

No. A.12034/18/2019-MH.II/MS  
Government of India  
Ministry of Health & Family Welfare  
Department of Health & Family Welfare  
Medical Services Section  
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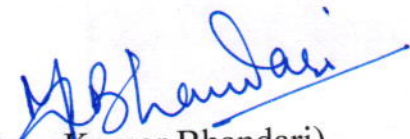
Nirman Bhawan, New Delhi  
Dated 17<sup>th</sup> July, 2019

**NOTICE**

**Subject: Placing the Draft notification on Clinical Establishments (Central Government) Third Amendment Rules, 2019 prescribing 'minimum standards for different categories of clinical establishments of Allopathy and AYUSH' in public domain for comments/suggestion-regarding**

MoHFW plans to notify the rules to prescribe for "minimum standards for different categories of clinical establishments of Allopathy and AYUSH " 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](mailto:help.ceact2010@nic.in) within 45 days from the date of issue of this notice.

  
(Mandeep Kumar Bhandari)

Joint Secretary

स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Ministry of Health & F.W.  
भारत सरकार/Govt. of India  
नई दिल्ली/New Delhi

**DRAFT**

**[To be published in the Gazette of India, Extraordinary Part II, Section 3, Sub-section (i)]**

**Government of India  
Ministry of Health and Family Welfare  
(Department of Health and Family Welfare)**

New Delhi, the 17<sup>th</sup> July, 2019.

**Notification**

G.S.R.\_\_\_\_(E). –The following draft of certain rules further to amend the Clinical Establishments (Central Government) Rules, 2012, which the Central Government proposes to make in exercise of the powers conferred by section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010) is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration on or after the expiry of a period of forty five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public;

Objections and suggestions, if any, may be addressed to Dr. Anil Kumar, Addl. DDG ,Dte.GHS, Ministry of Health and family Welfare , Room No. 560-A, Nirman Bhawan, New Delhi- 110011 or sent on email to [help.ceact2010@nic.in](mailto:help.ceact2010@nic.in);

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

1. (1) These rules may be called the Clinical Establishments (Central Government) Third Amendment Rules, 2019.  
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the said rules, after rule 8, the following rules shall be inserted, namely :

8B. Minimum Standards of Hindi and English versions of approved minimum Standards for following categories of Allopathic Clinical Establishments.

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 Counselling Centre

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. Otorhinolaryngology (Hospital) b. 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 – merged with Nephrology
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.

5. Minimum Standards of AYUSH (all 7 systems, namely Ayurveda, Unani, Siddha, Homoeopathy, Yoga, Naturopathy and Sowa Rigpa) Clinical Establishments

[ F. No. A.12034/18/2019-MH-II/MS]

Dr. Mandeep K. Bhandari, Joint Secretary

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i) vide notification number G.S.R. 387(E), dated the 23rd May, 2012 and last vide notification number G.S.R. 468(E), dated the 18th May, 2018.

**Clinical Establishments  
Act Standard for  
Clinic or Polyclinic  
(Only Consultation)**

**Standard No. CEA orClinic- 001**

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**Clinic or Polyclinic (Only Consultation)**

**1. Definition**

- 1.1 A clinic may be defined as a Clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by a single general practitioner or a specialist doctor or a super-specialist doctor.
- 1.2 A polyclinic may be defined as a Clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by more than one doctor or general practitioners or specialist doctors or super-specialist doctors.
- 1.3 A few minor procedures like dressing and administering Injections etc may be provided in the clinic or polyclinic however not requiring observation or short stay.

**2. Scope (as applicable)**

- 2.1 These set of common minimum standards framed are applicable to a single practitioner or more than one doctor clinic manned by a General physician or specialist doctor or super specialist or a group of doctors who are themselves providing patient care services like dispensing of medicines, Injection and dressing.
- 2.2 To provide examination, consultation, prescription to outpatients by a single doctor or general physician or specialist doctors or super-specialist doctor or group of doctors who are themselves providing patient care services like dispensing of medicines, Injection and dressing.
- 2.3 Advice for health education and health promotion;
- 2.4 **Any or more than one of the following are included:**
  - a) General Physician
  - b) Cardiology
  - c) Cardiothoracic surgery
  - d) Dermatology
  - e) ENT
  - f) Endocrinology
  - g) Gastroenterology



- h) Internal Medicine
- i) General Surgery
- j) Gastro Intestinal Surgery
- k) Gynecology & Obstetrics
- l) Medical Oncology
- m) Surgical Oncology
- n) Nephrology
- o) Neurosurgery
- p) Neurology
- q) Ophthalmology
- r) Orthopedics
- s) Pediatrics
- t) Pediatric Surgery
- u) Psychiatry
- v) Rheumatology
- w) Thoracic surgery
- x) Tuberculosis and Respiratory Diseases
- y) 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 local byelaws in force, if any, from time to time.
- 3.2 The minimum space requirement for carrying out the basic functions of the facility shall be as per **Appendix 1**.
- 3.3 The clinic facility shall be well illuminated, ventilated and clean with adequate water supply.
- 3.4 The clinic shall have a prominent board or 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 doctor(s) with registration number.
  - b) Fee structure of the various doctors or specialists.
  - c) Timings of the clinics (For example: 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 or polyclinic.
- 4.2 The furniture and fixtures shall be functional all the time. For indicative list of items refer **Appendix 2** (this list is indicative and not exhaustive).

#### 5. Human Resource

- 5.1 The general practitioner or specialist doctor or super-specialist doctors as per the scope of the clinic or polyclinic shall be registered with State or Central Medical Council of India.
- 5.2 The services provided by the medical professionals shall be in consonance with their qualification, training and registration.
- 5.3 In a clinic or 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 or instruments or drugs

- 6.1 The clinic or polyclinic shall have essential equipment as per **Appendix 3**, and emergency equipment as per **Appendix 4**.
- 6.2 Other equipment as per the scope of service being practiced shall be available.
- 6.3 Adequate space for storage of equipment and medicines shall be provided and if available medicines shall be stored as per manufacturer's guidelines. The equipment shall be of adequate capacity to meet work load requirement.
- 6.4 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment shall be done.

- 6.5 The clinic or polyclinic shall have basic minimal essential drugs as per **Appendix 5**; however other drugs as per the scope of service being practiced may also be available.

## **7. Support Service**

- 7.1 In a clinic or 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 or Statutory Requirements**

<b>SN</b>	<b>Name of the Act or License</b>	<b>Licensing body</b>
1	Registration of medical doctor with Central or State Medical Council	MCI or State Medical Council as applicable
2	Biomedical Waste Management Rules, 2016	State Pollution Control Board
3	Registration of the Clinic	State Council

## **9. Record Maintenance and reporting**

- 9.1 Every Clinical Establishment shall maintain medical records of patients treated by it and health information and statistics in respect of national programmes and furnish the same to the district authorities in form of quarterly reports.
- 9.2 All clinical establishments shall be responsible for submission of information and statistics in time of emergency or disaster or epidemic situation or as required from time to time by National Council, Clinical eEstablishments Act 2010.

## **10. Process**

### **10.1 Registration**

- 10.1.1 Every patient visiting the clinic shall be registered.
- 10.1.2 Patient shall be guided and informed regarding Patients' Rights and Responsibilities **Appendix 6**

## **10.2 Assessment**

10.2.1 Every patient shall undergo assessment, during the course of assessment, the patient findings, medications and investigations should be documented with working diagnosis, legibly in the assessment or OPD prescription with the signature of the consultant or Specialist or Super specialist with date and time.

## **10.3 Infection Control**

10.3.1 The clinic shall take all precautions to control infections like practising hand hygiene etc.

10.3.2 Availability of clean water for hand washing or liberal use of sanitizer shall be maintained throughout the working hours of the clinic.

10.3.3 Sanitation and hygiene of the toilets if available shall be maintained.

10.3.4 Mopping of all patient care areas with disinfectant shall be done at least once a day.

## **10.4 Safety Considerations**

10.4.1 The clinic shall ensure to take care of patient safety aspects like patient fall, etc.

10.4.2 The clinic shall be kept pest and termite free.

## **10.5 Biomedical waste Management**

10.5.1 Biomedical waste shall be managed in accordance with the Bio Medical Waste management Rules, 2016.

10.5.2 Clinic waste generated shall be segregated at source.

10.5.3 Needles and sharp waste shall be stored in tamper proof, leak proof and puncture proof container.

## **10.6 First aid**

10.6.1 Provision shall be made for providing First Aid.

10.6.2 Contact details of ambulance hospital etc shall be available in case of emergency.

**APPENDIX 1****Infrastructure Requirement (Desirable)**

Minimum area required for clinic shall be as follows:

SN	LOCATION	AREA REQUIRED	REMARKS
1	Common area (Reception and waiting)	35 sq ft carpet area	
2	Consultation room (ancillary area)	70 sq ft including storage	Area specified under consultation room is only for single clinic and shall be multiplied accordingly by the number of consultation chambers.

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

Ancillary areaorspace: Storage of records, reagents, consumables, stationery etc and eating area for staff.

**APPENDIX 2****Furniture or fixtures**

S.N.	Articles
1.	Table
2.	Chairs
3.	Examination Table or couch
4.	Screens
5.	Foot Step
6.	Stools
7.	Storage Cabinet for records etc.
8.	BMW storage area

**APPENDIX 3****Equipment or Instrument****I. Essential Equipment**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>No. of equipment</b>
1	Stethoscope		1
2	Thermometer	(Non Mercury)	1
3	Torch (flash lights)		1
4	Sphygmomanometer(Blood Pressure Apparatus)	(Non Mercury)	1
5	Weighing machine(Optional)	Adult	1

**APPENDIX 4****I. Emergency Equipment**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>No. of equipment</b>
1	Resuscitation Equipment	- Adult	1
	Ambu Bag or Air Way	- Pediatric	1
2	Oxygen Concentrator or Cylinder (Portable)		1
3	Fire Extinguisher	-	1

**APPENDIX 5****I. Emergency Drugs**

<b>S. No.</b>	<b>Name of the Drug</b>	<b>Minimum Quantity</b>
1	Injection Adrenaline	2 Ampoules
2	Injection Hydrocortisone	1 vial
3	Injection Atropine	1 Ampoule
5	Injection Pheniramine maleate	1 Ampoule
6	Injection Promethazine	1 Ampoule
7	Injection Deriyphylline	1 Ampoule
8	Injection. Frusemide	1 Ampoule
9	Injection. Metoclopramide	1 Ampoule
10	Injection Dexamethasone	1 Ampoule
11	Injection Diazepam	1 Ampoule
12	Injection Dicyclomine Hydrochloride	1 Ampoule
13	Injection 5% dextrose infusion	1 Vac
14	Injection Normal saline	1 Vac

## **APPENDIX 6**

### **Patients' Rights and Responsibilities:**

#### **Patients' Rights**

A patient and his or her representative has the following rights with respect to the clinical establishment-

1. To adequate relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs;
2. Rate of services provided by the clinical establishment would be displayed prominently.
3. To access a copy of case papers, patient records, investigations reports and detailed bill.
4. To informed consent prior to specific tests or treatment (e.g. surgery, chemotherapy)
5. To seek second opinion from an appropriate clinician of patients' choice, with records and information being provided by treating hospital
6. To confidentiality, human dignity and privacy during treatment.
7. To have ensured presence of a female person, during physical examination of a female patient by a male practitioner.
8. To non-discrimination about treatment and behaviour on the basis of HIV status.
9. To choose alternative treatment if options are available.
10. Rate of services provided by the clinical establishment would be displayed prominently.

#### **Patients' Responsibilities**

- Provide all health related information
- Cooperate with Doctors during examination and treatment
- Follow all instructions
- Pay hospitals agreed fees on time
- Respect dignity of doctors and other hospital staff
- Never resort to violence



**Clinical Establishments  
Act Standard for  
Clinic or Polyclinic  
with Dispensary  
Standard No.CEA/Clinic- 002**

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**Clinic or Polyclinic with Dispensary**

**11. Definition**

- 11.1 A clinic may be defined as a clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by a single or general practitioner or group of general practitioners or specialist doctor or super-specialist doctor.
- 11.2 A polyclinic may be defined as a clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by more than one doctor or general practitioner or group of general practitioners or specialist doctor or super-specialist doctor.
- 11.3 A few minor procedures like dressing, administering Injections, family planning etc may be provided in the clinic or polyclinic however not requiring observation or short stay.
- 11.4 Dispensing of medicines shall be done by qualified professionals to out- patients.

**12. Scope (as applicable)**

- 12.1 These set of common minimum standards framed are applicable to a single practitioner or more than one doctor clinic manned by a general physician or specialist doctor or super specialist or a group of doctors who are themselves providing patient care services like dispensing of medicines, Injections and dressings.
- 12.2 To provide examination, consultation, prescription to outpatients by a single doctor or general physician or specialist doctor or super-specialist doctor or group of doctors who are themselves providing patient care services like dispensing of medicines, Injections and dressings.
- 12.3 To deliver primary service in health education and health promotion;
- 12.4 To deliver health care services of rehabilitative nature.
- 12.5 **Any or more than one of the following are included:**
- a) General Physician
  - b) Cardiology
  - c) Cardiothoracic surgery
  - d) Dermatology

- e) ENT
- f) Endocrinology
- g) Gastroenterology
- h) Internal Medicine
- i) General Surgery
- j) Gastro Intestinal Surgery
- k) Gynecology & Obstetrics
- l) Medical Oncology
- m) Surgical Oncology
- n) Nephrology
- o) Neurosurgery
- p) Neurology
- q) Ophthalmology
- r) Orthopedics
- s) Pediatrics
- t) Pediatric surgery
- u) Psychiatry
- v) Rheumatology
- w) Thoracic surgery
- x) Tuberculosis and Respiratory Diseases
- y) Urology

### **13. Infrastructure**

- 13.1 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 local byelaws in force, if any, from time to time.
- 13.2 The minimum space requirement for carrying out the basic functions of the facility shall be as per **Appendix 1**.
- 13.3 The area shall be well illuminated, ventilated and clean with adequate water supply.
- 13.4 The clinic shall have a prominent board or signage displaying the name of the clinic in local language at the gate or on the building of the clinic.
- 13.5 The following other signages shall be well displayed in the language understood by the local public in the area:
  - a) Name of the doctor(s) with registration number(s).
  - b) Fee structure of the various doctors or specialists
  - c) Timings of the clinics (For e.g. from 8am -2pm)

- d) Services provided within the facility

#### **14. Furniture & Fixtures**

- 14.1 Furniture and fixtures shall be available in accordance with the activities and workload of the Clinic or polyclinic.
- 14.2 The furniture and fixtures shall be functional all the time. For indicative list of items refer to **Appendix 2** (This list is indicative and not exhaustive).

#### **15. Human Resource Requirements**

- 15.1 A single general practitioner or group of general practitioners or specialist doctors or super-specialist doctors as per the scope of the clinic or polyclinic shall be registered with State or Central Medical Council of India.
- 15.2 The services provided by the medical professionals shall be in consonance with their qualification, training and registration.
- 15.3 If dispensing is done by paramedic like pharmacist, he shall be qualified, trained and registered with the Pharmacy Council.

#### **16. Equipment or instruments or drugs**

- 16.1 The clinic or polyclinic shall have essential equipments as per **Appendix 3** and emergency equipment as per **Appendix 4**.
- 16.2 Other equipments as per the scope of service being practised shall also be available.
- 16.3 Adequate space for storage of equipments and medicines shall be provided and if available medicines shall be stored as per manufacturer's guidelines. The equipment shall be of adequate capacity to meet work load requirement.
- 16.4 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment shall be done.
- 16.5 The clinic or polyclinic shall have basic minimal essential drugs as per **Appendix 5**; however other drugs as per the scope of service being practised may also be available.

## **17.Support Service**

7.1 In a Clinic or 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.

## **18. Legal or Statutory Requirements**

<b>S. No</b>	<b>Name of the Actor License</b>	<b>Department or Area</b>	<b>Licensing body</b>
1	Registration of medical doctor with Central or State Medical Council	Administration	MCI or State Medical Council
2	Biomedical Waste Management Rules, 2016	Administration	State pollution control Board
3	Local registration of the Clinic	Administration	State Council
4.	Pharmacy License	Administration	Indian Pharmacy Council

## **19.Record Maintenance and reporting**

19.1 Every Clinical Establishment shall maintain medical records of patients treated by it and health information and statistics in respect of national programmes and furnish the same to the district authorities in form of quarterly reports.

19.2 All clinical establishments shall be responsible for submission of information and statistics in time of emergency or disaster or epidemic situation or as required from time to time by National Council, Clinical Establishments Act 2010.

19.3 Medicine Records and Registers

## **20. Basic processes**

### **10.1 Registration**

Every patient visiting the clinic shall be registered.

10.1.1 Patient shall be guided and informed regarding Patients' rights and responsibilities *Appendix 6*

## **10.2 Assessment**

10.2.1 Every patient shall undergo assessment, during the course of assessment, the patient findings, medications and investigations should be documented with working diagnosis, legibly in the assessment or OPD prescription with the signature of the consultant or Specialist or Super Specialist with date and time.

10.2.2 Medicines shall be dispensed by qualified doctor or pharmacist as allowed by law.

10.2.3 No medicines shall be dispensed from pharmacy store 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.

10.2.3.1 Medicine prescribed.

10.2.3.2 Dose of prescribed medicine.

10.2.3.3 Expiry date.

10.2.3.4 Particulate matter in liquid dosage forms and parenteral drugs.

10.2.3.5 Labels (if reconstituted drugs).

10.2.4 Labeling shall be done for every prepared or reconstituted medication, which shall include name, date of preparation, strength and frequency of administration of drug.

## **10.3 Infection Control**

10.3.1 The clinic shall take all precautions to control infections like practising hand hygiene etc.

10.3.2 The clinic shall have availability of clean water for hand washing or should be maintained throughout the working hours of the clinic.

10.3.3 Sanitation and hygiene of the toilets if available shall be maintained.

10.3.4 Mopping of all patient care areas with disinfectant shall be done at least once a day

#### **10.4 Safety Considerations**

10.4.1 Effort shall be made to take care of patient safety aspects like patient fall, etc.

10.4.2 Effort shall be made to keep clinic pest and termite free.

#### **10.5 Biomedical waste Management**

10.5.1 Biomedical waste should be managed in accordance with the BMW management Rules, 2016.

10.5.2 Clinic waste generated should be segregated at source.

10.5.3 Needles and sharp waste should be stored in puncture proof, leak proof and tamper proof containers.

#### **10.6 First aid**

10.6 Provision shall be made for providing First Aid.

10.7 Contact details of ambulance hospital etc shall be available.



**APPENDIX 1**

**Infrastructure requirement (Desirable)**

**Minimum area required for a clinic:**

<b>SN</b>	<b>LOCATION</b>	<b>AREA REQUIRED</b>	<b>REMARKS</b>
1	Common area (Reception and waiting)	35 sq ft carpet area	
2	Consultation room (ancillary area)	70 sq ft 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.
3	Store and pharmacy	40 sq ft	

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

Ancillary area or space: Storage of records, reagents, consumables, stationery etc

**APPENDIX 2**

**Furniture or fixtures**

<b>S.N.</b>	<b>Articles</b>
1	Table
2	Chairs
3	Examination Table or couch
4	Screens
5	Foot Step
6	Stools
7	Storage Cabinet for records etc.
8	BMW Storage area

**APPENDIX- 3**

**I. Essential Equipment:**

S. No.	Name of the equipment	Minimum Specifications	Number of equipment
1	Stethoscope		1
2	Thermometer	(Non Mercury)	1
3	Torch (flash lights)		1
4	Sphygmomanometer (B.P. Apparatus)	(Non Mercury)	1
5	Weighing machine (Optional)	Adult	1

**APPENDIX- 4**

**I. Emergency Equipment:**

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

**APPENDIX- 5**

**I. Emergency Drugs**

<b>S. No.</b>	<b>Name of the Drug</b>	<b>Minimum Quantity</b>
<b>1</b>	Injection Adrenaline	2 Ampoules
<b>2</b>	Injection Hydrocortisone	1 vial
<b>3</b>	Injection Atropine	1 Ampoule
<b>5</b>	Injection Pheniramine maleate	1 Ampoule
<b>6</b>	Injection Promethazine	1 Ampoule
<b>7</b>	Injection Deriphylline	1 Ampoule
<b>8</b>	Injection Frusemide	1 Ampoule
<b>9</b>	Injection Metoclopramide	1 Ampoule
<b>10</b>	Injection Dexamethasone	1 Ampoule
<b>11</b>	Injection. Diazepam	1 Ampoule
<b>12</b>	Injection Dicyclomine Hydrochloride	1 Ampoule
<b>13</b>	Injection. 5% dextrose infusion	1 Vac
<b>14</b>	Injection. Normal saline	1 Vac

## **APPENDIX 6**

### **Patients' rights and responsibilities:**

#### **Patients' Rights**

A patient and his or her representative has the following rights with respect to the clinical establishment-

11. To adequate relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs;
12. Rate of services provided by the clinical establishment would be displayed prominently.
13. To access a copy of case papers, patient records, investigations reports and detailed bill.
14. To informed consent prior to specific tests or treatment (e.g. surgery, chemotherapy.)
15. To seek second opinion from an appropriate clinician of patients' choice, with records and information being provided by treating hospital
16. To confidentiality, human dignity and privacy during treatment.
17. To have ensured presence of a female person, during physical examination of a female patient by a male practitioner.
18. To non-discrimination about treatment and behaviour on the basis of HIV status.
19. To choose alternative treatment if options are available
20. Rate of services provided by the clinical establishment would be displayed prominently.

#### **Patients' Responsibilities**

- Provide all health related information
- Cooperate with doctors during examination, treatment etc
- Follow all instructions
- Pay hospitals agreed fees on time
- Respect dignity of doctors and other hospital staff
- Never resort to violence

**Clinical Establishments  
Act Standard for  
Clinic or Polyclinic or  
Dispensary with  
Diagnostic Support Services**

**Standard No.CEA or Clinic-003**

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**Clinic or Polyclinic with Diagnostic Support Services**

**11 Definition**

11.1 A clinic with support services may be defined as a healthcare facility providing examination, consultation, prescription to outpatients by a single general practitioner or or a group of general practitioners or specialist doctor or super-specialist doctor. In addition, also have the support services like pharmacy, Injections, family planning facility, dressing room, and sample collection facility, basic laboratory, X- ray, USG with or without color Doppler, ECG or any other.

- It differs from Health checkup center which provides health preventive and promotive services.

**12 Scope (as applicable)**

12.1 These set of common minimum standards framed are applicable to a single practitioner or more than one doctor clinic manned by a General physician or specialist doctor or super specialist or a group of doctors who are providing patient care services like dispensing of medicines, Injection and dressing, with observation or 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.

12.2 To provide examination, consultation, prescription to outpatients by a single doctor or general physician or specialist doctors or super-specialist doctor or group of doctors who are providing patient care services like dispensing of medicines, Injection and dressing with observation or short stay facility.

12.3 To deliver primary service in health education and health promotion;

12.4 To deliver health care services of rehabilitative nature.

**12.5 Any or more than one of the following are included:**

- a) General Physician
- b) Cardiology
- c) Cardiothoracic surgery
- d) Dermatology
- e) ENT
- f) Endocrinology
- g) Gastroenterology

- h) Internal Medicine
- i) General Surgery
- j) Gastro Intestinal Surgery
- k) Gynecology & Obstetrics
- l) Medical Oncology
- m) Surgical Oncology
- n) Nephrology
- o) Neurosurgery
- p) Neurology
- q) Ophthalmology
- r) Orthopedics
- s) Pediatrics
- t) Pediatric surgery
- u) Psychiatry
- v) Rheumatology
- w) Thoracic surgery
- x) Tuberculosis and Respiratory Diseases
- y) Urology

### **13 Infrastructure**

- 13.1 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.
- 13.2 The minimum space requirement for carrying out the basic functions of the facility shall be as per **Appendix 1**.
- 13.3 The area shall be well illuminated, ventilated and clean with adequate water supply.
- 13.4 The clinic shall have a prominent board or signage displaying the name of the clinic in local language at the gate or on the building of the clinic.
- 13.5 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 or specialists
  - c) Timings of the clinics (For e.g. – from 8am -2pm)
  - d) Services provided within the Facility



## **14 Furniture & Fixtures**

- 14.1 Furniture and fixtures shall be available in accordance with the activities and workload of the Clinic or Polyclinic.
- 14.2 The furniture and fixtures shall be functional all the time. For indicative list of items, refer to **Appendix 2**. (This list is indicative and not exhaustive).

## **15 Human Resource**

- 15.1 The general practitioner or specialist doctor or super-specialist doctors as per the scope of the clinic or polyclinic shall be registered with State or Central Medical Council of India.
- 15.2 The services provided by the medical professionals shall be in consonance with their qualification, training and registration.
- 15.3 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.

## **16 Equipment or instruments or drugs**

- 16.1 The clinic or polyclinic shall have essential equipment as per **Appendix 3**, emergency equipment **Appendix 4** and other equipment as per the scope of service being practiced as per **Appendix 5**.
- 16.2 Adequate space for storage of medicines equipment etc shall be provided. The equipment shall be of adequate capacity to meet work load requirement.
- 16.3 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment shall be done.
- 16.4 The clinic or polyclinic shall have desired beds for observation or short stay facility.
- 16.5 The clinic or polyclinic shall have basic minimal essential drugs as per **Appendix 6**; however other drugs as per the scope of service being practiced may also be available.

## **17 Support Service**

- 7.1 In a Clinic or 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.

## **18 Legal or Statutory Requirements**

<b>S. No</b>	<b>Name of the Act or License</b>	<b>Department or Area</b>	<b>Licensing body</b>
1	Registration of medical doctor with Central or State Medical Council	Administration	MCI or State Medical Council
2	Biomedical Management & Rules, 2016	Administration	State Pollution Control Board
3	Local registration of the Clinic	Administration	State Council
4.	Pharmacy License	Administration	Indian Pharmacy Council (If applicable)
5.	USG	Administration	PC-PNDT
5	Approval for X-ray if available	Administration	AERB

## **19 Record Maintenance and reporting**

- 19.1 Every Clinical Establishment shall maintain medical records of patients treated by it and health information and statistics in respect of national programmes and furnish the same to the district authorities in form of quarterly reports.

- 19.2 All clinical establishments shall be responsible for submission of information and statistics in time of emergency or disaster or epidemic situation or as required from time to time by National Council Clinical establishments Act 2010.

## **10. Process**

### **10.1 Registration**

10.1.1 Every patient visiting the clinic shall be registered.

Patient shall be guided and informed regarding Patients' Rights and Responsibilities **Appendix 7**

### **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 or 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 or Specialist or 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 Labeling shall be done for every prepared or reconstituted medication, which shall include name, date of preparation, strength and frequency of administration of drug.

## **Clinical Establishments Act Standards for Clinic or Polyclinic with Dispensary /Clinic-002**

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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 or 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 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 BioMedical Waste management Rules, 2016.

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

### **10.6 First aid & basic life support**

10.6.1 Appropriate facility for First Aid shall be available.

**APPENDIX 1**

**Infrastructure requirement (Desirable)**

**Minimum area required for a clinic:**

<b>SN</b>	<b>LOCATION</b>	<b>AREA REQUIRED</b>	<b>REMARKS</b>
1	Common area (Reception and waiting)	35 sq ft carpet area	
2	Consultation room (ancillary area)	70 sq ft	Area specified under consultation room is only for single clinic and shall be multiplied accordingly by the number of consultation chambers.
3	Store and pharmacy	40 sq ft	
4	Observation and short stay (if applicable)	65 sq ft or bed	
5	For X-Ray or USG, if applicable	As per laws applicable	

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

Ancillary area or space: Storage of records, reagents, consumables, stationery etc eating area for staff

**APPENDIX 2**

**Furniture or fixtures**

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

**APPENDIX-3**

**I. Essential Equipment:**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>No. Of equipment</b>
1	Stethoscope		1
2	Thermometer	(Non Mercury)	1
3	Torch (flash lights)		1
4	Tongue depressor		1
6	Measuring Tape		1
7	Sphygmomanometer (B.P. Apparatus)	(Non Mercury)	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

**APPENDIX- 4**

**I. Emergency Equipment:**

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



**APPENDIX - 5**

**Specialty wise Equipment List**

**1. Cardiology**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	ECG Machine		1
2	Pulse Oximeter		1

**2. Cardiothoracic Surgery**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	ECG Machine		1
2	Pulse Oximeter		1

**3. ENT**

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

#### 4. Endocrinology

S. No.	Name of the equipment	Minimum Specifications	Number of equipment
1	Glucometer		1

#### 5. Gastroenterology

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

#### 6. General Medicine

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

#### 7. Gynaecology & Obstetrics

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

#### 8. Neurosurgery

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

**9. Neurology**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	EMG Machine		

**10. Ophthalmology**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
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 or Children		1
8	Trial Lens Set		1

**11. Orthopaedics**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	Ortho Fracture Table		1
2	Skeleton traction set		1
3	Cramer wire splints		1
4	Thomas Splint		1

**12. Paediatrics**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	Nebulizer baby		1
2	Weighing machine infant		1

**13. Tuberculosis and Respiratory Disease**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	Spirometer		
2	Nebulizer		
3	Face mask		
4	Peak Air flow meter		

**14. Urology**

<b>S. No.</b>	<b>Name of the equipment</b>	<b>Minimum Specifications</b>	<b>Number of equipment</b>
1	Uroflowmeter		

**APPENDIX- 6**

**I. Essential Drugs**

<b>S. No.</b>	<b>Name of the Drug</b>	<b>Minimum Quantity</b>
1	Injection Adrenaline	2 Ampoules
2	Injection Hydrocortisone	1 vial
3	Injection Atropine	1 Ampoule
5	Injection Pheniramine maleate	1 Ampoule
6	Injection Promethazine	1 Ampoule
7	Injection Deriphylline	1 Ampoule
8	Injection Frusemide	1 Ampoule
9	Injection Metoclopramide	1 Ampoule
10	Injection Dexamethasone	1 Ampoule
11	Injection. Diazepam	1 Ampoule
12	Injection Dicyclomine Hydrochloride	1 Ampoule
13	Injection 5% dextrose infusion	1 Vac
14	Injection. Normal saline	1 Vac

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

**APPENDIX 7**

**Patients' Rights and Responsibilities:**

**Patients' Rights**

A patient and his or her representative has the following rights with respect to the clinical establishment-

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22. Rate of services provided by the clinical establishment would be displayed prominently.
23. To access a copy of case papers, patient records, investigations reports and detailed bill.
24. To informed consent prior to specific tests or treatment (e.g. surgery, chemotherapy)
25. To seek second opinion from an appropriate clinician of patients' choice, with records and information being provided by treating hospital
26. To confidentiality, human dignity and privacy during treatment.
27. To have ensured presence of a female person, during physical examination of a female patient by a male practitioner.
28. To non-discrimination about treatment and behaviour on the basis of HIV status
29. To choose alternative treatment if options are available
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**Patients' Responsibilities**

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- Cooperate with Doctors during examination, treatment
- Follow all instructions
- Pay hospitals agreed fees on time
- Respect dignity of doctors and other hospital staff
- Never resort to violence