first set of standards for ensuring proper healthcare by the clinical establishments. The National Council may associate with itself any person or body whose assistance or advice it may desire in carrying out any of the provisions of this Act. The National Council shall follow a consultative process for determining the standards and for classification of clinical establishments. National Council shall also develop the standard Application forms. The National Council should frame Bye laws and the same will be sent to MOHFW for approval.

Dr. N.S. Dharmshaktu made a presentation on the bye-laws for fixing a quorum & regulating the procedures and conduct of all business to be transacted by the National Council. He proposed bye laws regarding Chairing of meeting, Time, Place & Date of meeting, Quorum etc. for consideration of council members. Ministry of Health and Family Welfare was requested to provide budget for smooth functioning of National Council. He stated that some budget provision to States/UTs particularly for district registering authority may also be considered as many of the activities are required to be carried out by them, at least in first two years. Minimum Secretariat Staff, TA/DA and contingency provision will be required.

Prof. H.S. Khaleefathullah wanted to know whether any Clinical Establishment of a State can register directly through online system even if the concerned state has not adopted this Act. Dr. Arun K. Panda replied that this is not legally tenable. Dr. T.K. Ravi requested that Pharmacies may also be included under this Act. The chairman replied that there is no provision of including Pharmacies/Chemist Stores under the Act. Dr. Arun K. Panda told that Pharmacy is not a Clinical Establishment by definition.

Dr. Nagaonkar suggested that the Clinical Establishments like Blood Bank, Imaging Centre etc. which are already covered under some other Act/Regulation should not be brought under the purview of Clinical Establishments Act. It was clarified that it is already mentioned under the Clinical Establishments Act that the existing legal requirements will continue to remain applicable on the Clinical Establishments even after the implementation of the Clinical Establishments Act.

The AYUSH representatives informed that the system of "Sowa-Rigpa" is now a recognized system of medicine, so it may be included under the Act. It was clarified that the Act is

applicable to the Medical Colleges but does not cover Clinical Research Centres. There was an apprehension regarding the inspection of Clinical Establishments by the registering Authority. Dr. Arun K. Panda clarified that prior intimation will be required to be given to the Clinical Establishment for carrying out the inspection. Dr. D. R. Rai suggested that registration number of the person in charge and the name of the concerned council should be mentioned in the Provisional Registration form.

AYUSH representatives raised the apprehension that Indian Medical Association (IMA) may not be in a position to undertake the survey of AYUSH Clinical Establishments. The QCI & IMA representatives informed that they have included AYUSH members in their core committee. There was another suggestion that there should be provision of cancellation of Provisional registration. It was clarified that the Act has sufficient provisions for cancellation of both Provisional and Permanent registration.

Dr. Zainab Zaidi made a presentation on the work being done by the QCI for development of minimum standards based on survey of clinical establishments in 11 States/UTs through Indian Medical Association as per an agreement signed with Ministry of Health & Family Welfare, Government of India. IMA has formed a committee comprising various stakeholders, with a sample representation of the key healthcare sectors under the Clinic Establishments Act. National core committee has been formulated with representatives from IMA, QCI, Central Council for Research in Ayurveda, Unani, Naturopathy and Siddha, Central Council for Research in Homeopathy, Dental Council of India, Physiotherapy Council of India and Delhi Nursing Home Cell. The survey shall have 2 components

Quantitative Listing of all clinical establishments and medical practitioners through Indian Medical Association in all (61) districts of the 4 states namely Arunachal Pradesh, Himachal Pradesh, Sikkim and Mizoram and 7 Union Territories.

Qualitative survey of the selected Clinical Establishments (about 40 per district) to capture details of each category of Clinical Establishment such as infrastructure, regulatory requirements, staffing, services and processes.

Based on the inputs of the survey, draft minimum standards will be developed which shall then be reviewed. After that ideal achievable standards will be drafted. The draft standards will be submitted for perusal and approval of National Council.

Mr. V. Ringe from National Informatics Centre (NIC) made a presentation on the development of the Web based portal for online registration of Clinical Establishments. He informed that the domain name for the web portal has been registered as <http://clinicalestablishments.nic.in> and <http://ceact2010.nic.in>.

Sh. Prasanth, NHSRC shared that there are various stakeholders who are looking eagerly at the developments of Clinical Establishments Act (CEA), especially the standards. Many of them e.g. Catholic Health Association of India (CHAI) have already worked on the same and have developed 'drafts of minimum standards' which can be resource materials for the National Council. Dr. Zainab Zaidi, replied that they have received the draft from CHAI. The Chairman Dr. Jagdish Prasad shared that, such materials will be useful in understanding perspectives of stakeholders and will be helpful while developing minimum standards, say in difficult areas.

Following drafts were presented for perusal of National Council members during the meeting.

- Application Form for Provisional Registration
- Certificate of Provisional Registration
- Broad Template of Minimum Standards
- Information to be displayed by Clinical Establishments

After discussions, following action points were recommended:

1. The “Application Form for Provisional Registration” to be shared with the aforesaid 11 State/UT and the States of UP, Rajasthan and Jharkhand for their inputs.
2. The Council members were requested to send their inputs on priority basis for finalizing the “Application form for Provisional Registration”. This should be sent with in a week.
3. The National Council authorized the Chairman to finalize the “Application Form for Provisional Registration” and the “Certificate of Provisional Registration” based on the feedback received from the National Council members and the States/UTs.
4. The Council members were requested to send their inputs on the following drafts with in 2 weeks of receipt of minutes.
 - Certificate for Provisional Registration
 - Broad Template of Minimum Standards
 - Information to be displayed by Clinical Establishments
5. The registration number of the person incharge and the name of the concerned council shall be mentioned in the Provisional Registration form.
6. System of Sowa-Rigpa (commonly known as Amchi system of medicine) which is now a recognised system of medicine under AYUSH was approved for inclusion in the application form for provisional registration as a recognized system of medicine.
7. The Council members opined that State Governments should be advised to make provision for minimum secretariat staff (minimum one technical officer (Doctor/Nurse/Health supervisor) and one Computer Data Entry Operator and other infrastructure for district registering authority to help the authority in implementing the Act.
8. Council members should suggest names for inclusion in the subcommittees to be formed under the National Council for carrying out different works like Categorization, review of draft standards, Statistics to be collected from Clinical Establishments, Format of National Register etc.
9. Following bye-laws for fixing a quorum & regulating the procedures and conduct of all business to be transacted by the National Council were approved.
 - (i) Every meeting should be presided over by the Chairman of the Council. However, in the situations when the DGHS is not able to chair the meeting due to some unforeseen urgent works, then the Chairman may nominate a senior member of the council from Government of India to chair the meeting.
 - (ii) **Time, Place & Date of Meeting:** Meetings of National Council will be held quarterly at Delhi on the date decided by the Chairman. However, special meeting if required can be called by chairman at short notice at any time.

- (iii) Notice of the meeting: At least **10** days prior notice along with agenda to be issued to all members.
 - (iv) Quorum of the meeting: **1/3rd of members** will form quorum.
 - (v) **All actions** of the council shall be decided **by majority**.
 - (vi) National council **may invite representative** from one or more of the state/UT council in the meeting.
 - (vii) Any **member desiring to resign** his seat shall send his resignation in writing to the Chairman & resignation shall take effect from the date of its acceptance by the Chairman.
 - (viii) When a **casual vacancy** occurs due to resignation or otherwise, the chairman will report it to the Government of India which will take steps to fill the vacancy by nomination or by election as the case may be.
10. QCI and IMA were advised to also include one member of the Pharmacy Council of India and one member of Indian Nursing Council in their core committee to discuss the issues of survey and development of standards.
 11. The Council members requested QCI and IMA to involve AYUSH representatives in carrying out the survey and development of standards.
 12. QCI and IMA were advised to expedite the survey work so as to carry out the work of drafting the minimum standards within the time-limit.
 13. It was agreed that the target should be to complete the Provisional Registration of all Clinical Establishments in 11 States/UTs in the current year.
 14. It was suggested to organize awareness workshops on the Clinical Establishment Act for a group of States/UTs with involvement of QCI, NIC and Council members. QCI offered to collaborate for organizing these workshops.

The meeting ended with a vote of thanks to & from the Chair.

List of Participants in 1st Meeting of 'National Council for Clinical Establishment' held on 01-06-2012 under chairmanship of DGHS

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