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Nirman Bhawan, New Delhi. Dated: 21st August, 2018

MINUTES OF MEETING

The minutes of 11th meeting of the National Council for Clinical Establishments held under the Chairmanship of Dr S.Venkatesh, DGHS on 13.07.2018 at Nirman Bhawan, New Delhi are enclosed for information and necessary action.

Action Taken Report may please be sent in due course to Dr. Anil Kumar, Addl DDG (AK), Room No. 560 - A, Nirman Bhawan, New Delhi-110011 or to his email id viz. dr.anilkumar@nic.in.

(Sudhir Kumar) Joint Secretary to the Government of India and Secretary, National Council for Clinical Establishments

То

- 1. All members of National Council for Clinical Establishments and all other participants as per the list annexed.
- 2. Chairman and Member Secretary, State Council for Clinical Establishments of Arunachal Pradesh, Himachal Pradesh, Sikkim, Mizoram, Bihar, Jharkhand, Rajasthan, Uttar Pradesh, Uttarakhand,Haryana and Assam and Union Territories of Puducherry, Chandigarh, Dadra and Nagar Haveli, Daman and Diu, Andaman and Nicobar, Lakshadweep.
- 3. Dr. Sujeet Kumar Singh, Director, NCDC, 22-Sham Nath Marg, Delhi- 110 054
- 4. Dr Manju Bala DDG(M), Nirman Bhawan, New Delhi
- 5. Dr. Mahesh Verma, Director & Principal, Maulana Azad Institute of Dental Sciences, New Delhi-2
- 6. Dr Rajni Gaind, Consultant & HOD Prof (Microbiology), Safdarjung Hospital, New Delhi,
- 7. Dr Raj Bahadur, Vice Chancellor, Baba Farid University of Health Sciences Sadiq Road Faridkot-151 203 Panjab
- 8. Dr. Rajani R. Ved, Executive Director National Health Systems Resource Centre, NIHFW Campus,Baba Gangnath Marg, Munirka,New Delhi 110067
- 9. Dr. Tanu Jain, ADG(TJ), Trauma div of DGHS, 530-C Nirman Bhawan, New Delhi

Copy to:

Secretary, Medical Council of India /Secretary, Dental Council of India /Secretary, Central Council of Indian Medicine /Secretary, Indian Nursing Council /Registrar –cum- Secretary, Pharmacy Council of India /Secretary, Central Council of Homoeopathy

Copy also to:

Principal Secretary (Health) of all the States/UTs who have not adopted the Clinical Establishments Act

Copy for information to:

- 1. PPS to DGHS /PPS to AS and DG
- 2. PPS to JS (SK)/ PA to Addl. DDG (SG)/PA to Addl.DDG(AK)
- 3. PA to Director (Bindu Tiwari)/ PA to US, MS division
- 4. SO (MH II), Dte.GHS
- 5. SO (MS), MoHFW

Minutes of 11th Meeting of National Council for Clinical Establishments held under the Chairmanship of Dr. S. Venkatesh, DGHS.

The 11th meeting of the National Council for Clinical Establishments was held on 13th July, 2018 under the Chairmanship of Dr. S. Venkatesh, DGHS, Govt.of India at Nirman Bhawan New Delhi. A copy of the agenda and related papers were circulated in advance through emails and also during the meeting.

Welcoming the participants, Dr. S.Venkatesh, DGHS remarked that Clinical Establishments Act (CEA) is important from both patients as well as Health Care Providers point of view. The main aim of the Act is standardization of Health Care facilities and provision of standard treatment by clinical establishments. The role of States is crucial as implementation and monitoring of the Act is in the remit of respective State / Union Territory Government. After introduction of participants, Shri Sudhir Kumar, the Joint Secretary MOHFW, Govt.of India and Secretary of National Council introduced the agenda of meeting to the participants. He stated that only few States have adopted the Act despite persistent pursuance with the States. Further, among those who have adopted, the implementation has not been as per expectations. States need to make more efforts and cooperation by all stakeholders is required.

The list of participants is annexed.

The hard copies of documents of Gazette notification in respect of minimum standards for medical diagnostic laboratories, Draft Charter of Patient Rights and status of implementation of the Clinical Establishments Act were circulated to participants.

Soft copies of following documents were shared with participants:

- 11th National Council Meeting Notice with Agenda 10th National Council Meeting Minutes
- Minimum Standards of Clinical Establishments of Ayush & Allopathy in Hindi & English (Allopathy Super Specialty Minimum Standards in Hindi is currently under translation)
- Operational Guidelines for implementation of CEA
- Patient Charter
- " NOTP Guidelines
- Status of registration and regulation of Clinical Establishments
- Gazette Notification of minimum standards for Medical Diagnostic Laboratories

A Power Point presentation was made by AddI.DDG (AK) regarding various agenda points and agenda-wise actions recommended/decided are as under:-

1. Confirmation of minutes of 10th meeting of National Council

The minutes of 10th meeting of National Council were confirmed with one modification. The following action point as mentioned in minutes in respect of point number VII on page no. 3.

% was again reiterated that Ministry may issue instructions to all concerned regarding mandatory registration under Clinical Establishments Act (CEA) for empanelment under any Govt. of India Scheme. States Government representatives were advised that they may also implement the same for State schemes+:

will be modified as

% or empanelment of Clinical Establishments under any Government of India / State Government scheme, the preference shall be given to those Clinical Establishments that are registered under the clinical establishments Act in the States/ UTs, wherever, the Act is applicable.

This change was keeping in view of the fact that many States have adopted the Act only for selected categories of clinical establishments and many others are in the initial stage of registration.

(Action: MOHFW/Dte.GHS)

2. Information regarding Gazette Notification dated 18 May 2018.

The members and participants were informed that minimum standards for Medical Diagnostic Laboratories have been notified by Ministry of Health and Family Welfare, in Gazette of India on 18-5-2018, as an amendment to Clinical Establishments (Central Government) Rules. Both hard and soft copies had been shared with the members. The National Council endorsed the Gazette notification.

3. Standard Treatment Guidelines:

3.1 It was desired by members that Hindi translation of Standard Treatment Guidelines may be carried out. Additional DDG(AK) informed that Standard Treatment Guidelines are for medical practitioners, who learn the subject in English Language. However, Hindi translation of AYUSH Standard Treatment guidelines would be carried out through Ministry of AYUSH. At present only Ayurveda treatment guidelines for 18 conditions have been provided by the Ministry of AYUSH. The AYUSH members of council were requested for providing treatment guidelines for other streams of AYUSH also.

(Action: Ministry of AYUSH/Dte.GHS)

3.2 It was informed that at present Allopathic Standard Treatment Guidelines (STG) for 227 medical conditions have been approved and available on the website of the Clinical Establishments Act. The Standard Treatment Guidelines for various National Health Programmes (NHP) are also available, compiled & put up on the website of CEA. A copy of the latest STGs for 12 medical conditions as finalised in coordination with NHSRC was handed over by the Chairman of National Council Dr. S. Venkatesh, DGHS to the IMA president Dr. Ravi Wankhedkar.

3.3 It was also informed by IMA President that there are more Standard Treatment Guidelines prepared by IMA which may be added to the pool of STGs as finalised by DGHS/MOHFW. Further, IMA has collaboration with Federation of Medical Specialties Association (FOMA) and they may get their help in developing more STGs as required by the MOHFW. The members welcomed the suggestion and invited IMA to provide the draft of the same to Dte. GHS.

(Action: IMA/Dte.GHS)

3.4 In response to concern of members regarding the scientific validity of the STGs and need of updating them regularly, it was informed that the STGs, as approved are evidence based.

3.5 It was recommended that the STGs should only be for guidance of medical Practitioners and may not be binding on them. Further, it was decided that the STGs need to be updated regularly to keep pace with the advancement in the field of medicine.

(Action: Dte.GHS)

3.6 Indian Dental Association Representative and Dental Council of India(DCI) members agreed that they will provide Standard Treatment Guidelines for other Dental Diseases. Dr Mahesh Verma, Director and Principal of Maulana Azad Institute of Dental Sciences, New Delhi was nominated as chairman for this task and he may coopt other members.

(Action: Dr. Mahesh Verma, MAIDS)

3.7 It was pointed out by DCI members that The Standard Treatment Guidelines for major Trauma have not included maxillofacial trauma. It was agreed that the draft of same will be provided by DCI expert members Dr. Janak Raj Sabharwal & Dr. Dhirendra Srivastav which then may be reviewed by the Committee for the STGs of Dental Conditions.

(Action: Dr. Mahesh Verma, DCI, IDA)

4. Rates of Medical Procedures & Services under Clinical Establishments Act

After due discussions and deliberations, it was decided that the states/UTs will develop standard cost of procedures and services using the list of procedures and services and standard template of costing as approved by National Council and shared already with the states. They should define such cost for common procedures as applicable to their states taking into account also the other local factors. The states were requested to send the first list of cost of procedures within next 2 months. The states were advised to constitute technical committees involving both public and private sector representatives for this purpose.

(Action: States/UTs)

5. Charter of Patients Rights

A presentation on draft Patient Charter was made by Consultant (CE), National Council Secretariat, as has been received from National Human Rights Commission. Draft Patient Charter was discussed by participants and it was adopted with following suggestions:

- i. Informed consent of patient should be taken before digitization of records.
- ii. Release of dead body of a patient cannot be denied for any reason by the hospitals.
- iii. It was recommended that patient seeking transfer to another hospital/discharge from a hospital will have the responsibility to settle the agreed upon payment+.
- iv. It may be specified in the charter that no discrimination in treatment for the transgenders may be allowed.
- v. Duties and Responsibilities of patient are already mentioned in the charter which were also endorsed by the National Council.
- vi. It was recommended that public comments may be sought by Ministry / National Human Rights Commission (NHRC) for a period of 30 days.
- vii. Some members expressed concern regarding existence of many stem cell therapy centres which are not being regulated. It was informed that a task force has been constituted by ICMR, as stem cell therapy is still at experimental stage. Further, for Stem Cell Therapy regulations, Drugs and Cosmetics division has framed draft rules which are available in public domain. Members were requested to send their comments to concerned authority.

(Action: MOHFW, All Members/Participants)

6. It was informed by respective members that code of ethics have been issued for respective health care providers by Medical Council of India,

Indian Nursing Council, Dental Council of India and under Pharmacy Registration Act. The same will remain applicable to these staff when they are working in a Clinical Establishment. It was also agreed to find out any such ethical guidelines if issued by Rehabilitation Council of India.

(Action:Dte.GHS)

7. Registration & Standards of Point of Care Test and Collection Centres

7.1 It was decided that the collection centres shall be part of main laboratories and responsibility and accountability in respect of compliance of minimum standards by collection centres shall be of the parent Laboratory. The collection centres will not be registered separately but as a component of the main laboratory.

7.2 It was decided to constitute a subcommittee under the Chairpersonship of Dr. Rajni Gaind, HOD Microbiology Safdarjung Hospital for drafting the following:

- " Minimum standards for point of care testing
- ["] Minimum standards for collection centres
- Quality of above point of care testing and collection centres including training of personal performing these tests.
- " Standards of quality of testing kits will be part of these guidelines.
- ["] Any other laboratory related issue.

One NHSRC Representative will also be member of this committee

(Action : Dr Rajni Gaind, ED, NHSRC)

8. Registration and Standards of Tele-medicine centre

Sub -committee under the chairmanship of Dr Manju Bala DDG(M) will finalise these guidelines with the help of NHSRC.

(Action: DDG(M), ED NHRSC)

9. Minimum Standards for Trauma Centre

Trauma division of Dte.GHS will finalise these guidelines. Dr Raj Bahadur, Vice Chancellor, Baba Farid University of Health Sciences, Faridkot will be the chairman for finalising these guidelines. Dr. Janak Raj Sabharwal, Member of Dental Council of India and Dr. Dhirendar Srivastava, Dean, ESIC Dental College will also be the members of this sub-committee.

(Action : Dr Raj Bahadur, DCI, IDA, Trauma div of DGHS)

10. Minimum Standards for Dental Laboratory

10.1 Minimum standards for dental laboratory have not been notified and the same should be defined along with definition of signatory authority for dental lab clinical establishments.

10.2 It was decided to constitute a Sub-Committee for Dental Lab. Dr Mahesh Verma, Director & Principal, Maulana Azad Institute of Dental Sciences will be the chairman of the sub-committee and IDA will be involved in finalising these Minimum Standards

(Action: Dr. Mahesh Verma, Principal, MAIDS & IDA representative)

11. Minimum Standards For Home Based Care

They may be finalised by BIS and draft may be shared with National Council. However, it was decided that for the time being the registration and regulation of home based care will not be done under CEA.

(Action: BIS)

12. Regulation of Training institution for nurses and paramedical under the clinical establishments Act

It was informed by respective members that Indian Nursing Council and Pharmacy Council of India regulate respective training institutions for Nurses and Pharmacy. Further they do not provide clinical care services directly, so they need not be regulated under CEA. Moreover they are attached to a hospital, which is required to be registered under CEA.

13. Use of Clinical Establishments data for Mapping

CBHI is working on mapping of all Clinical Establishments in the country. The CBHI was asked to make use of the available data of the Clinical Establishment registered under CEA which is available in public domain on the website of CEA.

(http://clinicalestablishments.gov.in)

(Action: CBHI)

14. It was clarified in response to queries from some states that at the lowest level, the registration of a Clinical Establishment owned /controlled/managed by a single doctor is allowed under the Act. Other paramedical professional like lab technicians, physiotherapist etc shall be work under the umbrella of registered clinical establishments owned /controlled/managed by Government/Private trust/ societies/corporation, local authority or a single doctor.

15. Some members highlighted the issue of digital security of data collected from the clinical establishments. It was informed by NHSRC representative that Ministry is in process of drafting Digital Information Security in Health Care+Act.

Once enacted, the finalized guidelines of the Act, would be used for security of digital information under clinical establishments Act.

16. Guidelines for BMW Management and Patient Safety

The concerned division of Dte.GHS dealing with these subjects shall prepare draft guidelines, with the help of inputs from Ministry of Environment and Forests, Central Pollution Control Board (CPCB) and hospital division, BIS, WHO will also be involved.

(Action: Dr Chhavi Pant Joshi, DADG, DteGHS)

17. Minimum Standards for infection control. NCDC will finalise.

(Action: Director, NCDC)

18. Minimum Standards for Human Milk Bank-

It was pointed out by NHSRC representative that human milk banks may also be considered for registration/ regulation. However, it was decided that it is not required to cover them at present.

19. Feed back of States / UTs on draft National Organ Transplant Program (NOTP) Guidelines

The participants were requested to send their comments on the draft circulated. The comments as received will be shared with NOTP steering committee.

20. It was informed that the chairman for various subcommittees, as nominated by National Council may decide to co-opt other members / experts as per the scope of the work.

Addl. DDG (SG) proposed vote of thanks.

The meeting ended with a vote of Thanks to the chair.

Annexure

LIST OF PARTICIPANTS

<u>11th Meeting of National Council for Clinical Establishments held under the chairmanship of Dr. S.Venkatesh, DGHS on 13-07-2018</u> at Nirman Bhawan, New Delhi

S.No	Name with Designation	Address	Telephone No./Mobile No./Fax No.	E-mail
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