

Standard No.CEA/Clinic- 011

Clinical Establishment Act Standard for Clinic / Polyclinic with Diagnostic Support Services

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Introduction

In 2010 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 prescribe 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. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

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Clinic/ Polyclinic with Diagnostic Support Services

1. Definition

- 1.1 A clinic with support services may be defined as a healthcare facility providing examination, consultation, prescription to outpatients by a single / general practitioner/ specialist doctor /super-specialist doctor. In addition also have the support services like pharmacy, injections, family planning facility, dressing room, sample collection facility, basic laboratory, X- ray, USG with or without color Doppler, ECG or any other.
- 1.2 A polyclinic with observation/short stay may be defined as a healthcare facility providing consultation to outpatients by more than one doctor/ general practitioner/ specialist doctor /super-specialist doctor. In addition also have the support services like pharmacy, injections, family planning facility, dressing room, sample collection facility, basic laboratory, X- ray, USG with or without colour Doppler, ECG or any other.

2. Scope (as applicable)

- 2.1 These set of common minimum standards framed are applicable to a single practitioner/more than one doctor clinic manned by a General physician/ specialist doctor/super specialist or a group of doctors who are providing patient care services like dispensing of medicines, injection and dressing. with observation/short stay facility. In addition also have the support services like pharmacy, injections, family planning facility, dressing room, sample collection facility, basic laboratory, X- ray, USG with or without colour Doppler, ECG or any other.
- 2.2 To provide examination, consultation, prescription to outpatients by a single doctor/ general physician / specialist doctors /super-specialist doctor or group of doctors who are providing patient care services like dispensing of medicines, injection and dressing with observation/short stay facility.
- 2.3 To deliver primary service in health education and health promotion;
- 2.4 To deliver health care services of rehabilitative nature.
- 2.5 **Any or more than one of the following are included:**
- a) Gen Physician
 - b) Cardiology

- c) Cardiothoracic surgery
- d) Dermatology
- e) ENT
- f) Endocrinology
- g) Gastroenterology
- h) Internal Medicine
- i) Gen Surgery
- j) GI –Surgery
- k) Gynecology& Obstetrics
- l) Medical/Surgical Oncology
- m) Nephrology
- n) Neurosurgery
- o) Neurology
- p) Ophthalmology
- q) Orthopedics
- r) Pediatrics/pediatric surgery
- s) Psychiatry
- t) Rheumatology
- u) Thoracic surgery
- v) Tuberculosis and Respiratory Disease
- w) Urology

3. Infrastructure

- 3.1 The physical facility shall be developed and maintained to provide safe and secure environment for patients, their families, staff and visitors. It shall be situated in a place having clean surroundings and shall comply with municipal byelaws in force from time to time.
- 3.2 The minimum space requirement for carrying out the basic functions of the facility shall be as per Annexure 1.
- 3.3 The area shall be well illuminated, ventilated and clean with adequate water supply.
- 3.4 The clinic shall have a prominent board/signage displaying the name of the clinic in local language at the gate or on the building of the clinic.
- 3.5 The following other signage shall be well displayed in the language understood by the local public in the area:
 - a) Name of the doctors with registration number.

- b) Fee structure of the various doctors/ specialist
- c) Timings of the clinics (For ex – from 8am -2pm)
- d) Services provided within the Facility

4. Furniture & Fixtures

- 4.1 Furniture and fixtures shall be available in accordance with the activities and workload of the Clinic/Polyclinic.
- 4.2 The furniture and fixtures shall be functional all the time. For indicative list of items refer to Annexure 2. (this list is indicative and not exhaustive).

5. Human Resource

- 5.1 The general practitioner/ specialist doctor /super-specialist doctors as per the scope of the clinic/polyclinic shall be registered with State/Central Medical Council of India
- 5.2 The services provided by the medical professionals shall be in consonance with their qualification, training, registration.
- 5.3 In a polyclinic minimum one support staff must be available to meet the care treatment and service needs of the patient. However number may depend upon the workload and scope of the service being provided by the clinical establishment.

6. Equipment/instruments/drugs

- 6.1 The clinic/polyclinic shall have essential equipments as per Annexure3, emergency equipment Annexure4 and other equipments as per the scope of service being practiced as per Annexure 5.
- 6.2 Adequate space for storage of medicines equipments etc shall be provided. The equipment shall be of adequate capacity to meet work load requirement.
- 6.3 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment shall be done.
- 6.4 The clinic/polyclinic shall have desired beds for observation/short stay facility.

7. Support Service

- 7.1 In a Clinic/polyclinic minimum one support staff must be available to meet the care treatment and service needs of the patient. However number may depend upon the workload and scope of the service being provided by the clinical establishment.

8. Legal/Statutory Requirements

| S. No | Name of the Act/License | Department/Area | Licensing body |
|--------------|---|------------------------|-------------------------------|
| 1 | Registration of medical doctor with Central/State Medical Council | Administration | MCI/State Medical Council |
| 2 | Biomedical Management & Handling Rules, 1998 | Administration | State pollution control Board |
| 3 | Local registration of the Clinic | Administration | State Council |
| 4. | Pharmacy License | Administration | Indian Pharmacy Council |
| 5. | USG | Administration | PNDT |
| 5 | Approval for Xray if available | Administration | AERB |

9. Record Maintenance and reporting

- 9.1 A copy of OPD Records, procedure records and referral /emergency record shall be maintained as per MCI guidelines. Notifiable diseases under IDSP Project as per Annexure VII weekly disease surveillance data on epidemic prone disease collected on 'S' syndromic; 'P' probable; & 'L' laboratory formats using standard case definitions.

10. Process

10.1 Registration

- 10.1.1 Every patient visiting the clinic shall be registered.

10.2 Assessment

- 10.2.1 Each patient shall undergo an initial assessment, which would include measurement of the vitals, height & weight.
- 10.2.2 The same shall be documented in an assessment/ O.P.D. card.
- 10.2.3 During the course of assessment, the patient findings, medications and investigations shall also be documented legibly in the card with the signature of the consultant/ Specialist / super specialist, date and time.
- 10.2.4 No medicines shall be dispensed from pharmacy store (if facility available) without a written prescription order of doctor, except in emergency cases. Medication dispensing shall be done with care to prevent any medication error. Following shall be checked before dispensing of medication. These checks shall be done at store level:
- 10.2.4.1 Medicine prescribed.
 - 10.2.4.2 Dose of prescribed medicine.
 - 10.2.4.3 Expiry date.
 - 10.2.4.4 Particulate matter in liquid dosage forms and parenteral drugs
 - 10.2.4.5 Labels (if reconstituted drugs).
- 10.2.5 Labelling shall be done for every prepared / reconstituted medication, which shall include name, date of preparation, strength and frequency of administration of drug.
- 10.2.6 The availability of support staff including nursing is essential to ensure safe observation or short stay facility.

10.3 Infection Control

- 10.3.1 The clinic shall take all precautions to control infections like religiously practicing hand washing.

10.3.2 Availability of running tap water for hand washing /liberal use of sanitizer shall be maintained throughout the working hours of the clinic.

10.3.3 The clinic environment shall be kept clean.

10.3.4 Sanitation and hygiene of the toilets shall be maintained.

10.3.5 Mopping of all areas with disinfectant shall be done at least once a day.

10.4 Safety Considerations

10.4.1 Floor shall have even surface and be non slippery in nature. There shall be no seepage in walls or any blockade of drains. There shall be provision of air circulation. Effort shall be made to keep clinic pest and termite free. Availability of mosquito net on windows shall be ensured by the clinician.

10.5 Biomedical waste Management

10.5.1 Clinic waste generated shall be segregated at source.

10.5.2 Biomedical waste shall be managed in accordance with the BMW management and handling Rules, 1998.

10.5.3 Needles shall be destroyed with the help of a needle destroyer before putting them in puncture proof container.

10.6 First aid & basic life support

10.6.1 Appropriate facility for First Aid shall be available.

Annexure 1
Infrastructure requirement

Minimum area required for a clinic:

| Clinic | COMMON AREA | | Consultation room Ancillary area/space | Remarks |
|--------|---|---------|---|--|
| | Reception | Waiting | | |
| | 35sqft carpet area | | 70 sqft carpet area including storage | Area specified under consultation room is only for single clinic and shall be multiplied accordingly by the number of consultation chambers. |
| | | | 40 sq.ft | Store and Pharmacy |
| | Observation & short stay facility (if applicable) | | 65 sq. ft/bed | |
| | For X-ray or USG if applicable | | | As applicable laws |

Note: Reception, waiting, consultation room etc shall be adequate as per the requirement and workload of the clinic.

Ancillary area²/space: Storage of records, reagents, consumables, stationary etc eating area for staff

Annexure 2

Furniture/fixtures

| S.No. | Articles |
|--------------|--|
| 1. | Table |
| 2. | Chairs |
| 3. | Examination Table/couch |
| 4. | Screens |
| 5. | Foot Step |
| 6. | Stools |
| 7. | Storage Cabinet for medicine, records etc. |
| 8. | Bed(s) for observation/short stay |
| 9. | BMW storage area |

Annexure- 3

I. Essential Equipment:

| S. No. | Name of the equipment | Minimum Specifications | No. Of equipment |
|---------------|----------------------------------|-------------------------------|-------------------------|
| 1 | Stethoscope | | 1 |
| 2 | Thermometer | | 1 |
| 3 | Torch (flash lights) | | 1 |
| 4 | Tongue depressor | | 1 |
| 6 | Measuring Tape | | 1 |
| 7 | Sphygmomanometer(B.P. Apparatus) | Digital | 1 |
| 8 | Height measuring Scale | | 1 |
| 9 | Needle Destroyer | | 1 |
| 10 | Weighing machine(Optional) | Adult | 1 |
| 11 | Bed(s) | | 1 or more |
| 12 | IV stand | | 1 |

Annexure- 4

I. Emergency Equipment:

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|---------------|---|-------------------------------|-------------------------|
| 1 | Resuscitation Equipment Ambu Bag/Air Way | - Adult - Pediatric | 1 1 |
| 2 | Oxygen Cylinder (Portable) | | 1 |
| 3 | Fire Extinguisher | ABC Type | 1 |

Annexure - 5

Specialty wise Equipment List

1. Cardiology

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | ECG Machine | | 1 |
| 2 | Pulse Oxymeter | | 1 |

2. Cardiothoracic Surgery

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | ECG Machine | | 1 |
| 2 | Pulse Oxymeter | | 1 |

3. ENT

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|--|------------------------|------------------|
| 1 | Examination instruments set(speculums, mirrors, Bull's lamp) | | 1 |
| 2 | Diagnostic Otoscope | | 1 |
| 3 | Head Light | | 1 |
| 4 | Oesophagoscope Adult | | 1 |
| 5 | Oesophagoscope Child | | 1 |
| 6 | Laryngoscope | | 1 |
| 7 | Tuning Fork | | 1 |

4. Endocrinology

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | Glucometer | | 1 |

5. Gastroenterology

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | Proctoscope | | 1 |
| 2 | Surgical Gloves | | 1 |

6. General Medicine

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | ECG Machine | | 1 |

7. Gynaecology & Obstetrics

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|------------------------|------------------------|------------------|
| 1 | Sim's vaginal speculum | | 1 |
| 2 | Infantometer | | 1 |

8. Neurosurgery

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | EMG Machine | | 1 |

9. Neurology

| S. No. | Name of the equipment | Minimum | No. of equipment |
|--------|-----------------------|---------|------------------|
|--------|-----------------------|---------|------------------|

| | | Specifications | |
|---|-------------|----------------|--|
| 1 | EMG Machine | | |

10. Ophthalmology

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|----------------------------|------------------------|------------------|
| 1 | Ophthalmoscope | | 1 |
| 2 | Slit Lamp | | 1 |
| 3 | Retinoscope | | 1 |
| 4 | Perimeter | | 1 |
| 5 | Distant Vision Charts | | 1 |
| 6 | Near Vision charts | | 1 |
| 7 | Trial Frame Adult/Children | | 1 |
| 8 | Trial Lens Set | | 1 |

11. Orthopaedics

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | Ortho Fracture Table | | 1 |
| 2 | Skeleton traction set | | 1 |
| 3 | Crammer wire splints | | 1 |
| 4 | Thomas Splint | | 1 |

12. Paediatrics

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-------------------------|------------------------|------------------|
| 1 | Nebulizer baby | | 1 |
| 2 | Weighing machine infant | | 1 |

13. Tuberculosis and Respiratory Disease

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | Spirometer | | |
| 2 | Nebulizer | | |
| 3 | Face mask | | |
| 4 | Peak Air flow meter | | |

14. Urology

| S. No. | Name of the equipment | Minimum Specifications | No. of equipment |
|--------|-----------------------|------------------------|------------------|
| 1 | Uroflowmeter | | |

Annexure- 6

I. Essential Drugs

| S. No. | Name of the Drug | Minimum Quantity |
|--------|--------------------------------|------------------|
| 1 | Inj Adrenaline | 2 A |
| 2 | Inj Hydrocortisone | 1 vial |
| 3 | Inj Atropine | 1 Ampoule |
| 5 | InjAvil | 1 Ampoule |
| 6 | InjPhenargan | 1 Ampoule |
| 7 | Inj. Deriphyline | 1 Ampoule |
| 8 | Inj. Frusemide | 1 Ampoule |
| 9 | Inj. Metoclopramide | 1 Ampoule |
| 10 | Inj. Dexamethasone | 1 Ampoule |
| 11 | Inj. Diazepam | 1 Ampoule |
| 12 | Inj. Dicyclomine Hydrochloride | 1 Ampoule |
| 13 | Inj. 5% dextrose infusion | 1 Vac |
| 14 | Inj. Normal saline | 1 Vac |

Note: Other drugs as per the scope of service being practised may also be available.

Glossary

1. **General Physician:**A physician whose practice consists of providing ongoing care covering a variety of medical problems in patients of all ages, often including referral to appropriate specialists. A medical doctor who attends to the everyday medical needs of individuals within a community.
2. **Ancillary area/Ancillary space:**The nonpublic areas or spaces of the stations usually used to house or contain operating, maintenance, or support equipment and functions
3. **Support Staff:** The people who work for an organization to keep it running and to support the people who are involved in the organization.(Ref: Cambridge Dictionary online)
4. **First Aid:**First aid is an immediate and temporary care given to a victim of an accident or sudden illness. Purpose of First Aid is to save life and prevent further injury