

Z.28015/91/2011-H/MH II /Vol II
Government of India
Directorate General of Health Services
National Council Secretariat

Nirman Bhawan, New Delhi

Dated: 20th November 2024

Minutes of Meeting

Subject: Minutes of 15th Meeting of National Council held under the Chairmanship of Dr.Atul Goel, Director General of Health Services, on 30th October 2024

The undersigned is directed to forward herewith the Minutes of the 15th Meeting of National Council on above subject held under the Chairmanship of Dr.Atul Goel, Director General of Health Services, on 30th October 2024, 10:00 AM–12:00 PM at 445-A, Resource Center, Nirman Bhawan, New Delhi.

This issues with the approval of competent authority.


20-11-2024

Dr. Ravi Kumar,
Head, Clinical Establishment Division,
DteGHS, MoHFW

Enclosure: **Minutes of 15th Meeting of National Council held dated 30th October 2024**

Copy To,
All the Participants

Copy for information to

1. PSO to DGHS, Dte. GHS, Nirman Bhawan
2. PPS to JS(ERS), MOHFW, Nirman Bhawan

Minutes of 15th Meeting of National Council for Clinical Establishments (NCCE)

Minutes of 15th Meeting of National Council for Clinical Establishments (NCCE) held under the chairmanship of Dr. Atul Goel, Director General of Health Services, on 30th October 2024, Wednesday 10:00 AM – 12:00 PM at 445-A, Resource Center, Nirman Bhawan, New Delhi

The list of participants is at Annexure-I.

The agenda is at Annexure- II

Dr Ravi Kumar, Head of Clinical Establishments Division & Nodal Officer, National Council Secretariat (NCS) welcomed the Chairman and the attendees to the 15th Meeting of the National Council for Clinical Establishments (NCCE). He also gave a brief introduction of the NCS team. He briefly outlined the purpose of the Clinical Establishments Act, 2010 and its significance in setting minimum standards for clinical establishments. He mentioned the agenda of the meeting, including discussing implementation and refinement of the legislation. He encouraged open dialogue, and constructive collaboration, in achieving fruitful outcomes from the discussions.

He highlighted that the NCS is in the final stages of launching the newly developed clinical establishments website and web portal (NCEP 2.0). It was also mentioned that the eight minimum standards for allopathic establishments have been translated into Hindi and will be gazetted by the Ministry at the earliest possible.

After welcome and introduction, DGHS highlighted the importance of 15th meeting of National Council for Clinical Establishment emphasizing its pivotal role in addressing key issues related to the Clinical Establishments Act, 2010 and its implementation. The members of National Council, State Council and other participants were invited to actively engage and share their perspectives on the agenda items scheduled for discussion.

Agenda Point I: A brief presentation was given on the Clinical Establishments Act, highlighting the National Council, its composition, and its role in providing technical input and periodically monitoring the Act's implementation. It was noted that 15 States/UTs have already implemented the Act, while 4 States/UTs are in the process of doing so. The committee members were given a preview of the new version of the website and portal. It was mentioned during the meeting that the Clinical Establishment 2.0 website will be launched shortly and will be accessible to all users.

Agenda point II: Discussion on matters related to CE Act

1. Inclusion of Members from the National Commission for Allied and Healthcare Professions Act, 2021 (NCAHP)

It was informed that a meeting was held with Chairperson, NCAHP on 5th September 2024, regarding the inclusion of Members from the NCAHP, wherein the NCAHP proposed having two representatives from healthcare and one representative from allied

health professions to be included in the National council for Clinical Establishments which would require an amendment to the Clinical Establishments Act, 2010.

This proposal was presented to the NCCE members for their inputs/comments. Some members expressed that three representatives might not be necessary, noting that other councils, such as the Dental Council, Medical Council, Nursing council, Pharmacy council and Indian Medical Association, are represented by only one member each. They suggested that the Chairperson of the NCAHP could represent all allied and healthcare professions, and one member would be sufficient.

The DGHS pointed out that the council does not include subject experts as members but invites them to participate in Sub-committees as needed. It was also noted that the current composition of the council includes members based on organizations rather than specific professions. The NCAHP representatives could be called as special invitees when matters related to their professions are discussed.

Additionally, the NCAHP may nominate their members to the sub-committees tasked with establishing minimum standards for Clinical Establishments, specific to their professions as required.

The Joint Secretary emphasized that representation from all professional groups may not be feasible and agreed that having one representative would be sufficient to participate and communicate outcomes to others.

Members were asked to send their feedback or opinions in the above-mentioned matter via email to the official CE mail address (help.ceact2010@nic.in), including their reasoning if applicable.

It was also mentioned that since the NCAHP is statutory body for all the allied and healthcare professions, the NCAHP by statute will be managing all legal and regulatory aspects for its allied and healthcare professions. Further, NCAHP will also provide advisories to the Clinical Establishments division on matters concerning these professions.

Other points related to NCAHP were presented to the NCCE for their feedback and comments.

- a. The matters related to the Physiotherapy profession will be overseen by NCAHP, as physiotherapy does not fall under the CE Act of 2010.
- b. Regarding the request of NCAHP for inclusion of member of NCAHP in multi-member Inspection Team mentioned in the CE Act, it was clarified that currently, the District Regulatory Authority under the CE Act has a team that conducts inspections, after which a license is issued to the Clinical Establishment (CE). However, it was mentioned that it is within the jurisdiction of the state to define the members of the multi-member inspection team. While the Directorate can suggest to the States/UTs

council regarding NCAHP's request, but this can only be implemented if NCAHP has councils established in the state. Once that is in place, the state council can make a decision and provide their input.

- c. DDG AYUSH, suggested that when inspecting a particular clinical establishment, a doctor from the relevant profession should be included in the inspection team. However, the DGHS clarified that it would be impractical to have representatives from every profession, such as dentistry, nursing, and pharmacy, on the team. Instead, the state council, once established, could be put in charge of overseeing the inspection team, and a member from the state council could participate in the inspections.
 - d. The DGHS further explained that the composition of the state council, as outlined in the Act, includes members such as the Secretary of Health, the Director of Health Services (DHS), representatives from various streams of the Indian system of medicine, and members from the medical, nursing, AYUSH, pharmacy and dental councils.
 - e. It was suggested that “State council from the allied and health professions” could be added in the composition of the State council as an amendment in the CE Act. The NCAHP and AHS division was requested to confirm whether the paramedical term be replaced with the Allied And healthcare professions.
 - f. Additionally, it was suggested that member representing the Rehabilitation Council of India (RCI) can be included as well in the National Council.
 - g. Regarding involvement of NCAHP in the State council, the CE division can communicate the same officially to MoHFW which would require amendments in the CEA act.
2. Representations from Medical laboratory Technologists Associations regarding authorised signatory authority.

The NCAHP emphasized that medical laboratory technologists (MLTs) are included among the listed professions under the NCAHP. During the meeting with the NCAHP, it was agreed that all regulatory and legal matters concerning allied healthcare professions, such as MLTs, will be managed by the NCAHP. The Chairperson of the NCAHP informed that they are in the process of establishing a professional council for MLTs.

The DGHS proposed that a letter be sent to the representatives of the MLT association, informing them that the matter has been taken up by the NCAHP.

Once the NCAHP rules are established on the matter, the Clinical Establishments (CE) will adopt them accordingly.

It was suggested that till the time NCAHP make their rules and regulations w.r.t MLT matters, the ministry of MOHFW may consider issue of bringing the Abeyance of

Signatory Authority of Basic Composite laboratories in Clinical Establishments (Central Government) Rules, 2020.

The NCCE members agreed for the consideration of the above-mentioned Abeyance subject to approval by the ministry.

It was also reiterated that any signatory authority who may get provision under above-mentioned abeyance if agreed upon must be provisional, without any interpretations or opinion of laboratory results and the reports are strictly for the use of medical practitioners and are not medical diagnosis as such. The signing authority will be legally liable for the signature on the lab report and put full name and signature, registration number with mentioning the “provision report” on the lab report.

3. Representations from NATHEALTH for inclusion in the NCCE as a member

NATHEALTH, a conglomerate of private hospitals, diagnostic centres in India have expressed interest in becoming a member of the NCCE. However, it was also noted that there are multiple organizations representing the private sector, they may all seek membership. To address this, it was proposed that membership could be rotated annually, with amendment in the CE Act.

4. Representations from ABDM NHA for incorporating guidelines for generation and sharing of the Specified Health Records

Representatives from the ABDM and NHA have proposed incorporating guidelines for the “generation and sharing of Specified Health Records” in Rule no 9 of CE Act. According to Rule 9 of the Clinical Establishments Act, 2010: "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 State government, as the case may be, from time to time.

The NHA's aim is for clinical establishments with digital health records to share them with the NHA through the provisions of the CE Act, enabling integration with the ABDM. The NCCE members raised no objections to this proposal.

5. Representations from MDS Oral Pathologists and Microbiologists Association

This is regarding recognition of M.D.S. (Oral Pathology and Microbiology) postgraduate degree holders as Authorized Signatories in the minimum standards for medical diagnostic laboratories under Clinical Establishments (Central Government) Rules, 2012.

The DGHS clarified that these degree holders would be permitted to sign only oral pathology and oral histopathology tests, restricting their authority to their specific field of expertise. An amendment in the CE Act, 2010 would be required to implement this, ensuring that the scope does not extend beyond their domain.

6. Regarding the signing of all the lab reports, it was decided that a full signature is required. A signature using only a single capital letter or initials is not valid. The report must include the complete signature of the signing authority, along with their name and qualifications.
7. Representation from Hon'ble Deputy CM of Uttar Pradesh

The representation mentioned that the stringent standards of the Clinical Establishments Act pose challenges for relatively small private hospitals, making it difficult for them to complete their renewal processes and causing ongoing concerns about potential legal actions. It was proposed that these hospitals could adhere to the standards set for hospital empanelment under the Ayushman Bharat Pradhan Mantri Jan Arogya Yojana.

The council agreed that standards established by NCS must be maintained and should not be compromised. There should be no dual standards. It was decided that a letter should be sent to the NHA, requesting that they refrain from empaneling hospitals that do not comply with the minimum standards set by the CE Act.

8. Amendment in the CE Act related to Physiotherapy matter

The proposed Amendment in Section 2(c)-(e):

a single doctor **or any other professional defined under the National Commission for Allied Health Professionals Act, 2021 may be allowed to run a clinical establishment in compliance to minimum standards prescribed under the CE Act**

NCAHP Acknowledged the same.

9. The representative from Uttar Pradesh suggested that in the State council if “elected /nominated” be added to the composition, to which council approved. He also raised some queries regarding the requirements for a Fire NOC for small private hospitals. It was clarified that in cases where a Fire NOC is not available in small establishments, clinical establishments must ensure comprehensive fire safety measures. These include having a fire preparedness plan, a clearly displayed evacuation plan, trained staff capable of handling emergencies, conducting regular fire safety audits, and maintaining essential fire safety equipment. These measures are intended to enhance the safety and readiness of small private hospitals in dealing with potential fire emergencies.

The certificates for NOC (Fire Safety), Pollution Control, Biomedical, etc., should be obtained in accordance with state bylaws and regulations.

The representative from Lucknow, Uttar Pradesh, was advised to compile all challenges and doubts and submit them via official mail. This would allow for thorough consideration and deliberation, enabling the council to revisit and address these concerns in subsequent meetings.

10. The representative from Pharmacy Council of India made a presentation regarding doubts on pharmaco-vigilance and clinical trials. The DGHS clarified that these are overseen by ICMR and CDSCO, while pharmaco-vigilance is handled by the Indian Pharmacopoeia Commission.

Agenda point III: Updates on Minimum standards

1. The twenty-three minimum standards (including AYUSH) have been approved by NCCE and are currently in the process of being gazetted.
2. Seventeen minimum standards have been translated into Hindi. Both the Hindi and English versions of the standards will be sent to the Secretary for approval, and the gazette notification will follow shortly.
3. The minimum standards for physiotherapy have been prepared and will be shared with NCAHP for review and finalisation.
4. The minimum standards for Mortuary & Post-mortem facilities and AYUSH wellness centers were submitted for approval. The DGHS has suggested to all members for review and send their feedback for the same within a week via email to the official CE mail address (help.ceact2010@nic.in).
5. Proposed Minimum Standards:
 - i. Dialysis Centers
 - ii. Blood Banks
 - iii. Infertility Clinics
 - iv. ART (Artificial Reproductive Techniques) Centers
 - v. CE Guidelines for Online and Social Media Activities
 - vi. Guidelines for Establishment of Standardized healthcare testing Packages
 - vii. Standards for Integrated Setups (AYUSH and Allopathic)

Suggestions are invited for the logo and name of the Clinical Establishments Act website via email to the official CE mail address (help.ceact2010@nic.in).

Annexure-I**List of Participants**

The 15th meeting of National Council for Clinical Establishment under the Chairmanship of Dr. Atul Goel, DGHS on 30/10/2024, 10:00 A.M onwards in the Resource Centre, Room No. 445-A Wing, Fourth Floor, Nirman Bhawan, New Delhi

S.no	Name with Designation	Organization/State/UT	E-mail id
1.	Dr Atul Goel DGHS	DGHS	dghs@nic.in
2.	Dr Ravi Kumar Consultant (DDG) –DGHS	DGHS	dr.kumarravi@gov.in
3.	Elangam Robert Singh Joint Secretary, MoHFW	MoHFW	Robert.elangam@gov.in
4.	Mrs. Shalaka Kujur Joint Director (AHS Division)	MoHFW	shalaka.kujur@nic.in
5.	Dr. Yagna Shukla Chairperson, NCAHP	NCAHP	yagnashukla@yahoo.com
6.	Dr. A. Raghu DDG (Ayush)	Ayush Vertical, DGHS	a.raghu@nic.in
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8.	Dr. V K Monga Chairman	IMA	drvkmonga@yahoo.com
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10.	Sh. Vinay Gupta Deputy Secretary	Dental Council of India	gupt_vin@yahoo.co.in
11.	Sh. Anil Mittal Registrar-cum- Secretary	Pharmacy Council of India	registrar@pci.nic.in
12.	Dr. Mohammad Mazahir Alam Member, Board of Ethics & Registration	NCISM	mazahiralam532@gmail.com
13.	Dr. Suryakiran P. Wagh Member, NCISM	NCISM	suryakiran_wagh@rediffmail.com
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15.	Dr. S.K katharia Former EC Member	Dental Council of India	katharia_sk@yahoo.com
16.	Sh. Anil Jauhri Ex-CEO, NABCB	Voice	jauhriani@gmail.com
17.	Mr. Sween Samuel Sr. Consultant, NCAHP.	NCAHP	sweensamuel@gmail.com
18.	Dr Narayan Jadhav NCISM	NCISM	member.berison1@ncismindia.org
19.	Dr S.Mathu kumar Member, NCISM	NCISM	member.buss1@ncismindia.org
20.	Dr. Siddalingesh M. Kudari Member, NCISM	NCISM	member.berison@ncismindia.org

21.	Dr Avijit Basu Additional Director of Health Services, DHS Guwahati, Assam	DHS, Guwahati, Assam	dr.b.avijit@gmail.com
22.	Pankaj Johri Director, NABL	NABL	pankajjohri@nabl.qcin.org
23.	Shweta Sinha Deputy Director, NABL	NABL	shweta@nabl.qcin.org
24.	Dr. Umesh D. Suranagi Professor	DGHS	ud.suranagi@lhmc-hosp.gov.in
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26.	Ms. Raj Preeti, Consultant IT	DGHS	ncsrajpreeti@gmail.com
27.	Mr. Shashi Shekhar Singh, Consultant IT	DGHS	ncsshshishshekhar@gmail.com
28.	Mrs. Anuradha, Statistical assistant	DGHS	ncscea.anu@gmail.com
Online Participants			
29.	Dr Navjot State Nodal officer, CEA Haryana	Haryana	sc.haryana-dra@nic.in
30.	Dr Birender Kumar Singh State Nodal Officer, Jharkhand	Jharkhand	Sc.jharkhand-dra@nic.in
31.	Rahul Kumar Singh State Coordinator, CEA, Jharkhand	Jharkhand	ceajrhms1@gmail.com
32.	Dr Shipra Pandey Joint Director Medical Care and Nodal Officer CEA	Uttar Pradesh	director.medical.care.up@gmail.com
33.	Dr S. Chitra Devi Project Director (Aids) Cum State Coordinator	Puducherry	cea2010pdy@gmail.com
34.	Ms. Neelathachi. Admin Assistant CEA Pudducherry	Puducherry	cea2010pdy@gmail.com
35.	Dr Md. Imran Khan	Lucknow	
36.	Dr Syed Belal Hassan	Lucknow	
37.	Vaidya Santosh Nevpurkar Member, National Council for Clinical Establishment Delhi	Delhi	nevpurkarsantosh@gmail.com
38.	Asha Sharma Former Vice President, INC	Indian Nursing Council	asha3547@yahoo.co.in
39.	Dr. C. Vanlalhriatchhungi, State Level Coordinator, CEA, Mizoram	Mizoram	ceamizoram@gmail.com
40.	Dr. T. Targain, Joint Director, Sikkim	Sikkim	thotuptargain789@gmail.com
41.	Representative, Arunanchal Pradesh	Arunanchal Pradesh	
42.	Representative, DG Health, Uttarakhand	Uttarakhand	
43.	Representative, DHS, Ladakh	Ladakh	
44.	Representative, Dadra and Nagar Haveli	Dadra and Nagar Haveli	
45.	Representative, Jharkhand	Jharkhand	
46.	Representative, Himachal Pradesh (DHSR)	Himachal Pradesh	
47.	DHS-cum-MD NHM, UT Chandigarh	Chandigarh	
48.	Dr. Sunita Tamta, Director, Health	Uttarakhand	

15th Meeting of National Council for Clinical Establishments (NCCE)

445-A, Resource Center, Nirman Bhawan, Delhi
30th October 2024, (10:00 AM - 01:00 PM)

Agenda

Particular	Time	Facilitator
Welcome Address	10:00 am – 10:05 am	Dr Ravi Kumar, Consultant (DDG), Nodal officer- NCS Dte.GHS
Opening Remarks	10:05 am – 10:10 am	Dr Atul Goel, Director General of Health Services MoHFW
Agenda Point I : Updates on CEAct, 2010 implementation including the Amendments (if any) in the CEAct	10:10 am – 10:30 am	Dr Umesh Suranagi, Professor, NCS Dte.GHS
Agenda Point II : Discussion of matters related to implementation of CEAct	10:30 am- 11:30 am	Dr Bhawna Gupta, Consultant CE division
Agenda Point III : Update on minimum standards under CEAct	11:30 am – 12:00 pm	Dr Bhawna Gupta, Consultant CE division
Concluding Remarks	12:00 pm – 12:15 pm	Dr Umesh Suranagi, Professor CE Division
Vote of Thanks	12:15 pm-12:20 pm	Dr Ravi Kumar, Consultant (DDG), Nodal officer- NCS Dte.GHS
Lunch (12:20pm -01:00pm)		