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FTS-121839

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Government of India
Directorate General of Health Services
National Council Secretariat

Nirman Bhawan, New Delhi.
Dated: 23rd August, 2021

MINUTES OF MEETING

The minutes of the 12th meeting of the National Council for Clinical Establishments held under the Chairmanship of Dr Sunil Kumar, DGHS on 14.07.2021 at 11.00 AM through video-conferencing at Nirman Bhawan, New Delhi are enclosed herewith for information and necessary action please.

(Padmaja Singh)
Joint Secretary to the Government of India
and Secretary, National Council for Clinical Establishments
Tel No. 23063155

To

All Participants as per the list mentioned in the minutes

Copy to

1. Other Members of National Council for Clinical Establishments who did not attend the meeting:
    i. Shri C.H. Kharshing, Planning Advisor and Addl. Charge of Advisor(Health)
    ii. Dr Janak Raj Sabharwal, Dental Council of India
    iii. Shri Ashim Sanyal, National Level Consumer Group
    iv. Dr. Kumar Vivekanand, Secretary, Central Council of Homoeopathy
2. Director Health Services (Member Secretary) State Council for Clinical Establishments, States of Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, Uttar Pradesh, Uttarakhand, Bihar, Jharkhand, Rajasthan, Assam and Haryana and All UTs except NCT of Delhi and Ladakh

Copy for information to:

1. Sr.PPS to DGHS
2. PPS to AS(MA), MoHFW
3. PS to JS (PS), MoHFW
4. PA to DS (MS)
5. US, MS division, MoHFW
6. SO (MS), MoHFW
7. Staff of National Council Secretariat

Meeting Name :	The 12th meeting of the National Council for Clinical Establishments held under the Chairmanship of Dr Sunil Kumar, DGHS through Video-conference
Meeting Purpose:	To review the work done by the National Council so far, status of implementation of the Act by the States/UTs and defining further Roadmap and consideration/decisions of specific agenda points.
Date:	**14.07.2021**
Time:	**11am to 2pm**
Location:	Resource room 4th Floor, Nirman Bhawan, New Delhi, through Video-conferencing
Meeting Facilitator:	Dr. Anil Kumar, Addl DDG, Dte.GHS

List of Participants

S.No.	Name	Designation	State/Institution
Members of National Council for Clinical Establishments			
1.	Dr. Sunil Kumar	DGHS, Chairman	Dte.GHS, MOHFW
2.	Dr. Vijayendra Kumar	Member of UG Medical Education Board on National Council for CE	National Medical Commission, Dwarka
3.	Dr. K. Reddemma	Nodal Officer	Indian Nursing Council
4.	Professor. B. Jaykar	Registrar, Vinayaka Missions University, Sankari Main Road (NH-47), Ariyanoor, Salem-636 308.	Pharmacy Council of India
5.	Dr. Mangesh Pate	Hony. Secretary, IMA Hospital Board of India	Indian Medical Association
6.	Dr. V. B. Vijayakumar	Senior Medical Officer, Nodal Officer (Siddha), Govt. of Kerala, Board of Studies (Representative of Siddha)	CCIM
7.	Dr.Suryakiran Parshuram Wagh	Kolhapur, Maharashtra, (Representative of Ayurveda)	CCIM
8.	Dr. Zubair Shaikh	(Representative of Unani)	CCIM

	9.	Sh. PV Mathew	Scientist 'E' and Head (Medical Equipment and Hospital Planning Department) Manak Bhawan, 9 Bahadur Shah Zafar Marg, New Delhi-110002 (MHD)	BIS
	10.	Dr. Mira Shiva	Consumer Representative	National level Consumer Group, Hauz Khas
	11.	Dr.Ulhas Marulkar	O/oDHS, Maharashtra	Representative of Zonal Council
	12.	Dr. T.Geetha Prasadini, dir_health@yahoo.co.in	Joint Director (IEC), State Nodal Officer (APAPMCE Act) O/o Director of Public Health & Family Welfare, Gollapudi, Vijayawada, shebdphfwap@gmail.com	Representative of Zonal Council
	13.	Sh. Dhananjay Kulkarni	President, Paramedical Council of Maharashtra	Representative of Paramedical Systems
	14.	Vaidhya Santosh Nevpurkar	Association of Indian Systems of Medicine, Ayurveda, Siddha & Unani	Aurangabad, Maharashtra
	15.	Dr. Atul Mohan Kochhar	CEO, NABH	Quality Council of India
	Ministry/Dte.GHS			
	16.	Ms. Padmaja Singh	JS	MoHFW
	17.	Dr.K.T. Bhowmik	Principal Consultant	Dte.GHS,MoHFW
	18.	Dr.AnilKumar	Addl DDG	Dte.GHS,MoHFW
	19.	Dr. Manas Pratim Roy	ADG	Dte.GHS,MoHFW
	20.	Prasanth K. S	Senior Consultant	Public Health Administration, NHSRC
	21.	Dr. Niharika	Consultant(CE), NCS	National Council Secretariat
	22.	Ms.Vasudha Khanna	Consultant	Public Health Administration, NHSRC
	Members of State Council for Clinical Establishments			

23.	Dr. N Lal Sim	State Nodal Officer, CEA	Assam
24.	Dr. Nirmal S. Sidhu	Nodal Officer, CEA	O/o DGHS, Haryana
25.	Dr. Manju Behl	Incharge (CEA)	Chandigarh
26.	Dr. Ram Niwas Meena	Nodal Officer , CEA	Rajasthan
27.	State Nodal Officer	Health Department	Uttarakhand
28.	Dr. Anupama Upadhyaya	SPO incharge of CEA	Himachal Pradesh
29.	Dr.Parkash Daroch,	CMO Bilaspur	Himachal Pradesh,
30.	Dr. S.N. Jha	Nodal Officer, CEA	Jharkhand
31.	Sh. Kaushal Kishore	Joint Secretary, Department of Health	Bihar
32.	Dr. R. Murali	Deputy Director (Public Health) cum-DRA, CEA:	Health Department, Puducherry
33.	Dr.Tasso Kampu	State Nodal Officer, CEA	Arunachal Pradesh
34.	Dr. Baroon, Thotup Targain	State Nodal Officer, CEA	Sikkim
35.	Dr. Lalthlengliani	State Nodal Officer of CEA	Mizoram
36.	Dr. Jigna Patel	State Coordinator	Dadra and Nagar Haveli
Other Participants /Experts			
37.	Ms. Devaki Devi Mandawa	Deputy Director	NABL
38.	Dr. Gayathri	Advisor	NABH

Minutes vetted By:	Ms. Padmaja Singh, Secretary, National Council for Clinical Establishments

Discussion: (Items/Knowledge Shared)

The Secretary of National Council for Clinical Establishments, Ms Padmaja Singh welcomed members of National Council for Clinical Establishments, State Councils and other participants. She informed the members that the National Council has been carrying out important work which has brought about phenomenal success in the area of health regulation in the country. From almost no concept of registration and regulation existing about a couple of decade earlier, today we have come to a stage when healthcare is more organized, standardized and accountable. We now have registration and regulation of health care establishments in almost entire country either in the form of model central Clinical Establishments Act or the States having their own legislation for the purpose.

Objective of the Meeting is to review the work done by the National Council for Clinical Establishments so far and current status of implementation of the Act by the States/UTs and defining

further Roadmap. There are other important specific agenda items which will be discussed today.
Welcoming the participants, Dr Sunil Kumar, DGHS, the Chairman of the National Council remarked that the aim of the Clinical Establishments Act is to improve quality of healthcare in the country. He stated that Quality Health Care is the one which is free from errors (as envisaged through Minimum Standards of facilities and services), is consistent (as envisaged through Standard treatment Guidelines) and that ensures great service (as envisaged through Standard processes and protocols). He further pointed out the Benefits of the Act which include:

- Establishing a comprehensive Digital Registry of clinical establishments which helps in Policy formulation, better surveillance, response and management of outbreak & public health emergencies and engagement with private providers
- Uniform standards of a specific category of clinical establishment
- Bringing in transparency: process of registration and data in public domain.
- Multi stakeholder participation in institutional mechanisms provided under the Act, to arrive at consensus based decisions
- Registration increases patient confidence and improves brand value of Clinical establishment. And the provisions of the Act are a deterrent against quackery and unethical practices.

However as Health is a State subject, the States and district level authorities are mainly responsible for implementing the provisions and guidelines/rules issued under the Act
The agenda of the meeting was adopted by the members unanimously.
A power point presentation was made by Dr Anil Kumar, Addl. DDG (AK) regarding various agenda points. He also gave a brief overview of the provisions and salient features of the Act, its applicability in 11 States (Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, Bihar, Jharkhand, UP, Uttarakhand, Rajasthan, Assam, Haryana and 6 UTs (all except NCT of Delhi and Ladakh). He informed about the various functions to be carried out by National Council as per the Act and also informed that, so far National Council has approved minimum standards for 15 general categories and 34 speciality and super-speciality categories of clinical establishments/departments and all 7 recognised systems of AYUSH. National Council had earlier also approved categorization of clinical establishments, proforma for collection of information and statistics, template of display of rates, a standard template of costing and a standard list of procedures.
MoHFW had invited public comments on the standards other than Labs. The comments received have been compiled and circulated to all participants for their consideration.
Some members pointed out that the Grievance Redressal Mechanism has hardly functioned, especially during the Covid Pandemic both 1st and 2nd waves , Non implementation by the existing norms by many Corporate and private commercial hospitals have created tremendous physical , mental and financial distress . The need for Clinical Establishments to be implemented has only increased and accountability demanded .
For implementation of CEA there is a need for more financial and human resources. This was brought up by one of the State representatives about expectations from the Centre.

Miscellaneous Items:

Decisions Made: (What, Why, Impacts)

After discussions and deliberations, by the National Council members and other participants, the following agenda wise actions were recommended/ decided**:**

1. Action taken report on the minutes of the last meeting was reviewed and it was noted no information has been received in respect of actions which were to be taken by IMA and DCI. As many of the members now nominated are new, so it was decided to take up the matter with respective organization requesting for expediting the actions to be taken by them

(Action: National council Secretariat (NCS), DteGHS)

2. State/UT council representatives were requested again to work out the rates of common procedures and services, as applicable to their State/UT, based on the template of costing and list of procedures as approved by National Council earlier and available on the website of the Act. They may constitute the committees involving experts and stakeholders and take into account local and other factors while working out the rates. They were requested to complete the task expeditiously and submit the same to the Ministry of Health and Family welfare, Government of India at the earliest. After receiving the rates from the States/UTs, the National Council will be in a position to prescribe the range of rates for compliance by the clinical establishments as required under Rule 9(ii) of Clinical establishments (Central Government) Rules 2012.

(Action: State Council, All States/UTs)

3. **Inclusion of provision of mini oxygen plant/PSA plant and norms of oxygen availability as part of the minimum standards for hospitals for implementation under CE Act.**

a. It was agreed that the primary focus should be to ensure availability of Oxygen as per requirement for all the services envisaged to be provided by the hospital. At least one third of total number of beds should be oxygen beds. Atleast 48 hours (preferably 72 hours) of oxygen of the total calculated oxygen requirement of the hospital should be available at any given time, as backup.

b. Oxygen requirement may be calculated as per the ME Division norms of oxygen cylinders based on Oxygen/ICU beds – NRBM/NIV/HFNC/Ventilator Bed capacity in the hospital for management of COVID-19, as mentioned in DO letter dated 21-6-2021 as at Annexure 1

c. Regarding the **"establishment of Mini Oxygen Plants in hospitals and Clinical Establishments having more than 50 beds",** following action points were recommended:

i. Every new clinical establishment/hospital having more than 50 beds may be mandated to install Mini-Oxygen/PSA plants of appropriate capacity and specifications for their registration under Clinical Establishments Act, 2010.

ii. For the existing hospitals having more than 50 beds, a time period of 6 months (desirable) and 1 year (mandatory) may be given for compliance to the condition of installation of Mini-Oxygen/PSA plant.

iii. Accordingly it is recommended that this requirement may be included in the minimum standards for Hospitals and a notification in this regard may be considered to be issued by the MoHFW, as amendment to the Clinical Establishments (Central Govt) Rules under the Clinical Establishments Act, 2010.

iv. The same advice as at points 3C (i), (ii) and (iii) above may be disseminated to the States/UT not covered by Clinical Establishments Act 2010 for enforcement under the respective State Clinical establishments Act or Disaster Management Act.

v. All small hospitals i.e 50 beds or less should also build infrastructure and add capacities to meet their oxygen requirements for the services envisaged to be provided by them, as per the type of the hospital.

(Action (i) to (v):NCS, MS division, MoHFW)

vi. National Health Systems Resource Centre (NHSRC) is carrying out the revision of Indian Public Health Standards (IPHS) under NHM, accordingly they may clearly define oxygen requirements for various categories of hospitals ranging from 50 to 500 bedded in the revised IPHS guidelines. Further NHSRC may define the capacity/specifications of equipment/ Mini-Oxygen/PSA plants to meet the oxygen requirement along with ensuring sustained Oxygen supply in Government Health facilities under NHM as a part of IPHS. They may consider defining the standards separately for difficult/remote/ inaccessible areas, if deemed necessary.

(Action: NHRC and NHM division, MoHFW)

4. Issues related to minimum standards for Medical Diagnostic Laboratories under the Clinical Establishments Act, 2010 (w.r.t suggestions received in respect of inclusion of **PhD genetics and PhD scientists** in minimum standards for Medical Diagnostic Laboratories)

   The Council members were informed that the amended Gazette Notification in respect of Human resource requirements for Medical Diagnostic Laboratories has already been issued on 14-2-2020, which includes provision of MSc and MSc Phd with specified qualification and experience. They are permitted to conduct the tests, generate and sign test reports as authorized signatory for the specified types of tests of their domain area in the specified category of Laboratory, without recording any opinion or interpretation of the test results. All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such. The Gazette notification is available in public domain on the website of the Act. The participants endorsed the same.

5. The National Council approved the **draft of Minimum Standards for Collection Centres,** as finalized by the subcommittee and circulated with the agenda. The same may be submitted to Mohfw for notification.

(Action: NCS, DteGHS and MS division, MoHFW)

6. The National Council considered the **issue of regulation of online health services aggregator and related service providers** under Clinical Establishments Act and their standards etc. It was noted that there is no specific provision for their regulation under the Act

   a. The National Council endorsed the following recommendations of the "subcommittee for drafting standards for collection centre"

   -
     - Public to be made aware of such illegal online health aggregators
     - Need to frame IT / Digital laws/rules to regulate them by the Ministry of Electronics and IT. Ministry of Health and Family may take it up with them and also consult Ministry of Law and Justice in this regard.
     - The online Lab service aggregators and service providers should have a registration number and provide information regarding the lab where the samples are being sent for testing.

   It was noted that a letter has been written by MoHFW to all States and UTs in this regard; however the respective States/UTs are required to take the necessary steps to

regulate them.

b. It was recommended that all online service providers should have a linkage with the registered clinical establishments. Thus only a registered clinical establishment may be permitted to provide online services. MoHFW may issue necessary instructions to States /UTs in this regard. This may be enforced by the District Registering Authority at the district level and the State Council for clinical establishments at State level.

(Action a and b: All State/UT Councils, Ms division, MoHFW)

c. It was approved that a **subcommittee under JS (Padmaja Singh),** the Secretary of National Council may further examine the issue of regulation of online health aggregators in detail in consultation with stake holders and Law ministry, for taking appropriate action in the matter.

(Action: MS division, MoHFW

7. **Inclusion of Additional Charter of patients' rights in minimum standards**-

The National Council for Clinical Establishments **approved for inclusion of the following additional patient rights**, as per NHRC Advisory, in the already approved list of patient rights.

i. **Right to care** according to prescribed rates wherever relevant
ii. **Right to choose source for obtaining medicines or tests**

The hospitals especially corporate hospitals and other clinical establishments should not force the patients to purchase the medicines from the Hospital Pharmacies, and if they are able to get medicines from outside at lower price/cost, that should be acceptable.

Thus, No patient is forced to buy medications from hospital pharmacy. He can choose the pharmacy from where he wants to purchase the medicine.

Similarly if the patient wants to get his tests done from outside, that may be accepted and facilitated by the hospitals or clinical establishments.

iii. Right to **protection and compensation** for patients involved **in clinical trials**, as per Drugs and Cosmetics Act and other Government Guidelines.
iv. Right to **protection and compensation for** participants involved in **biomedical and health research** as per ICMR and other Government Guidelines.
v. **Right to Patient Education**
vi. **Right to be heard and seek redressal:** Every Hospital shall have/establish a time bound Grievance redressal mechanism to address the grievances of the patients. A Grievance redressal officer will be identified by the hospital and his name and contact details will be displayed at a conspicuous place in local language and in English. The records of grievances received and remedial action taken will be maintained. The name and contact details of the district registering authority will also be displayed who may be contacted in case of non-redressal of the grievance of patients to their satisfaction
vii. **Right to proper referral and transfer, which is free from perverse commercial influences**

a. In case of referral by the hospital, the referring hospital will provide proper referral transport

facility in the most appropriate vehicle/ambulance for transfer of patient to the nearest possible hospital where facilities for appropriate and timely management of the condition of the patient, are available.

b. Such transfer of patient will not be refused even if not referred by the treating hospital and even if the patient is leaving against medical advice (LAMA). The applicable reasonable charges may be levied by the Clinical Establishments for such transfers. However, in case of an emergency situation, such referral transport will be provided free of cost as far as possible and will not be refused for want of any payment.
c. State/UT Government may consider to define various charges for different types of ambulance for compliance by the hospitals and other clinical establishments. The Clinical Establishments will be required to display the rates of charges of ambulance(s)
d. The referring hospital shall provide a qualified and trained person to monitor and manage the condition of the patient enroute till the patient is received by the referee hospital

The information about the above additional rights should be widely disseminated by the Ministry and State Governments among **Hospitals, doctors, patients and public so that everyone is aware that the rights exist .**

(Action: MoHFW/NCS/State Councils)

8. **It was recommended t**o include AERB license as part of statutory requirements in the minimum standards as a pre-requisite for issuance of registration under CE Act, wherever applicable. **Further it was approved to i**nclude AERB license in list of documents to be uploaded for grant of permanent registration to the clinical establishments, wherever applicable.

(Action: NCS)

9. Standard Treatment Guidelines of Siddha as received from National Institute of Siddha, Chennai were **approved for issue by MoHFW and may be made available in public domain.**

(Action: MoHFW/NCS)

10. **Patient information sharing by the hospital with the private &/or foreign company.**

It was recommended not to permit the same by the hospitals ordinarily and this will be included as part of process standard for the hospitals. Detail guidelines in this regard may be drafted by National Council Secretariat (NCS) in consultation with the experts.

(Action: NCS)

11. **Ministry may consider to increase** Financial and human resources for implementation of the Clinical Establishments Act at State and district level.

(Action: MoHFW/NHM/NHSRC)

12. Following other Subcommittees were approved for carrying out the specific work:

a. **Subcommittee for Ophthalmology Day care centre:**

Chairman Dr. Rajiv Garg, Prof. of Excellence

(Action: NCS/NPCB division, Dte.GHS)

b. **Subcommittee for drafting Minimum Standards for Day Care Centre**

Chairperson: Joint Chairpersonship of MS of DR RML/SJH to refine, update and finalize the draft.

(Action: NCS/MS SJH and MS Dr.RMLH)

c. **Sub-committee for Point of care testing (POCT)Minimum Standards-**

Chairman: Dr. Sunil Gupta, Addl DG to refine, update and finalize the draft

(Action: NCS/ Dr. Sunil Gupta, Addl DG, Dte.GHS)

d. **Sub-committee for** examining the issue of Inclusion of **Prosthetic & Orthotic Establishment under the Clinical Establishments**

Chairperson: HOD PMR SJH hospital

(Action: NCS/ HOD PMR SJH hospital)

e. **Sub-committee for Drafting Minimum standards of Emergency /Trauma management for healthcare facilities**

Chairperson: Dr. Sunil Kumar, DGHS

Co-Chairperson: Dr Kanwar Sen, Addl.DGHS

(Action: Trauma and Burns division, Dte.GHS)

Some of the Agenda items could not be taken up due to paucity of time, which will be taken up in the next meeting.

The meeting ended with a vote of thanks to the Chair and participants.

Next Steps: (Task, Assigned to, Checkpoint Date)	**Person/ Authority Assigned**	**Due Date**
Follow up Action on the recommendations/decisions of the National Council for Clinical Establishments	Staff of National Council Secretariat Dr. Manas Pratim Roy, ADG	

Annexure-1

2219090/2021/MH-II-DGHS

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN

निपुण विनायक, भा.प्र.से.
संयुक्त सचिव
NIPUN VINAYAK, IAS
Joint Secretary

D.O.No. T-20017/03/2021-NCD (FTS- 8110554)

21st June, 2021

Dear Madam/Sir,

You will appreciate that oxygen cylinders are the mainstay for oxygen delivery in smaller health facilities and also play an important supportive role in bigger facilities. In order to have an indicative norm for estimating their requirement, a Committee of Experts was constituted by the DGHS.

2. The Committee has after due deliberations and consultation with stakeholders submitted such indicative norms for Oxygen cylinder requirement, separately for non-ICU Oxygen beds and ICU beds. These norms will be useful to States/UTs in estimating the requirement of oxygen cylinders and planning accordingly, especially from the point of view of COVID-19 management.

3. A copy of the these Norms is enclosed. States/UTs are requested to take note of the same and take further appropriate action.

With regards,

Yours sincerely,

Nipun Vinayak

(Nipun Vinayak)

Encl: As above.

Additional Chief Secretary/Principal Secretary (Health)
All States/UTs

Room No. 244 'A' Wing, Nirman Bhawan, New Delhi - 110011
Tel. : 011-23061706, 23061398 E-mail : js.me-mohfw@gov.in

Norms for Oxygen cylinders based on Oxygen / ICU beds-NRBM/ NIV / HFNC/Ventilator Bed capacity in the hospital for management of COVID-19

I. Hospitals which has only oxygen cylinders for oxygen therapy

A. Requirement of oxygen for oxygen bed: 10 litres/ minute/ bed

- 15 B type cylinders (capacity of 1500 Litres) OR 3 D type cylinders (capacity of 7000 Litres) (filled) per oxygen bed will be required for 24 hours to provide uninterrupted oxygen for therapy if the cylinders are refilled on daily basis.

- For every one day delay in refilling, a backup of filled 15 B type cylinders OR 3 D type cylinders/ bed /day would be required.

B. Requirement of oxygen for ICU beds-NRBM/ NIV / HFNC/Ventilator: 30 litres/ minute/bed

- D type cylinders (capacity of 7000 Litres) required 7 per day per NRBM/ NIV / HFNC/Ventilator bed if refilling is on a daily basis.

- For every one day delay in refilling, a backup of filled 7 D type cylinder per day would be required.

II. Hospitals which have facility for PSA plant with manifold

- If the hospital has PSA plant (Oxygen generator) connected to the manifold, the back up of cylinders should be available for at least 24 hours, if there is interruption of PSA plant in unavoidable circumstances e.g., Electricity shut down, machine failure, filter replacement etc.

III. Hospitals which has facility for LMO Tanks

- A ratio of 1:6 should be kept when calculating the reserve of Gaseous Oxygen, for every 2 ton daily demand of a hospital set up,a cylinder bank of 33 D type cylinders should be kept.

IV. Others norms

- For ambulance facility 2 B type (capacity of 1500 Litres) of Oxygen cylinders per ambulance will be required.
- There is a requirement of one flowmeter with pressure regulator per bed for both Oxygen & ICU beds.
- A separate dry, well ventilated and lit room away from main area should be available for storage of cylinders.