

#### Foreword

The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribing the minimum standards of facilities and services provided by them.

The Ministry has notified the National Council for Clinical Establishments and the Clinical Establishments (Central Government) Rules, 2012 under this Act vide Gazette notifications dated 19th March, 2012 and 23rd May, 2012 respectively.

The National Council had constituted a Sub-Committee on "Categorization & Classification of Clinical Establishments under the Clinical Establishments (Registration and Regulation) Act, 2010. The said committee met on 3<sup>rd</sup> and 4<sup>th</sup> October 2013 at JSS University, Mysore, and discussed the subject matter.

The committee taking into account the clinical establishments from the public and private sectors, of various recognized systems of medicine and allied health health services have made recommendations to the National Council on the categorization and classification of clinical establishment.

The committee thanks the Council and the Ministry for providing the said opportunity.

Dr. B Suresh Chairman Minutes of the Sub-committee meeting on "Classification & Categorization" with regard to implementation of Clinical Establishments (Registration & Regulation) Act, 2010, held on 3<sup>rd</sup> and 4<sup>th</sup> October 2013 at JSS University, Mysore.

## Members Present

- 1. Dr. B Suresh, Vice Chancellor, JSS University, Mysore (Chairman)
- 2. Sri Sunil Nandraj, Advisor, MOHFW, GOI, New Delhi
- 3. Dr.T.K. Ravi, National Council Member, Principal, College of Pharmacy, Shri Rama Krishna Hospital Campus, Coimbatore
- 4. Dr. Chander Prakash IMA, Delhi , 4/1-A, Racquet Court Road, Civil Lines, Delhi-110054
- 5. Dr. Mira Shiva, Consumer Education Research Centre, New Delhi,
- 6. Dr. R N Dass, CMO, Directorate of Health Services Govt. of NCT of Delhi
- 7. Ms. Malti Jaswal, Consultant, General Insurer Public Sector Association of India, New Delhi, 7032, Pocket D-7, Vasant Kunj, New Delhi
- 8. Dr. Chandranathan, Director of Medical & Health Services, Tamil Nadu (Representative of Secretary, Department of Health and Family Welfare, Tamil Nadu)

## Members Absent:

- 1. Dr. Padmanabhan, Advisor, NHSRC, New Delhi leave of absence requested on Health grounds
- 2. Dr. Mrs. Keskar, Dy. Health Officer, Mumbai Municipal Corporation, Mumbai
- 3. Representative of Secretary, Health, Govt of UP
- 4. Representative of Health Secretary of Arunachal Pradesh (leave of absence requested due to an important meeting at HQ
- 5. Representative of Health Secretary, Govt of Chandigarh
- 6. Representative of Health Secretary, Govt of West Bengal
- 7. Representative of Health Secretary, Govt. of Karnataka
- 8. Representative of Health Secretary, Govt of Andhra Pradesh

## Preamble:

The National Council for Clinical Establishments as per the 3<sup>rd</sup> meeting had constituted the Sub-committees "**Categorization & Classification of Clinical Establishments**" under the Chairmanship of Dr. B. Suresh, Vice Chancellor JSS University, Mysore, Karnataka, with the terms of reference as below:

**Terms of Reference:** To categorize and classify the clinical establishments as per the definition in the CEA 2010, with regard to the services & facilities offered, system of medicine offered, type of establishments, specialty, ownership, size, location among other aspects.

**Outcome:** A draft document providing the categorization & classification of clinical establishment to be submitted to the National council.

**Meeting:** The sub committee was held as scheduled on 3<sup>rd</sup> and 4<sup>th</sup> October, 2013 at JSS University, Mysore - 570015. The agenda for the meeting and other reference materials are given as annexure to the minutes.

#### Minutes:

Dr. B Suresh, Chairman of the Sub-Committee for 'Categorization & Classification' and Vice Chancellor, JSS University, extended a warm welcome to all the members and thanked the Ministry of Health, Government of India, for having nominated him as the Chairman of the Sub-Committee. Dr. Basavannagowdappa the Principal of the JSS Medical college and Dr B Manjunatha the Registrar of the JSS University, also extended welcome to the members and thanked for having given the opportunity to host the meeting.

After a round of self introduction the Chairman stated that the subject of 'Categorization and Classification of Clinical Establishments' needs to be deliberated in depth as the recommendations of the committee will become the basis for other sub-committees to set standards and enable the implementation of the Act. Speaking further, Dr. B Suresh said that the emerging challenges in the delivery of the Healthcare had necessitated the enactment of the 'Act' and that the registration of clinical establishments will also provide for a national database of clinical establishments thereby helping the government and also stakeholders to plan the availability of services and provide a clear Health Map of the country. Attention of the members was drawn to Sec.5 of the Act, where it is mandated for the establishment of the National Council with the following functions:

- i) compile a national register
- ii) classification of clinical establishments under different categories
- iii) Develop minimum standards and periodic review of the standards
- iv) Statistical information of / from clinical establishments

After the opening remarks by the chairman the agenda was taken for discussion:

# Agenda 1: Brief background of the Act, the progress, National council, terms of reference and expected outcomes:

A brief presentation on the salient features of the Clinical Establishment (Registration and Regulation) Act 2010 was made by Sri Sunil Nandraj, Advisor and highlighted that this is the first sub committee to have it's meeting and is of importance as the recommendations of the committee become the basis for other committees to develop templates and then provide for standards. He said that at present the Act is applicable to four states viz. Himachal Pradesh, Andhra Pradesh, Mizoram and Sikkim, while states like Rajasthan, UP, Bihar, Jharkhand have adopted this by passing a resolution in their respective state assembly. In his presentation he briefed about definition of the Act, background, salient features of the Act, functions of National Council, Subcommittees of the National Executive Council, terms of reference and categorization and classification of clinical establishments, importance of the recommendations of the categorization and classification, its members etc. He emphasized that the categorization and classification of clinical establishments need to adhere to the definition as provided by the CEA 2010.

This was followed by discussions on the opening remarks and the presentation. Dr Chandra Prakash raised the issue with regard to registration of single practitioner clinical establishments which would form the major chunk of such documentation. Dr. R N Das said that single doctor can be brought under one classification and said that single doctor establishment itself amount to 95% in the country. Dr. Mira Shiva while endorsing the view expressed that to do this whole exercise and to deal with bigger hospitals or Medical Colleges may be difficult and whether we can phase the categorization process. Dr. B Suresh clarified that the categorization process of different types of services needs to be done as a complete exercise; however the implementation is upto the ministry. Separate categorization for single doctors was in general agreed upon so that it can facilitate having a national overview and database and perhaps the subcommittee on setting standards and templates may for such registrants seek only basic information like, name, region, location, type of practice etc.

## Agenda 2: Discussions and recommendations on classification and categorization of Clinical establishments.

The committee deliberated on various challenges in classifying and categorizing of clinical establishments and after detailed discussions recommendations were made and are given as Annexure-1

#### Agenda 3: Conclusion and Vote of thanks-

The committee while submitting their recommendations expressed that the sub committees that would be preparing templates and standards for the various categories of clinical establishments shall keep in perspective that this classification and categorization needs to looked at holistically and while setting standards will have to consider that a combination of all the above factors and variables associated with it may necessitate the categorization proposed to be further elaborated or consolidated. In such case it may be important for the committee be consulted for giving its perspectives.

The committee thanked the Ministry of Health and Family welfare, government of India and the Hosts, JSS University for all the logistic support provided to the committee. The meeting was adjourned with thanks to the Chair.

## Recommendations of the Subcommittee on 'Classification and Categorization of clinical Establishments':

- I. The committee <u>narrated</u> the definition as provided in the CEA 2010 for clarity in the classification and categorization processes-
  - 1. 'Clinical establishment' means
    - i. a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or
    - ii. a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not.
  - 2. 'Hospital bed' means- (WHO defines a hospital bed as) a bed that is regularly maintained and staffed for the accommodation and full-time care of a succession of inpatients and is situated inwards or a part of the hospital where continuous medical care for inpatients is provided. The total of such beds constitutes the normally available bed complement of the hospital.
  - 3. *'Clinics'* means- often is run by a single or group of physicians or health practitioners. Clinics generally provide only <u>outpatient</u> services.
  - 4. 'Hospital' means- a <u>health care</u> institution providing <u>patient</u> treatment by specialized staff and equipment.
  - 5. 'General Hospital' is- a set up having facilities, medical staff and all necessary personnel to provide diagnosis, care and treatment of a wide range of acute conditions, including injuries, and normally has an <u>emergency</u> <u>department</u> to deal with immediate and urgent threats to <u>health</u>.
  - 6. 'Speciality Hospital' are hospitals having facilities, medical staff and all necessary personnel to provide diagnosis, tertiary care and treatment of a limited specialized group of acute or chronic conditions such as <u>psychiatric</u>

problems, certain disease categories such as cardiac, oncology, or orthopedic problems, and so forth.

- 7. *Multi-specialty hospitals* are hospitals offering specialized and tertiary care in single or multiple facilities segregated units each of which are devoted to a complexity of patient care defined in this subsection.
- 8. 'Medical Day care Facility' is a facility providing evaluation, diagnosis, and limited ambulatory treatment services for individuals whose unit of service to each client is a minimum of four hours and a maximum of twelve hours with referral agreement with a nearby hospital in case of complications during the evaluation, diagnosis and treatment and also where referral is needed for patients.
- 9. *Classification* means the action or process of classifying something according to shared qualities or characteristics.
- 10. *Categorization* is the <u>process</u> in which ideas and objects are <u>recognized</u>, <u>differentiated</u>, and <u>understood</u>.
- 11. Dental clinics are places where dentists provide dental care with no inpatient facilities.
- 12. *Dental hospitals* are places where dentists provide out patient dental care with inpatient facilities
- 13. Inpatients residents hospitalized for indoor care across all types of hospital beds
- 14. Outpatients where care is provided without admission/hospitalization as inpatient.
- 15. *Diagnostic Centre* means- stand alone organized facilities to provide simple to critical diagnostic procedures such as laboratory and radiological investigations supervised by a Pathologist / radiologist usually performed through referrals from physicians and other health care facilities.
- 16. *Clinical laboratory* means a laboratory where microbiological, serological, chemical, hematological, immune-hematological, immunological, toxicological, cytogenetical, exfoliative cytological, histological, pathological or other examinations are performed of materials/fluids derived from the human body for the purpose of providing information on diagnosis, prognosis, prevention, or treatment of disease are provided.

II. The committee classified and categorized the hospitals as follows based on location, ownership, systems of medicine, type, size, services offered, speciality, etc.,

#### a) Location :

- a. Rural
- b. Urban
- c. Metro
- d. Notified / inaccessible areas ( including Hilly / tribal areas)

#### b) Ownership :

- a) Government / Public
  - i. Central Government
  - ii. State Government
  - iii. Local Government (Municipality, Zillaparishad, etc)
  - iv. Public Sector Under taking
  - v. Other ministries and departments( Railways, Police, etc.)
  - vi. Employee State Insurance Corporation
  - vii. Autonomous organization under government
- b) Non-Government/Private.
  - i. Individual Proprietorship
  - ii. Partnership
  - iii. Registered companies (registered under central/provincial/state Act)
  - iv. Society/trust (Registered a central/provincial/state Act)

## c) Systems of Medicine in the establishment

- a. Allopathy (modern medicine)
- b. Any one or multiple disciplines of AYUSH (as defined by the AYUSH Dept., GOI)

## d) Type/ size :

The type and size of clinical establishments shall be as under:

- Clinics (outpatient)- a medical facility smaller than a hospital run by a single physician or a private <u>partnership</u> of physicians. Clinics generally provide only <u>outpatient</u> services. The Clinics shall be further categorized as follows:
  - ✓ Single practitioner

- ✓ Poly clinic
- / Dispensing
- 2. Hospitals (outpatient and inpatient)- a <u>health care</u> institution providing <u>patient</u> treatment by specialized staff and equipment. The **Hospitals** shall be further categorized as follows:
  - ✓ Medical Day Care facility
  - ✓ Hospitals shall be of following sizes-
    - Upto 10 beds
    - Upto 30 beds
    - Upto 100 beds
    - Upto 200 beds
    - Upto 300 beds
    - Upto 500 beds
    - Above 500 beds

Further the clinics and hospitals should be further categorized based on the providing of following services.

- General Practice
- Single speciality
- Multi speciality
- > Super speciality

The fields of clinical medical and surgical specialty and super specialty shall be as listed by Medical council of India in its Act and regulations and also include those mentioned below, viz.

Medical Specialties – for which candidates must possess recognized degree of M.D. (DOCTOR OF MEDICINE) (or its equivalent recognized degree)

- i. Anesthesiology
- ii. Aviation Medicine
- iii. Community Medicine
- iv. Dermatology, Venerology and Leprosy
- v. Family Medicine
- vi. General Medicine
- vii. Geriatrics
- viii. Immuno Haematology and Blood Transfusion
- ix. Nuclear Medicine
- x. Paediatrics
- xi. Physical Medicine Rehabilitation
- xii. Psychiatry
- xiii. Radio-diagnosis
- xiv. Radio-therapy

- xv. Rheumatology
- xvi. Sports Medicine
- xvii. Tropical Medicine

xviii. Tuberculosis & Respiratory Medicine or Pulmonary Medicine

Surgical specialties - for which candidates must possess recognized degree of M.S. (MASTER OF SURGERY) (or its equivalent recognized degree).

- xix. Otorhinolaryngology
- xx. General Surgery
- xxi. Ophthalmology
- xxii. Orthopedics
- xxiii. Obstetrics & Gynecology

Medical Super specialities -

- i. Cardiology
- ii. Clinical Hematology
- iii. Clinical Pharmacology
- iv. Endocrinology
- v. Immunology
- vi. Medical Gastroenterology
- vii. Medical Genetics
- viii. Medical Oncology
- ix. Neonatology
- x. Nephrology
- xi. Neurology
- xii. Neuro-radiology

Surgical Superspecialities-

- i. Cardiovascular thoracic Surgery)
- ii. Urology
- iii. Neuro-Surgery
- iv. Paediatrics Surgery.
- v. Plastic & Reconstructive Surgery
- vi. Surgical Gastroenterology
- vii. Surgical Oncology
- viii. Endocrine Surgery
- ix. Gynecological Oncology
- x. Vascular Surgery

As regards to the definition of services provided atspeciality and super speciality or multi speciality hospitals the same shall be as defined in the various schemes of the government.

#### 3. Dental Clinics and Dental Hospital:

- a. Dental clinics
  - i. Single practitioner
  - ii. Poly Clinics (dental)
- b. Dental Hospitals (specialities as listed in the IDC Act.)
  - i. Oral and maxillofacial surgery
  - ii. Oral medicine and radiology
  - iii. Orthodontics
  - iv. Conservative dentistry and Endodontics
  - v. Periodontics
  - vi. Pedodontics and preventive dentistry
  - vii. Oral pathology and Microbiology
- viii. Prosthodontics and crown bridge
- ix. Public health dentistry
- 4. Clinical Laboratories: There are two main types of labs that process the majority of medical specimens. Hospital laboratories are attached to a <u>hospital</u>, and perform tests on patients. Private (or community) laboratories receive samples from <u>general practitioners</u>, insurance companies, <u>clinical research sites</u> and other health clinics for analysis. These can also be called reference laboratories where more unusual and obscure tests are performed. Clinical Laboratories could be general Labs and/or Advanced Labs that provide services in the following fields:
  - Pathology
  - Bio-chemistry
  - Microbiology
  - Molecular Biology and Genetic Labs
  - Virology
- **5. Diagnostic centres:** Diagnostic centers could be general and/or Advanced that provide following services:
  - a. Radiology
    - i. General radiology
    - ii. Interventional radiology
  - b. Electromagnetic imaging (Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) Scan)
  - c. Ultrasound

Collection centers for the clinical labs and diagnostic centres shall function under registered clinical establishment

- 6. Any other– Allied Health professions: Allied health professions generally indicate that they are health professions distinct from medicine, dentistry, pharmacy and nursing. The list of allied health professions includes but is not limited to the following disciplines:
  - <u>Audiology</u>
  - <u>Behavioral health</u> (counseling, marriage and family therapy)
  - Exercise physiology
  - Nuclear medicine technology
  - Medical Laboratory Scientist
  - <u>Dietetics</u>
  - Occupational therapy
  - Optometry
  - Orthoptics
  - Orthotics and prosthetics
  - Osteopathy
  - Paramedic
  - Podiatry
  - Health Psychology
  - Physiotherapy
  - Radiation therapy
  - Radiography / Medical imaging
  - <u>Respiratory Therapy</u>
  - Sonography
  - Speech pathology

# Implementation of Clinical Establishments (Registration & Regulation) Act, 2010

## Sub-Committee meeting on "Classification and Categorization"

Date: October 3-4, 2013	Venue: College Council Hall, JSS Medical College, JSS
	University, Mysore

## Agenda

## Day-1 : Thursday - October 03, 2013

10.00-10.20 Hrs	Welcome of the sub-committee members by Dr. B Suresh, Chairman and Vice Chancellor, JSS University and introduction of		
	the sub-committee members		
1020-11.00 Hrs	Brief on the background of the Act, the progress, National Council, Terms of Reference, expected outcome etc. by Sri Sunil Nandraj,		
	Advisor (Clinical Establishment Act) Ministry of Health and Family		
	Welfare, Govt. of India, New Delhi,		
11.00-11.15 Hrs	Tea Break		
11.15-13.15 Hrs	Discussions – Classification and Categorization on the basis of:		
	a) Location		
	b) Ownership		
	c) Systems of Medicine		
	d) Type / Size		
	e) Services Offered		
	<li>f) Nature of Services and speciality</li>		
	g) Dental		
	h) Clinical Laboratories		
	i) Diagnostic Centres		
13.15-14.00 Hrs	Lunch Break		
14.00-16.00 Hrs	Discussions continued		
16.00-16.15 Hrs	Tea Break		
16.15-17.00 Hrs	Outcome/Suggestions of the discussions		

## Day-2 : Friday - October 04, 2013

10.00-10.20 Hrs	Sub-committee meeting continued - Review	
1020-11.00 Hrs	Preparation of Recommendations	
11.00-11.15 Hrs	Tea Break	
11.15-13.15 Hrs	Conclusion, Vote of thanks and wrap up session	

## Enclosures:

Annexure-I	Gazzette Notification on The Clinical Establishments (Registration and Regulation) Act, 2010 – Ministry of Law and Justice, Govt. of India (English)	
Annexure-II	Gazette Notification by Ministry of Health and Family Welfare, ( Department of Health and Family Welfare) dated 23.5.2012	
Annexure-III	Minutes of the 3 <sup>rd</sup> Meeting of National Council for Clinical Establishments.	
Annexure-IV	Constitution of sub-committee on "Categorization and Classification of Clinical Establishments" and terms of reference.	
Annexure-V	Categorization of Clinical Establishments as per various State Acts	
Annexure-VI	Draft on the Classification and Categorization of clinical establishments by Dr. P Padmanabhan, Advisor, NHSRC, New Delhi.	

## **Annexure III**

## Minutes of Meeting The third meeting of National Council for Clinical Establishments was held under the

Chairmanship of Dr. Jagdish Prasad, DGHS, Govt. of India on 24-06-13. **Venue:** Resource Centre, Room No.445 'A' Wing, Nirman Bhawan, New Delhi. The list of participants is annexed.

After the welcome and introduction of participants, the Chairman pointed out that there has been a delay on part of the Quality Council of India (QCI) and Indian Medical Association (IMA) to submit the report of survey of Clinical Establishments to the Ministry of Health & Family Welfare because of which, the latter is not able to progress with regard to development of the minimum standards etc. He emphasized that it is important that the Clinical Establishments Act (CEA) gets implemented in all metro cities which have a large number of various types of Clinical Establishments, which need to be regulated. He expressed concern regarding the CEA not covering the States/UTs like Delhi, West Bengal, and Maharashtra etc. which have a large number of private clinical establishments. However, steps are being taken to address this issue.

The Secretary of the Council, Dr. Arun K. Panda, Joint Secretary (Regulation), MOHFW, GOI, pointed out, States/UTs which have their own Acts are required to also repeal their Acts before the Clinical Establishments Act can be implemented in such States. The Chairman was of the view that State and UT should not find an excuse in the form of the schedule, for not implementing the Act.

Dr. K.K. Kalra, CEO NABH, informed that QCI is competent to develop any type of standards including regulatory standards. He pointed out that they are waiting for the survey report from IMA, which IMA is likely to submit soon. Dr. Arun K. Panda said that QCI should formally ask IMA to submit the survey report immediately, so that they are able to take into account the ground situation while drafting minimum standards.

Dr. Zainab Zaidi made a presentation on the data collected by IMA

during the survey, on behalf of the IMA. The members of the Council desired that IMA should submit the detailed survey report, which may then be examined for utilizing the relevant findings. The IMA representative, Sh. Nitin N. Singh (Manager, IMA Headquarter) informed that IMA is in the process of finalizing the survey report and will be able to submit the report by 3<sup>rd</sup> of July, 2013. The QCI representative informed that they will be able to submit the draft minimum standards within 4 to 6 weeks of receiving the survey report from IMA.

There was a question raised by a member pointing out that many of the AYUSH doctors are prescribing allopathic medicines which is against the Supreme Court guidelines and same should be included in the minimum standards. The Chairman pointed out that wherever the AYUSH doctors are working under a National programme, they may prescribe the medicines given under that programme.

A presentation was made by Dr. Anil Kumar, CMO, Dte.GHS, regarding the action taken report on the minutes of the second meeting, which is summarized as under:

i. The minutes of second meeting of National Council were confirmed. 1

- ii. The members were reminded of the timelines for publication of the national register and standards of proper health care as per the Act.
- iii. It was informed that after the enforcement of the Act, the States of Bihar, Jharkhand, Rajasthan and Uttar Pradesh have adopted the Act and are in the process of drafting/finalizing the state rules.Trainings are being conducted through NIC coordinators in the states. Online registration has started in the state of Himachal Pradesh. Budget is being provided through NRHM and other mechanisms to the States and UTs where the CEA 2010 is applicable and adopted.

- iv. The "Application Form for Provisional Registration" has been translated into Hindi and was shared with the participants and requested for inputs if any.
- v. Draft recommendations by Committee on Electronic Medical Records Standards developed and uploaded on the website of CEA.
- vi. The formats of qualitative detailed survey were shared with all Council members by QCI/IMA for their inputs.
- vii. As informed by QCI/IMA, IMA has completed both quantitative and qualitative survey in 11 States/UTs and made one presentation of the draft data. Report is yet to be submitted.
- viii. Inputs were provided to IMA by nodal officer Dr. Anil Kumar and Advisor Sh. Sunil Nandraj for analysis and finalization of Report.
- ix. First draft of minimum standards as developed by QCI was shared with council members and all the States/UTs where the Act is applicable.
- x. One Draft of range of rates of procedures and services, as may be charged by clinical establishments, has been prepared and shared with AIIMS New Delhi, for their suggestions.
- xi. Standard Treatment Guidelines on following areas have been developed and are in the process of finalization in consultation with the experts. The soft copies of the STGs were shared with the participants and members of council during the meeting.
- 1. Cardiovascular
- 1. ENT
- 2. General Surgery

7. Laboratory Medicine 9. Organ Transplant 11. Oncology

13. Nephrology 15. Medicine Respiratory 17. Critical Care 19. Neurology

2. Endocrinology 4. Gastro-Enterology 6. Interventional Radiology 8. Obstetrics and Gynaecology 10. Paediatrics 12. Urology 14. G.I. Surgery 16. Medicine Non-Respiratory 18. Ophthalmology 20. Orthopaedics

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It was also pointed out that STGs for AYUSH systems of medicines are also required to be formulated. There was a mixed opinion about the requirement of STGs for AYUSH. Most of the experts were of the opinion that it is feasible to formulate STGs for AYUSH systems and the same needs to be developed.

Regarding the need for increasing awareness about the Clinical Establishments Act, it was pointed out that Ministry of Health and FW may consider taking suitable action.

Prasanth K.S. from NHSRC shared that there is an expert committee formulated by MoHFW working on development of standards for public health institutions for provision of RMNCHA (Reproductive, Maternal, Newborn, Child and Adolescent Health) services. Dr. Arun Panda said that this report can be submitted to National Council and will be a resource material for the subcommittee working on development of minimum standards.

Presentation was made by Mr. Sunil Nandraj, Advisor CEA, regarding the proposed sub- committees and their terms of reference. The participants were informed that periodic communications have been sent to the State Governments and National council members to suggest names for the 5 sub committees proposed in the 2nd council meeting. The draft list of members of the sub-committees was circulated to the participants. The participants agreed with the names included in the draft subcommittees. The members of the National Council were keen to suggest a few more names and it was suggested that the same could be forwarded before July 1st 2013.

The following Terms of Reference (1-7) for the Sub-committees were agreed.

- 1. Standards may be developed phase wise: first phase may include where there is consensus.
- 2. The sub-committees shall include experts, stakeholders, representatives of State Govts. Private & public sectors, NGOs, professional bodies, academia and research institutions. There will be option to co-opt members & experts as per requirement of the Terms of Reference.
- 3. The Methodology and functioning of the sub-committees shall be as under:

 $\hfill\square$  To meet frequently and review the work being done and through emails

☐ May commission some tasks of the work to experts identified who could be from outside the subcommittee under approval of the Chairman of the National Council.

 $\hfill\square$  Circulate draft outputs with various stakeholders for their inputs & suggestions.

□ Review & incorporate inputs from available surveys conducted by various stakeholders (including the QCI & IMA) & existing information, documents, literature, existing acts, rules, byelaws and material available.

4. The TA/DA to the subcommittee members shall be payable as applicable to the members of National Council for Clinical

Establishments as per Clinical Establishments (Central Government) Rules 2012.

- 5. Budget shall be provided to subcommittees for holding workshops as per requirement including providing water, tea, snacks and lunch on the days of the workshops.
- 6. Chairperson would coordinate with the Clinical Establishments Act division of Dte.GHS / MOHFW for the above.
- 7. Specific tasks and timelines for each sub-committee shall be as under:

## Sub-Committee on Categorization and Classification

To classify the clinical establishments into categories, with regard to the services & facilities offered, system of medicine offered, type of establishments, specialty, ownership, size, location among other aspects.

• Timeline: 1 month •Outcome: A draft document providing the categorization & classification of

clinical establishments.

## **Sub-Committee on Template for Developing Minimum Standards**

Develop standard templates for the development of minimum standards for various categories of Clinical Establishments.

• •Timeline: 1 month

• Outcome: Draft templates for the development of minimum standards for various categorization of clinical establishments **Sub-Committee for development of minimum standards** To develop draft minimum standards for various categories of Clinical Establishments of different systems of medicine.

• •Timeline: 6 months

• Outcome: A draft document providing the minimum standards for the various categories of clinical establishments to be submitted to the National council. Sub Committee on Information & Statistics to be collected from clinical establishments To identify information and statistics to be collected especially with regard to services and facilities, outbreak of diseases, medico-legal cases, accidents, morbidity and mortality data, Government programmes among others & to develop template for the display of the rates charged for each type of service provided and facilities by the clinical establishment.

• •Timeline: 2 months

Outcome: The Information & Statistics to be collected from various categories of clinical establishments Sub-Committee for defining range of rates of procedures & services To define the range of rates of procedures and services provided by the clinical establishments. The sub-committee would review and examine the existing rates being charged under the various schemes and reimbursed by insurance companies.
Timeline: 6 months
Outcome: Suggested range of rates of procedures and services

# In summary, after discussions and deliberations, following action points were recommended:

- 1. National Council members were requested to suggest names for each subcommittee by 1<sup>st</sup> of July, 2013. The DGHS, the Chairperson of the National Council was requested to finalize suitable names based on their qualifications, affiliation, experience and expertise in the proposed sub committees.
- 2. QCI should formally ask IMA to submit the survey report immediately and after receiving the Report from IMA, QCI should formulate the draft minimum standards at the earliest in consultation with the experts and other professional medical

associations, taking into account the findings of the Survey Report.

- 3. The DGHS shall take a meeting of both IMA and QCI representative on 8<sup>th</sup> July, 2013 or later at a convenient date to review the submission of Survey Report and progress made.
- 4. There shall be one subcommittee for development of minimum standards of AYUSH. This subcommittee shall have subgroups to develop minimum standards for respective systems under AYUSH. Each subgroup shall have experts from the respective systems under AYUSH namely Ayurveda, Unani, Siddha, Homoeopathy, Yoga, Naturopathy and Sowa Rigpa.
- 5. The subcommittee of AYUSH may also take action for formulating Standard Treatment Guidelines for the respective system under AYUSH, wherever feasible.
- 6. Ministry of Health and Family Welfare may consider taking action for spreading awareness about the Clinical Establishments Act and may also consider constituting a committee for development of IEC material.
- 7. Dte.GHS would complete the task of vetting the Standard Treatment Guidelines (STGs) expeditiously, to be uploaded on the website. The meeting ended with a vote of thanks to and from the Chair.

# List of Participants in 3rd Meeting of 'National Council for Clinical Establishment held on 24-06-2013 under chairmanship of DGHS

Annexure

S.No.	Name with Designation and	Designation and Telephone & Mobile	
	Address	No.	
1.	Dr. Jagdish Prasad, DGHS (Chairman)	011-23061438, 011- 23061063	dghs@nic.in
2.	DR. A.K. Panda, Joint Secretary, MOHFW	011-23063155, 011- 23063156	arunpanda84@gmail.c om
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21.	Sh. Sunil Nandraj, Advisor, Clinical Establishments Act, MOHFW	9811419292	sunil.nandraj@gmail.co m
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25.	Dr. Anil Kumar, Chief Medical Officer, Dte. G.H.S	01123061259, 9811637663	dr.anilkumar@nic.in

## **Annexure IV**

## F.No. Z. 28015/91/2011-H(Part-1)/MH 2

Government of India Ministry of Health and Family Welfare Directorate General of Health Services

## **Office Memorandum**

Nirman Bhawan, New Delhi. Dated: 26-7-2013

The undersigned is directed to inform that consequent upon authorization by the National Council, the Chairman of the National Council for Clinical Establishments has approved the constitution of the two Sub-committees as follows.

- I. Subcommittee on "Classification and Categorization" under the Chairmanship of Dr. B. Suresh, Vice Chancellor JSS University, Mysore, Karnataka
- II. Subcommittee on "Template of Minimum Standards" under the Chairmanship of Dr. B.D. Athani, Special DGHS and Medical superintendent, Safdarjung Hospital, New Delhi

The details of members, Terms of Reference of the Subcommittees etc. and a copy of the minutes of third meeting of National Council are enclosed.

-sd-

(Dr. Anil Kumar) Chief Medical Officer (AK)

Telefax : 23061259 Email: dr.anilkumar@nic.in

To

- 1. All members of Subcommittees as per the list annexed.
- 2. All members of National Council as per the list annexed.

- 3. The Principal Secretary Health States of Chandigarh, Arunachal Pradesh, UP, West Bengal, Tamil Nadu, Karnatka, Andhra Pradesh with request to nominate their one representative for the Sub-committee on "Classification and Categorization"
- 4. The Principal Secretary Health States of Bihar, Sikkim, West Bengal, Tamil Nadu, Karnatka, Andhra Pradesh and UT of Daman and Diu with request to nominate their one representative for the Sub-committee on "Template of Minimum Standards"

## Copy for information to-

- 1) PPS to DGHS/JS(AKP)/DDG(NSD)
- 2) PA to Director (TC)/US(AC)
- 3) MS division, MOHFW

## **Sub-Committees for Categorization & Classification**

**Terms of Reference:** To categorize and classify the clinical establishments as per the definition in the CEA 2010, with regard to the services & facilities offered, system of medicine offered, type of establishments, specialty, ownership, size, location among other aspects. **Outcome:** A draft document providing the categorization & classification of clinical establishment to be submitted to the National council.

**Timeline**: 1 month **Chairperson** - Dr. B Suresh, VC, JSS University, Mysore, Karnataka, Email sureshbhojraj@gmail.com / vc@jssuni.edu.in Phone - 821254839

SI.No .	Name	Organization	Contact Details	Phone & Email
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10.		Representative of Secretary Health, UP		
11.		Representative of Secretary Arunachal Pradesh		
12.		Representative of Secretary, Chandigarh		
13.		Representative of Secretary, West Bengal		
14.		Representative of Secretary, Tamil Nadu		
15.		Representative of Secretary, Karnataka		
16.		Representative of Secretary, Andhra Pradesh		

## Annexure V

## CATEGORIZATION OF CLINICAL ESTABLISHMENTS AS PER VARIOUS STATE ACTS

#### West Bengal

- 1. Nursing Home & or Maternity Home, dispensary with beds, day care centers with beds and physical therapy establishments.
  - a. upto 10 beds
  - b. 11 to 20 beds
  - c. 21 to 30 beds
  - d. more than 30 beds
- 2. Pathological laboratories
  - a. small
    - b. medium
    - c. large
    - d. collection centers for pathological labs
- 3. Imaging, X-ray and others
  - a. USG(Ultra Sonography) only
  - b. Echo
  - c. Color Doppler
  - d. C.T. Scan(Computerized Tomographic Scan)
  - e. M.R.I.(Magnetic Resonance Imaging)
  - f. X-ray
  - g. Others-ECG(Electro Cardiography), EEG(Electro Encephalography), EMG(Electro Myography), Scopy procedures, holter monitoring and others not specified above
  - h. Angiography
- 4. ICCU(Intensive Coronary Care Unit)/ITU(Intensive Care Unit)/RCU(Respiratory Care Unit)/NCU (Neo-natal Care Unit)Dialysis
  - a. upto 10 beds
  - b. 10+ beds
- 5.
- a. Polyclinics & other clinics
- b. Individual clinic (modern medicine & dental)
  - i. Graduates
  - ii. Post graduates diploma & degree holders
- c. Ayurvedic / Homeo/Unani / Acupuncture therapist
  - i. Graduates
  - ii. Post graduates diploma & degee holders
- 6. Hospitals having specialty clinics
  - a. 25 to 50 beds
  - b. more than 50 beds
- 7. Specialty clinics
  - a. surgery/Eye/ENT(Ear, Nose Throat) / Orthopedics/ Cardio thoracic / plastic surgery
  - b. Medicine / Pediatrics / Cardiology / Endo crinology
  - c. Gynae & Obst.

d. Neurology / Skin / Dental Any other discipline not included above

#### Andhra Pradesh

- 1. Clinics / Consultation Rooms (Solo Practitioners)
- 2. Poly clinics (Group practitioners)
- 3. Hospitals / Nursing Homes less than 20 beds.
- 4. Hospitals / Nursing Homes with 21 to 50 beds
- 5. Hospital / Nursing Homes with 51 to 100 beds
- 6. Hospital / Nursing Homes with 101 to 200 beds
- 7. Hospital / Nursing Homes with more than 200 beds
- 8. Diagnostic Centers (Basic Lab facilities)
- 9. Diagnostic Centers with Hi-end equipment (CT etc.)
- 10. Physiotherapy units
- 11. Dental Clinics / Hospitals

#### Delhi

- 1. Nursing Home
- 2. Maternity Home

#### Jammu & Kashmir

- i. Clinical Establishment including medical laboratory, a physio-establishment, a clinical or an establishment analogous to any of them by whatever means called
- ii. Hospital
- iii. Maternity Home
- iv. Medical laboratory
- v. Nursing Homes
- vi. Physiotherapy Establishments

#### Karnataka

- i. Hospital or dispensary with beds or without beds
- ii. nursing home
- iii. clinical laboratory
- iv. diagnostic centre
- v. maternity home
- vi. blood bank
- vii. radiological centre
- viii. scanning centre
- ix. physiotherapy centre
- x. clinic, polyclinic, consultation centre and such other establishment by whatever named called where investigation, diagnosis, preventive curative or rehabilitative medical treatment facilities are provided to the public and include voluntary or private establishments

#### Maharashtra

- i. Hospitals
- ii. Nursing Homes
- iii. Maternity Homes
- iv. Health Centres
- v. Dental Hospitals

#### Manipur

- i. Clinic
- ii. Maternity Home
- iii. Nursing Home

#### Nagaland

- i. General Hospital
- ii. Maternity Hospital
- iii. Nursing Homes

& Clinics

#### Madhya Pradesh

- i. Clinical establishment means a laboratory a physiotherapy establishment a clinic or an establishment analogous to any of them by whatever named called,
- ii. Hospital,
- iii. Maternity home,
- iv. Medical laboratory
- v. Nursing home
- vi. Physiotherapy establishment means an establishment where massaging, electrotherapy, hydrotherapy, remedial gymnastic or similar processes are usually carried on for the purpose of treatment of diseases or for improvement of health

#### Orissa

- 1. Clinical establishments
- 2. nursing homes
- 3. maternity homes
- 4. physical therapy establishment
- 5. clinical laboratory
- 6. blood bank
- 7. private hospital
- 8. dispensary
- 9. place under which medical termination of pregnancy is carried out

**10.** X-ray institutions and such other institution or establishment as the director of health services may with the approval of the state government by notification from time to time specified

#### Punjab

- 1. Nursing home
- 2. Maternity home

## **Annexure VI**

## Classification and Categorization of Clinical Establishments

## A. Location

- i. Rural
- ii. Urban
- iii. Notified difficult/inaccessible areas

## **B. Systems of Medicine**

- i. Modern Medicine (Allopathy)
- Medicine
- Surgery
- Obstetrics & Gynecology
- Pediatrics
- Physical medicine
- Others –

#### ii. AYUSH

#### a)Ayurveda

Types
Kaya chikilsa
Bala chikilsa
Graha chikilsa
Urdhwanga chikilsa
Salya chikilsa
Visha chikilsa
Jara (Rasayana) chikilsa
Vajikarma chikilsa

b)Yogac)Unnanid)Siddha (could have sub categories similar to Ayurveda)

**e)Homeopathy** (Categories would be – facilities with Out Patient & Inpatient services)

- i. General
- ii. Speciality

## **C. Ownership of Services**

#### i. Government

- Central government
- State government
- Local government (Municipal, Zillaparishad etc.)
- Public Sector undertaking
- Other Ministries & Departments (e.g. Railways, Police)
- Employee State Insurance Corporation (ESIC)
- Autonomous organization under government

#### ii. Non-Government

- Individual Proprietorship
- Partnership
- Registered Company (registered under a Central, Provincial or State Act)
- Society, Charitable Trust (registered under a Central, Provincial or State Act)

## D. Services & Facilities offered

i. OP Services

- ii. IP Services
- iii. Single Specialty Services
- iv. Multi Specialty Services
- v. Multi System Services
- vi. Diagnostic Services

## E. Nature of Services & Specialty

- i. Primary
- ii. Secondary
- iii. Tertiary

## F. Dental

- i. Oro and Maxiofacial surgery
- ii. Oro and Maxiofacial Radiology
- iii. Orthodontics
- iv. Endodontics
- v. Periodontics
- vi. Pedodontics
- vii. Oral Pathology
- viii. Prosthodontics

## **G. Clinical Laboratories**

- i. **Pathology** 6 categories as per the tests conducted
- ii. Biochemistry 6 categories as per the tests conducted
- iii. Microbiology
  - Bacteriology
  - Mycobacteriology
  - Serology / Immunology

- Parasitology
- Mycology
- Molecular diagnostic Lab
- iv. Genetics Labs

## **H. Diagnostics**

## i.Imaging & Scan Centres

- Orthopentogram (OPG)
- CT Scan(Computerized Tomographic Scan)
- Magnetic Resonance Imaging (MRI)
- Positron Emission Tomography (PET) Scan
- Uro-flowmetry
- Echocardiography
- Tread Mill Test
- Electro Myography (EMG)
- Electro Encephalography(EEG)
- Electrophysiological studies

## ii.Ultrasound