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Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
Medical Services Section

Nirman Bhawan, New Delhi Dated 17th July, 2019

NOTICE

Subject: Placing the draft of 'Categories of Clinical Establishments' in public domain for comments/suggestion- regarding

MoHFW plans to notify the rules for "Classification and Categorization of Clinical Establishments" under the relevant provisions of the Clinical Establishments (Registration and Regulation) Act, 2010.

2. The comments/suggestions on the draft may be forwarded to Dr. Anil Kumar, Addl. DDG, Dte.GHS, Ministry of Health and Family Welfare, Room No. 560-A, Nirman Bhawan, New Delhi- 110011 or by email to help.ceact2010@nic.in within 45 days from the date of issue of this notice.

(Mandeep Kumar Bhandari)

Joint Secretary

CATEGORIES OF CLINICAL ESTABLISHMENTS

- I. Definition for classification and categorization of Clinical Establishments
 - 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 where pathological, diseases or treatment of diagnosis biological chemical, radiological, genetic, bacteriological, 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.
 - Classification means the action or process of classifying something according to shared qualities or characteristics.
 - Categorization is the <u>process</u> in which ideas and objects are recognized, <u>differentiated</u>, and <u>understood</u>.
 - 4. '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.
 - Inpatients residents hospitalized for indoor care across all types of hospital beds.
 - Outpatients where care is provided without admission/hospitalization as inpatient.
 - Clinics' means a medical facility run by a single or group of physicians or health practitioners smaller than a hospital. Clinics generally provide only <u>outpatient</u> services and can have an observation bed for short stay.
 - 8. Day care Facility (Medical/Surgical) Day care facility as part of an existing hospital. Here it is in the form of service offered by any hospital on its own premises or as extension outside its premises. Responsibility of the Day Centre will be of parent organization/institution/hospital. Day care facility specific to a specialty e.g. Ophthalmic Services, ENT services

etc. These centers should have referral mechanisms in place i.e. in case of need the patient can be shifted to a link hospital already identified. These referral mechanisms should be displayed prominently.

9. 'Hospital' (WHO) means - Health care institutions that have an organized medical and other professional staff, and inpatient facilities, and deliver medical, nursing and related services 24 hours per day, 7 days per week. Hospitals offer a varying range of acute, convalescent and terminal care using diagnostic and curative services in response to acute and chronic conditions arising from diseases as well as injuries and genetic anomalies. In doing so, they generate essential information for research, education and management. Traditionally oriented on individual care, hospitals are increasingly forging closer links with other parts of the health sector and communities in an effort to optimize the use of resources for the promotion and protection of individual and collective health status.

Under Clinical Establishment Act, 2010 the Allopathic Hospitals will be broadly defined under following **four** levels:

9.1 Hospital Level 1 (A) -

General Medical Services with indoor admission facility provided by recognized allopathic medical graduate(s) and may also include general dentistry services provided by recognized BDS graduates.

Example: PHC, Government and Private Hospitals and Nursing Homes run by MBBS Doctors etc.

9.2 Hospital Level 1 (B) -

This level of hospital shall include all the general medical services provided at level 1(A) above and specialist medical services provided by Doctors from one or more basic specialties namely General Medicine, General Surgery, Paediatrics, Obstetrics & Gynaecology and Dentistry, providing indoor and OPD services.

Level 1(A) and Level 1(B) Hospitals shall also include support systems required for the respective services like Pharmacy, Laboratory, etc.

Example: General Hospital, Single/Multiple basic medical Specialties provided at Community Health Centre, Sub Divisional Hospital, and Private Hospital of similar scope, Nursing Home, Civil/District Hospital in few places etc.

9.3 Hospital Level 2 (Non-Teaching)

This level may include all the services provided at level 1(A) and 1(B) and services through other medical specialties given as under, in addition to basic medical specialty given under 1 (B) like:-

- a. Orthopaedics
- b. Otorhinolaryngology
- c. Ophthalmology
- d. Dental
- e. Emergency with or without ICU
- f. Anaesthesia
- g. Psychiatry
- h. Dermatology, Venerology and Leprosy
- i. Pulmonary Medicine
- j. Rehabilitation, etc.

And support systems required for the above services like Pharmacy, Laboratory, Imaging facilities, Operation Theatre etc.

Example: District Hospital, Corporate Hospitals, Referral Hospital, Regional/State Hospital, Nursing Home and Private Hospital of similar scope etc.

9.4 Hospital Level 3 (Non-Teaching) Super-specialty services -

This level may include all the services provided at level1 (A), 1(B) and 2 and services of one or more or the super specialty with distinct department and/or also Dentistry if available. It will have other support systems required for services like pharmacy, Laboratory, and Imaging facility, Operation Theatre etc.

Example: Corporate Hospitals, Referral Hospitals, Regional/ State Hospital, Nursing Home and Private Hospital of similar scope etc.

9.5 Hospital Level 4 (Teaching) -

This level will include all the services provided at level 2 and may also have Level 3 facilities. It will however have the distinction of being teaching/training institution and it may or may not have super specialties. Tertiary healthcare services at this level can be provided through specialists and may be super specialists (if available). It will have other support systems required for these services. It shall also include the requirement of MCI/other registering body for teaching hospitals and will be governed by their rules. However registration of teaching Hospitals will also be required under Clinical Establishment Act for purpose other than those covered under MCI such as, records maintenance and reporting of information and statistics, and compliance to range of rates for Medical and Surgical procedures, etc.

- 10. Nursing Home 'Nursing Home 'means any premises used or intended to be used for reception of persons suffering from any sickness, injury or infirmity and providing of treatment and nursing for them and include a maternity home.
- 11. Maternity Home 'Maternity Home' means any premises used or intended to be used for reception of pregnant women or of women in labour or immediately after child birth;
- 12. '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 emergency department to deal with immediate and urgent threats to health.
- 13. 'Specialty 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 psychiatric problems, certain disease categories such as cardiac, oncology, or orthopedic problems, and so forth.
- 14. 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.
- 15. Dental clinics are places where dentists provide dental care with no inpatient facilities.
- 16. Dental hospitals are places where dentists provide outpatient dental care with inpatient facilities
- 17. Diagnostic Centre means- stand alone organized facilities to provide simple to critical diagnostic procedures such as radiological investigation supervised by a radiologist and clinical laboratory services by laboratory specialist usually performed through referrals from physicians and other health care facilities.
- 18. Clinical/Medical Diagnostic laboratory means a laboratory with one or more of the following where microbiological, serological, chemical, hematological, immune-hematological, immunological, toxicological, cytogenetic, exfoliative cytogenetic, 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.

II. The categories of clinical establishments based on location, ownership, systems of medicine, type, size, services offered, specialty, etc. are as follows:

a) Location:

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

b) Ownership:

- a) Government / Public
 - i. Central Government
 - ii. State Government
 - iii. Local Government (Municipality, Zilla parishad, 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 under central/provincial/State Act)

c) Systems of Medicine in the establishment

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

d) Type/ size :

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

- 1. Clinics (outpatient) The Clinics shall be categorized as follows:
 - Single practitioner (Consultation services only/with diagnostic services/with short stay)
 - Poly clinic (Consultation services only/with diagnostic services/with short stay)
 - Dispensary

Health Checkup Centre

Mobile clinic((Consultation services only/with diagnostic services/procedures)

2. Day Care facility

- Medical/Surgical
- Medical SPA
- Wellness centers (where qualified medical professionals are available to supervise the services).
- Hospitals including Nursing Home (outpatient and inpatient) a <u>health care</u> institution providing <u>patient</u> treatment by specialized staff and equipment.

The Hospitals including Nursing Homes should be categorized based on the following criteria.

- General Practice
- Single specialty
- Multi specialty (including Palliative Care Centre, Trauma Centre, Maternity Home)
- Super specialty

The fields of clinical medical and surgical specialty and super specialty shall be as per list of Medical Council of India regulation and currently it will cover following:

- a) Medical Specialties for which candidates must possess recognized post graduate degree of M.D. (DOCTOR OF MEDICINE) or Diploma (or its equivalent recognized degree/diploma)
 - 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

- b) Surgical specialties for which candidates must possess, recognized degree of M.S. (MASTER OF SURGERY) or Diploma (or its equivalent recognized degree).
 - i. Otorhinolaryngology
 - ii. General Surgery
 - iii. Ophthalmology
 - iv. Orthopedics
 - v. Obstetrics & Gynecology including MTP & Artificial Reproductive Techniques (ART) Centers
- c) Medical Super specialties
 - i. Cardiology
 - ii. Clinical Hematology including Stem Cell Therapy
 - 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
- d) Surgical Super specialties
 - 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 at specialty and super specialty or multi specialty allopathic hospitals the same shall be categorized based on level of care into:

- Hospital Level 1 a
- Hospital Level 1 b
- Hospital Level 2
- Hospital Level 3 (Non teaching)
- Hospital Level 4 (Teaching)

4. Dental Clinics and Dental Hospital:

a. Dental clinics

- Single practitioner
- ii. Poly Clinics (dental)
- Dental Hospitals (specialties as listed in the IDC Act.)
 - Oral and maxillofacial surgery
 - Oral medicine and radiology
 - Orthodontics
 - Conservative dentistry and Endodontics iv.
 - Periodontics ٧.
 - Pedodontics and preventive dentistry vi.
 - Oral pathology and Microbiology vii.
 - Prosthodontics and crown bridge viii.
 - Public health dentistry ix.

5. Diagnostic Centers

- a) Medical Diagnostic Laboratories: There are two main types of labs that process the majority of medical specimens. Hospital laboratories are attached to a hospital, and perform tests on patients. Private (or community) laboratories receive samples from general practitioners, insurance companies, clinical research sites 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
 - b) Diagnostic Imaging centers: Diagnostic Imaging centers could be general and/or Advanced that provide following services:

i Radiology

- General radiology
- Interventional radiology
- ii Electromagnetic imaging (Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET) Scan)
- iii Ultrasound
- c) Collection centers for the clinical labs and diagnostic centres shall function under registered clinical establishment

- 6. 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:

 - Behavioral health (counseling, marriage and family therapy etc.)
 - Exercise physiology
 - Nuclear medicine technology
 - Medical Laboratory Scientist
 - **Dietetics**
 - Occupational therapy
 - Optometry
 - Orthoptics
 - Orthotics and prosthetics
 - Osteopathy
 - Paramedic
 - Podiatry
 - Health Psychology/Clinical Psychology
 - **Physiotherapy**
 - Radiation therapy
 - Radiography / Medical imaging
 - Respiratory Therapy
 - Sonography
 - Speech pathology

7. AYUSH

- Ayurveda Ausadh Chikitsa, Shalya Chikitsa, Shodhan Chikitsa, Rasayana, Pathya Vyavastha
- Yoga Ashtang Yoga
- Unani Matab, Jarahat, Ilaj-bit-Tadbeer, Hifzan-e-Sehat
- Siddha Maruthuvam, Sirappu Maruthuvam, Varmam Thokknam & Yoga
- Homeopathy General Homeopathy
- Naturopathy External Therapies with natural modalities Internal Therapies
- Sowa Rigpa

The above list is not exhaustive: section 13(1) under the Clinical Establishments (Registration and Regulation) Act, 2010 reads;

"Clinical Establishment of different systems shall be classified into such categories as may be prescribed by the Central Government from time to time".