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Ministry of Health and Family Welfare

Nirman Bhawan, New Delhi. 20th October 2015 Dated:

MINUTES OF MEETING

The minutes of 7th meeting of National Council for Clinical Establishments held under the Chairmanship of Dr. Jagdish Prasad, DGHS on 18th September 2015 at Nirman Bhawan, New Delhi are sent herewith for information and necessary action.

> (Dr. Tarsem Chand) Joint Secretary

To

- All participants including members of National Council as per the list annexed.
- Other Members of the National Council for Clinical Establishments
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 - (ii) President, Medical Council of India, Pocket 14, Sector 8, Dwarka, New Delhi-77
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 - (v) Dr. K Reddemma, Dean, Behaviral Sciences, Department of Nursing, National Institute of Mental Health and Neuro Sciences, Bangalore
 - (vi) Dr. T K Ravi, Principal, College of Pharmacy, Sri Rama Krishna Institute of Paramedical Sciences, 395 Sarojini Naidu Road, Coimbatore, Tamil Nadu-641044
 - (vii) Advisor (Planning), North Eastern Council, Ministry of Development of North Eastern Region, North Eastern Council Secretariat, Nongrim Hills, Shillong-793003
 - (viii) Sh. Ashim Sanyal, Voice Society, O-45, Lajpat Nagar II, Ring Road, New Delhi

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- 2) Secretary, Dental Council of India
- 3) Registrar-cum-Secretary, Central Council for Indian Medicine
- 4) Secretary, Indian Nursing Council
- 5) Secretary, Central Council of Homoeopathy
- 6) PPS to DGHS
- 7) PPS to JS (TC)

Minutes of Meeting

The 7th Meeting of National Council for Clinical Establishments was held under the Chairmanship of Dr. Jagdish Prasad, DGHS on 18th September, 2015 at Nirman Bhawan, New Delhi. The objective of the meeting was to finalise/approve all preparatory material for starting permanent registration in the implementing States/UTs. The soft copies of following draft documents were distributed in advance to all the members and other invitees and hard copies were distributed during the meeting.

- 1. Categories of Clinical Establishments
- 2. Application Form for Permanent Registration
- 3. Certificate of Permanent Registration
- 4. Information & Statistics to be collected from Clinical Establishments
- 5. List of Medical Procedures
- 6. Template of Costing of Procedures
- 7. List of Recognised Qualifications of person incharge of Clinical Establishments
- 8. Minimum Standards (General) of Clinical Establishments
- 9. Minimum Standards of Specific speciality/super speciality clinical departments/establishments
- 10. Annexures for Hospital and Clinic and Dental Clinical Establishments
- 11. Minimum Standards of AYUSH (all 7 systems) Clinical Establishments.

After welcome and introduction of participants, the Secretary of the Council, Dr. Tarsem Chand, informed that although the Sub-Committees of National Council were working and holding meetings, but meeting of National Council may be held on time. Some of the Sub-Committees have taken a long time for completion of the task. National Council has been given specific timeframe for completing the assigned tasks and therefore may consider reconstituting the sub-committee, if unreasonable delays are happening. The NIC has also appointed man power for management of website of Clinical Establishments Registration and Regulation (CERR) Web portal which should also be closely monitored by National Council Secretariat. Status of online and offline registration should be reported to National Council as a separate agenda item. Issue of payment gateway may be resolved by NIC at the

earliest. He also expressed concern about less utilisation of funds under CEA.

The minutes of 6th meeting of National Council were confirmed.

CMO (AK) made a presentation on the Action Taken report and informed following:

- 1. Comments were invited from members and implementing states on the permanent registration application form and the draft as circulated has been finalized based on that.
- 2. The categorization has been finalized based on minutes of last meeting.
- 3. Draft of minimum standards for Trauma care facilities was received from programme division and circulated to members. AYUSH informed that medical spa is not covered under purview of AYUSH.
- 4. Draft Minimum Standards after obtaining comments from public, states and other stakeholders were reviewed by subcommittee of Minimum Standards and chairman of each subject subgroup. Professional association of each speciality/super speciality subject and Indian Medical Association (IMA) were also consulted. The comments as received were shared with expert groups who further updated the drafts and the final draft are as circulated to National Council.
- 5. Draft Master List of procedures and template of costing has been prepared and circulated.
- 6. Physiotherapy as allied health profession has been included in categorization.
- 7. Instructions were issued to implementing States/Union Territories for allowing only clinical establishments of recognised system of medicine to be registered and not to consider unrecognised system like electropathy and electro-homoeopathy etc
- 8. An advocacy cum training workshop was held in the State of Rajasthan chaired by Hon'ble State Health Minister.

He informed the following status of implementation of the Clinical establishments Act (CEA) and health regulation in the country:

1. States and UTs where the CEA is applicable (15):

Himachal Pradesh, Sikkim, Mizoram, Arunachal Pradesh, Bihar, Jharkhand, Uttar Pradesh, Uttarakhand, Rajasthan and all UTs except Delhi.

- 2. States which have their own legislation, listed in schedule to the Act, to which provisions of CE Act (9) do not apply:
 - Andhra Pradesh, Maharashtra, Delhi, Madhya Pradesh, Manipur, Nagaland, Punjab, Orissa, West Bengal
- 3. Other States which have their own Act (6): J&K, Goa, Chhattisgarh, Karnataka, Tamil Nadu (not implemented), Assam (Not implemented)
- 4. **Kerala, Gujarat, Punjab, Haryana & Meghalaya (5)** are in the process of enacting legislation on the lines of central act with modifications
- 5. **Maharashtra, Goa & Delhi (?)** are in the process of repealing existing legislation & enacting one on the lines of CEA with modifications.

Status of Implementation of the CEA by above mentioned 15 States/UTs where the Act is applicable:

- 1. Notification of State Rules: All 15 except State of U.P. and Union Territories of Chandigarh and Lakshadweep
- 2. Notification of State / UT council: All 15 except U.P. and Chandigarh
- 3. Notification of District Registration Authorities: All 15 except **U.P.**
- 4. **Online registration functional** in Himachal Pradesh, Jharkhand and UT of Andaman & Nicobar Islands, Daman & Diu, Rajasthan and Chandigarh (> 7300 clinical establishments registered)
- 5. **Offline registration started** in Sikkim, Arunachal Pradesh, Puducherry, Dadar and Nagar Haveli, Mizoram & Lakshadweep. (822 clinical establishments registered)

The Chairman of the Council, DGHS stressed on the following point:

Delhi is a model to which other States and UTs look forward to. It is important that Delhi should adopt Clinical Establishment Act by repealing the existing Delhi Nursing Home Registration Act for provision of better health care to the citizens. Most of the States who have adopted the Act

but have not taken the actions that are required for implementing it properly.

IMA representative, Dr. S.S. Aggarwal raised following objections about the Act:-

- i) Regarding the composition of District Registering Authority, he objected to the presence of police, District Magistrate and NGO in the District Registering Authority and wanted that IMA representative must be a mandatory member of District Registering Authority as they have presence in every district.
- ii) They have objection to minimum standards and standard treatment guidelines as mandatory requirements for clinical establishments.
- iii) IMA representative opined that it would be difficult to prevent online registration of unqualified persons and even if documents are obtained from them they cannot be verified.
- iv) They want single doctor clinics and smaller nursing homes to be exempted from registration under the Act.
- v) IMA was also of the view that there is no provision of prosecution of the quacks under the Act as only the fine will not act as deterrent.

DGHS emphasised that Minimum standards are required for proper healthcare and they are specific for specific category of clinical establishments. DGHS pointed out that Clinical Establishment Act is important for policy and planning in the State; however the State may have flexibility in the standards for different categories of clinical establishments. The State may also be allowed to have its own rates. However, the Chairman emphasised that regulation of the rate is important as lot of Government funds are paid to corporate sector hospitals for reimbursement of medical bills of Government employees.

CMO (AK) informed that Act gives flexibility to the state to decide different dates of implementation of the Act for different categories of Clinical Establishments and for different systems of medicines. The representative from the Chandigarh pointed out that the categorisation has not included the beds in the Clinical Establishments. The Chairman stated that it is because of the changing scenario in the country where the level of facilities

is not related to the number of beds as even a small hospital having 10-15 beds may have advance cardiac/neurology etc. facilities. Regarding the general hospitals, no. of beds is already included for example, in CHC Subdistrict and District Hospitals. If required the state may sub-categorise clinical establishments based on the no. of beds.

DGHS pointed out that initially we are doing only provisional registration just to know the number of practitioners in the area who are required to be regulated. At the time of Permanent registration, the document verification will be done and there will be provision of uploading documents/photos. Every new clinical establishment will be required to apply for permanent registration within a period six months from the date of notification of standards.

IMA representative said that permanent registration may be started soon and we may not wait for six months. CMO(AK) informed that six months is the time given in the Act.

Dr. Rajesh Narwal from WHO informed that with concurrence of the Ministry, a study is being conducted by NIHFW supported by WHO, the preliminary findings of the study indicate the following issues in non-adoption/non-implementation of the Act:-

- i) There is resistance from the private sector
- ii) There is fear of minimum standards among the medical Associations and they are afraid that small clinics and nursing homes may not be able to meet minimum standards.
- iii) Fixation and display of the rates. While most agree to display of rates but they vehemently oppose fixation of charges.
- iv) He informed that corporate sector clinical establishment has no issue with the Act accept resistance to the fixation of rates.
- v) The opinion is divided regarding maintenance of Electronic Medical Records and compliance to standard treatment guidelines. The Chairman of the National Council stated that Standard Treatment Guidelines are guidelines for practitioners and also to avoid unnecessary treatment and investigations. The guidelines may not be followed upto

- 100% but there should also not be deviation in treatment to the extent of more than 20%.
- vi) Making the stabilisation mandatory under the Clinical Establishment Act is also being resisted by the clinical establishments as it may mean a huge expenditure on the part of the Clinical Establishment. The Chairman of the National Council stated that the purpose of stabilisation clause is that if the facilities are available in a particular category of clinical establishment as indicated by the minimum standard for that category, the treatment should not be denied and after stabilisation the patient may be shifted to other/referral/Government clinical establishment.

The IMA representative also pointed out that as per the Act the data of a clinical establishment applying for a permanent registration is required to be put up in public domain for inviting objections, if any. This should not be implemented as clinical establishments may make false complaints against other clinical establishments. Mr. Prashant from NHSRC pointed out that this provision is required for maintaining transparency.

Delhi Government representative Mr. Hashmi, Special Secretary, who participated as observer in the meeting commented that clinical establishment act has good provisions for registration and regulation of clinical establishments including treatment of emergency cases. It is good to know that price regulation is also covered under the Act and it may be possible to link the Act with the EWS scheme being implemented by Delhi Government.

IMA stated that self-regulation for the practitioners is required and they have no problem in display of the rates. IMA representatives were specifically asked about their comments on categorisation, minimum standards, application format and other draft document that have been circulated to the members. They offered no comments except again repeating the objections to the Act which they want to be resolved first before proceeding in the matter further. However, the Chairman and other Council members requested IMA to send comments, if any on the draft documents within next week to which they agreed. If no comments are received, then the drafts will be taken as approved as all other National

Council members agreed. They were advised that their objections to the Act will be dealt separately as it is not within the mandate of the National Council. They said that the rates may be worked out internally and rationally and cost involved may be calculated by the clinical establishments themselves. This rate may be displayed or made available by the clinical establishment in the form of a printed document.

Dr. Ramji Singh from CCH objected to the certain provisions in the minimum standards of Homeopathy. He was requested to send his objections in writing to the National Council Secretariat within a week to 10 days so that corrections, if required, may be carried out and submitted for approval of Chairman of the Council. If no comments are received, then the draft minimum standard for Homeopathy shall also be taken as approved.

Dr. Mira Shiva opined that maximum rate of a procedure and a service is important to consumers and no lobby should block it. IMA strongly objected to Government determining the range of rate of a procedure. Further Dr. Mira Shiva stated that cases of overcharging or exploitative charging by the clinical establishments are rampant and there is a need to regulate unethical practices. IMA representative stated that IMA has no problem to take care of the patients interest and they would be first to take up issues related to exploitation by clinical establishments.

The Council members were of the view that there are many factors like volume of procedures to be done, location of clinical establishments, experience of doctors which determine the cost so it was recommended that instead of defining the upper ceiling of a cost, the standard procedure cost of a procedure may be defined and it may be best determined by the states/UTs themselves taking into account the local factors.

The Chairman invited comments from the members from the states. Mr. Piyush Singh, from the Govt. of Maharashtra informed that they are in the process of having their own act. The North Eastern Council member was requested that next meeting of National Council may be organised by the North Eastern Council and Nagaland may be a good option.

In conclusion, following actions were decided:

- (1) The National Council approved the following documents:
 - i) Categories of Clinical Establishments
 - ii) Application Form for Permanent Registration
 - iii) Certificate of Permanent Registration
 - iv) Information & Statistics to be collected from Clinical Establishments
 - v) List of Medical Procedures
 - vi) Template of Costing of Procedures
 - vii) List of Recognised Qualifications of person incharge of Clinical Establishments
 - viii) Minimum Standards (General) of Clinical Establishments as listed under:
 - 1. Clinic or Polyclinic: Only Consultation, With Dispensary, With Diagnostic Support and With Observation facility
 - 2. Mobile Clinic: Only Consultation, With Procedures and Dental Mobile
 - 3. Hospitals: Level 1 to 3
 - 4. Health Check up Centre
 - 5. Dental Lab
 - 6. Physiotherapy
 - 7. Dietetics
 - 8. Integrated Counseling Centre
 - ix) Minimum Standards of Specific speciality/super speciality clinical departments / establishments
 - 1. Anaesthesiology
 - 2. a. Paediatrics (Hospital) b. Paediatrics (Clinic)
 - 3. Burn Care Facility (Hospital)
 - 4. a. Plastic Surgery(Hospital) b. Plastic Surgery(Clinic)
 - 5. a. Cardiology(Hospital) b. Cardiology Services(Clinic)
 - 6. Dental Set Up a. Stand Alone b. Hospital Set Up
 - 7. a. Dermatology (Hospital) b. Dermatology (Clinic) c. STD Clinic
 - 8. a. Gastroenterology (Hospital) b. Gastroenterology (Clinic)
 - 9. a. General Surgery(Hospital) b. General Surgery(Clinic)
 - 10. a. Neurology (Hospital) b. Neurology (Clinic)

- 11. a. Neurosurgery (Hospital) b. Neurosurgery (Clinic)
- 12. a. Gynae and Obstetrics Indoor Services (Hospital) b. Gynae and Obstetrics (Clinic) c. IVF Centre /Clinic (ICMR Norm)
- 13. a. Orthopaedic(Hospital) b. Orthopaedic Services (Clinic)
- 14. a. Otorhinolaryngologyb. Otorhinolaryngology (Clinic) c. Deaf And Dumb Clinic
- 15. a. Psychiatry Services (Hospital) b. Psychiatry Services (Clinic)c. Deaddiction Centre
- 16. a. Ophthalmology (Hospital) b. Ophthalmology (Clinic)c. Optometrist Services
- 17. a. Urology (Hospital) b. Urology Services (Clinic)
- 18. Dialysis Centre
- 19. a. CTVS (Hospital) b. CTVS (Clinic)
- 20. Radiotherapy
- 21. Medical Diagnostic Laboratories
- 22. a. Imaging Centers X-Ray Clinic / Cathlab / DSA / OPG and Dental / DEXA Scan
 - b. Imaging Centers Sonography (Color Doppler) Clinic
 - c. Imaging Centers CT Scan Center / PET CT Scan
 - d. Imaging Centers MRI
- 23. a. Rheumatology b. Rheumatology Clinic /Polyclinic
- 24. a. Pulmonology b. Pulmonology Clinic
- 25. a. Medical Oncology /Clinical Haematology b. Medical Oncology /Clinical Haematology Clinic /Polyclinic
- 26. a. Gynae Oncology b. Gynae Oncology Clinic/ Polyclinic
- 27. a. Surgical Oncology b. Surgical Oncology Clinic / Polyclinic
- 28. a. Neonatology Clinic b. Neonatology
- 29. a. Paediatric Surgery b. Paediatric Surgery Clinic Polyclinic
- 30. Palliative Care
- 31. GI Surgery a. Hospital b. Clinic
- 32. Endocrinology a. Hospital b. Clinic
- 33. PMR clinic
- 34. Nephrology a. Hospital b. Clinic
- 35. Medicine and geriatrics a. Hospital b. Clinic
- x) Annexures for Hospital & Clinic and Dental Clinical Establishments

- xi) Minimum Standards of AYUSH (all 7 systems, namely Ayurveda, Unani, Siddha, Homoeopathy, Yoga, Naturopathy and Sowa Rigpa) Clinical Establishments.
- (2) Draft Minimum standards for Trauma care facilities and stem cell to be further worked upon through consultative methods and finalized.
- (3) There is no need to develop minimum standard for medical spa for the time being.
- (4) States may be advised to define "standard procedure cost" in respect of the list of procedures prepared by the sub-committee of National Council and any other procedure if so, decided by the state council and using the template of costing as approved by National Council as far as possible. The information on standard procedure cost should be available to the stakeholders and general public. The Clinical establishments may be permitted to have their own costs but there should not be extreme deviations from the standard procedure cost.
- (5) Regional/State advocacy and awareness meetings about the Act, Rules, Minimum Standards, Standard Treatment Guidelines etc. may be organised in different parts of the country for various stakeholders in collaboration with the states and involving regional directors of health and family welfare.
- (6) Continuing Medical Education Programmes may be organised in all 15 implementing States/UTs.
- (7) WHO representative was requested to get the study on CEA expedited and share the findings of the study with National Council members.
- (8) Road Map for further action will be as under:
 - Notification of Minimum Standards
 - Digitalization of Application Formats and Statistics Formats by NIC
 - Operational Plan for implementing states to be formulated
 - Receiving documents from Clinical Establishments along with application form for permanent registration
 - Starting Permanent Registration in the implementing states
 - Start quarterly collection of Statistics
 - Identifying Gaps in Standard treatment Guidelines and Minimum Standards and drafting the same.

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

ATTENDANCE SHEET

7th Meeting of National Council for Clinical Establishments held under the chairmanship of Dr. Jagdish Prasad, DGHS on 18-09-2015 in the Resource Centre Room No- 445A, 4th Floor, Nirman Bhawan, New Delhi

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