

Standard No. CEA/Wellness Centre- 018

Clinical Establishment Act Standard for Wellness Centre- Executive Health Check up

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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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Wellness Centre-Executive Health Checkup

1. Definition

The standards for wellness centre are framed based on the basic functions of the unit/centre /provider.

Type of Services	Scope of Services
Wellness	Wellness is a state of optimal health covering physical, mental, social aspects of an individual.
Wellness Centre	Wellness centre is an healthcare facility that provided scientifically proven physical interventions with repeatable positive outcome for improvement or maintenance of physical form, enhancement of functions or improvement of beauty (as define by the customer) for achieving the state of wellness of an individual. Wellness Centre will address at least two related to the Structure, Function and Beauty of human beings.
Wellness Interventions	Wellness interventions are those interventions that do not require overnight stay at the wellness centre for medical reasons; leaving the treatment after any stage should not cause any harm to the individual.
Centers	Executive Health Checkup Centre

2. Scope (as applicable)

2.This includes the services being provided by the facility to which the standards will be applicable.

2.1. List of services:The scope of services that may be provided at an centre may include services in any or all of the following specialties, but not necessarily limited to:

Specific Services under each category to be decided by the centre	
Executive Health Checks	
1.	Laboratory services
2.	Imaging services
3.	Fitness check
4.	Consultation – Optional

2.2. List of Support Services:

2.2.1 Laboratory services to be available either in-house or outside the centre.

2.2.2 Imaging services to be available either in-house or outside the centre.

Sr. no.	Support Service	Applicability
1.	Accounting,	Optional
2.	Billing	Applicable
3.	Essential commodities like water supply, electric supply etc.	Applicable
4.	Finance	Optional
5.	Financial accounting and auditing	As required by Law
6.	Housekeeping and Sanitation	Applicable
7.	Inventory Management	Optional
8.	Laundry services	Optional
9.	Medical records	Applicable
10.	Office Management (Provision should be made for computerized medical records with anti-virus facilities whereas alternate records should also be maintained)	Applicable
11.	Personnel Department	Optional
12.	Pharmacy/ Dispensary	Optional
13.	Purchase	Applicable
14.	Reception,	Applicable
15.	Security services	Optional
16.	Stores	Optional
17.	Waste management Housekeeping/ sanitation,	Applicable
18.	Equipment Management	Applicable

3. Infrastructure Requirements

3.1 Basic signage- A signage within or outside the facility shall be made available containing the following information.

3.1.1 A signage within or outside the facility should be made available containing the following information.

3.1.2 *All signage meant for customer and visitors shall be bilingual – Local language and Hindi / English

3.2 Following **Informative signage** shall be displayed:

3.2.1 Name of the care provider with registration number

3.2.2 Name of organization.

- 3.2.3 Display of Registration under clinical establishment act
 - 3.2.4 Fee structure,
 - 3.2.5 Availability of tariff list.
 - 3.2.6 Timings of the facility
 - 3.2.7 Availability of timings with names and respective specializations
 - 3.2.8 Services provided
 - 3.2.9 Directional signage for customers for utilities and conveniences like toilets, drinking water, telephone booths, shops.
 - 3.2.10 Display of Executive Health checks centre scope of services
 - 3.2.11 Floor Plan With Location Of Departments
 - 3.2.12 Plan of Facility, if stand-alone building.
- 3.3 Following **Safety signage** shall be displayed:
- 3.3.1 Safety Hazard and Caution signs
 - 3.3.2 Display of all radiation hazard signage in radiation areas (if applicable).
 - 3.3.3 Display of Biomedical waste segregation at all location where BMW bins are kept
 - 3.3.4 Display of danger signage at all electric panels and other dangerous areas
 - 3.3.5 Display of General instructions like 'No Smoking', 'Keep Silence', 'Use dustbin', etc. at various customer and visitor areas in the hospital
 - 3.3.6 Display of hand--washing techniques compliant with WHO guidelines at all hand wash basins
 - 3.3.7 Display of important phone contact numbers of hospital authorities
 - 3.3.8 Displays required by regulations like PNDT, Lifts, Fire, etc.
 - 3.3.9 Display of Material Safety Data Sheet at all locations where Hazardous Materials are stored
 - 3.3.10 Display of customer rights and responsibilities

3.3.11 Display of safety instructions in areas where any kind of safety hazard may be expected. This includes areas like transformers, Cylinder storage, LPG storage etc

3.3.12 Hazards- electrical, fall, pipe locations, prohibited areas

3.3.13 Notice board for general information to staff

3.3.14 Notice board in front of all customer

3.3.15 Routes for all areas

3.3.16 Signage for parking. (Signage for ambulance parking shall be separately mentioned)

3.3.17 Appropriate Fire exit signage's

3.3.18 Display of how to use fire extinguisher at all point where fire extinguisher is installed

3.3.19 Emergency exit signage (preferably in auto illumination material, like radium)

3.3.20 Safety signage will be displays as per the requirements of respective Indian Standards: Ex. Fire Protection Safety Signs IS 12349:1988

3.4. Functional space planning of the facility like reception area, waiting area should be as per the scope of services.

3.4.1 Consultation & examination room

- i. Consultation room should be adequate to accommodate:
- ii. Table for Consultancy
- iii. Consultation chair,
- iv. Two stools/ chairs,
- v. Examination bed, if necessary, will be of the size 6 ft X 2.5 ft.,
- vi. Privacy screen around examination area while having free mobility

3.4.2 Laundry (optional)

- i. Laundry services can be in-house or outsourced.
- ii. If it is provided in house, it should have necessary facilities for drying, pressing and storage of soiled and cleaned linens.
- iii. If outsourced, quality of outsourced work is monitored by the organization.

3.4.3 House-Keeping:

- i. Housekeeping services should be made available for effective cleanliness.
- ii. Housekeeping services can be outsourced.

- iii. A designated area within functional areas for safe storage of housekeeping materials has to be in centre.

3.4.4 Security Services:

- i. There is a designated location for security staff on duty.

3.4.5 Clinical laboratory specifications:

- i. Laboratory services to be available either in-house or outside the Hospital. for quick diagnosis of blood, urine, etc.,

3.4.6 Radiology section

- i. Imaging services to be available either in-house or outside the Hospital.
- ii. The department should be located at a place which is accessible to customers.
- iii. The size of the room should depend on the type of instrument installed.
- iv. It should conform to AERB requirements.
- v. The room should have a sub-waiting area with toilet facility and a change room facility, if required.
- vi. Film developing and processing (dark room) shall be provided in the department for loading, unloading, developing and processing of X-ray films.
- vii. Separate Reporting Room for doctors should be provided.

3.4.7 Customer / Medical record-room:

- i. Customer /Medical record-storage should be of adequate size as per the load of the documents of the centre.
- ii. Tamperproof material and locking facility Cabinets/ cupboards/ Boxes will be used.
- iii. Fire extinguishers of correct type should be made available nearby all locations.

3.4.8 Store rooms:

- i. Store room should be lockable & of adequate size with exhaust fan.
- ii. Area should be clean, well ventilated, well lit, without any dampness or fungal growth on walls.

3.4.9 Duty rooms for doctors

- i. To accommodate 1 bed of 6 feet X 3 feet and a side table.
- ii. Separate beds if sharing for same gender.
- iii. Separate rooms for separate genders will be provided.

3.4.10 Duty rooms for technicians:

- i. To accommodate 1 bed of 6 feet X 3 feet and a side table.

- ii. Separate beds if sharing for same gender.
- iii. Separate rooms for separate genders will be provided.

3.4.11 Dirty utility room:

- i. Separate area of minimum 15 sq feet.

4. Furniture &Fixtures

- 4.1 Furniture and fixtures shall be available in accordance with the services and workload of the centre. For indicative list refer to Annexure 1.
- 4.2 The furniture and fixtures shall be functional all the time.

5. Human Resource

- 5.1 A suitably qualified and individual heads the organization and manages in ethical manner. For detail refer to Annexure 2.
- 5.2 The technical staff employed should have the relevant education / registration, training and experience to provide service to customer care without supervision.
- 5.3 The additional staff member shall be adequately trained on specific job duties or responsibilities related to customer safety and well being.
- 5.4 Personnel record containing personal and professional information shall be maintained for each staff.
- 5.5 Periodic skill enhancement/up gradation /refresher trainings shall be provided for all categories of the staff relevant to their job profile.

6. Equipment/Instruments

- 6.1 The centre shall have equipment's / instruments as per the scope of services provided. For indicative list refer to Annexure 3
- 6.2 Adequate space for placement and usage of equipment's and Instruments shall be provided.
- 6.3 The equipment should be of adequate capacity to meet work load requirement.

- 6.4 All equipment should be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment should be done.

7. Drugs and Consumables

- 7.1 Drugs and consumables as per the scope of services provided. For indicative list refer to Annexure 4.
- 7.2 Storage of drugs, cosmetic and consumables shall be stored as per manufacturer's guidelines.
- 7.3 The drugs are handled by appropriate personnel in accordance of the regional, local and national regulations.

For Legal requirement refer to Annexure 4

For record maintenance refer to Annexure 5

OTHER REQUIREMENTS AS PER STANDARD NO. CEA-NABH /WELLNESS CENTRE- 017SHALL ALSO BE COMPLIED WITH.

Annexure 1

Furniture/fixture

I. Furniture/Fixture Requirements: as per the scope of services		
Sr. No.	Name of the Equipment	Executive Health checks Centre
1.	Adequate lockable storage space	As per requirement
2.	Air conditioning	As per requirement
3.	An examination table of 6 ft. X 2.5 ft. With privacy screen	As per requirement
4.	Blood pressure apparatus	1 per Centre
5.	Ceiling Fans	As per requirement
6.	Clock 1 per Centre	1 per Centre
7.	Computers (if required)	1 per Centre
8.	Consultant's chair	As needed
9.	Consultant's or Office table	1 per Centre
10.	Duty table for staff	1 per Centre
11.	Emergency resuscitation kit	1 per Centre
12.	Essential diagnostic tools required for examination of customer as per the scope of services offered by the Centre.	As per requirement
13.	Fire extinguisher	ABC 1 per ward/ floor based on layout
14.	Foot stools	1 per consultation room
15.	Heavy duty Torch light	1 per Centre
16.	Hot Water Bags	As per requirement
17.	Hot Water geyser	As per requirement
18.	Light source which gives light colour and temperature similar to solar light, Light intensity of at least 500 lux at the point of examination.	As per requirement
19.	Office chairs	1 per Centre
20.	Customer locker	1 per Centre
21.	Refrigerator if temperature sensitive medication are stored (if required)	1 per Centre
22.	Steel or Wooden cup board	As per requirement
23.	Steel rack	As per requirement
24.	Stethoscope	1 per Centre
25.	Stools	As per requirement

26.	Stools revolving	2 per Centre
27.	Hammock Stretcher/ Stretcher/ Customer trolley – 1 per Centre	1 per Centre
28.	Telephone/ Fax equipment	As per requirement
29.	Thermometer	1 per Centre
30.	Waiting chairs / benches for customer's relatives	50% of the customer strengths
31.	Weighing machine	1 per Centre
32.	Wheel chair	1 per Centre
33.	X-ray viewer	1 per Centre

II. Other Furniture/Fixture Requirements		
Sr. No.	Name of the Equipment	Executive Health checks Centre
1.	Air conditioners Central A/C	As per requirement
2.	Computer with modem with UPS, printer with internet connection	As needed
3.	Coolers	As needed
4.	Drinking Water purifier	As needed
5.	Emergency lamp	2 Per Area/ Ward
6.	Exhaust Fan	As needed
7.	Fire extinguishers	As needed
8.	Geyser	1 per ward
9.	Refrigerator	1 per ward
10.	Tables & Chairs	As needed
11.	Telephone/ cell phone	1 per ward
12.	Tube lights	As needed
13.	Vacuum cleaner	As needed
14.	Computer with Modem with UPS, Printer with Internet Connection	As needed
15.	Xerox Machine	As needed
16.	Intercom (10 lines)	As needed
17.	Fax Machine	As needed

Annexure 2

Human Resource Requirement

1. This includes the Designation, minimum qualification & number of people required in the facility as per the scope of services.

1.1 Medical practitioners

1. **Category:** MBBS Doctors.
2. **Minimum Qualifications:** Degree/ Post Graduate Degree from recognized university **Registration:** (if applicable): with state or central council of related to the profession.
3. **Trained / skilled:** Trained

Sr. no.	Executive Health Checks
1.	As per Allopathy standards in relevant specialties as the profile of checkup provided at the centre

1.2 Nurses:

- ANM/ GNM/ BSc/MSc nurses,
One per shift per for 50% of the total number of consulting room

1.3 Paramedics

1. **Category:** Paramedics
2. **Minimum Qualifications:** (diploma/degree from recognized university.)
3. **Registration with the concerned council**(if applicable): state or central council
4. **Trained / skilled:** Trained

Sr. no	Paramedics	Minimum qualification	Executive Health Checks
1.	ECG Technician (if ECG services are provided in-house)	1 year experience of taking ECG	As per requirement
2.	Laboratory Attendant (if lab is in-house)	Ability to read national or local language	As per requirement
3.	Laboratory Technician (if Lab is in-house)	Qualified Laboratory Technician	As per requirement
4.	Medical Records Officer / Technician	Minimum qualification-12th Standard passed.	As per requirement
5.	Radiographer (if Imaging is in-house)	Qualified Radiographer	As per requirement

6.	Ward Ayah	Eight standard completed	As per requirement
7.	Ward boy	Eight standard completed	As per requirement

1.4. Administrative staff: The number would vary as per scope of the centre/ requirement and may be outsourced.

Administrative staff		
Sr. no	Administrative staff	Executive Health Checks
1.	Office Administrator	As per requirement
2.	Accountant	As per requirement
3.	Multi purpose worker	As per requirement

Annexure 3

Equipment/Instrument

Following emergency equipment shall be available as follows:

Sr. No.	Emergency Equipment	Executive Health Checks Centre
1.	Emergency equipment box for first aid & BLSS	Minimum 1
2.	Crash-Cart trolley:1	Minimum 1
3.	Portable defibrillator:1	Optional
4.	Disposable syringes	As needed
5.	Ambu Bag:1	Minimum 1
6.	Laryngoscope with cells & adult and pediatric blades	Minimum 1
7.	Sealed battery cell	Minimum 1
8.	Endotracheal tubes	As needed
9.	Pulse Oxymeter	Minimum 1
10.	Suction Apparatus	Minimum 1
11.	ECG Machine	Minimum 1
12.	BP Apparatus & Stethoscope	Minimum 1
13.	Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs	Minimum 1

Other necessary and sterilizing equipment as per the scope of services shall also be available.

Annexure 3

Drugs, Medical devices and Consumables

I. Emergency drugs:

Category:Emergency Drugs			
Sr. no.	Name of the Drug	Strength	Minimum Quantity
1.	Inj. Adrenaline	As per I.P.	Minimum 10 Ampoules/ Vials
2.	Inj. Atropine	As per I.P.	Minimum 10 Ampoules/ Vials
3.	Inj. Calcium Carbonate	As per I.P.	Minimum 10 Ampoules/ Vials
4.	Inj. Dopamine	As per I.P.	Minimum 10 Ampoules/ Vials
5.	Inj. Dobutamine	As per I.P.	Minimum 10 Ampoules/ Vials
6.	Inj. Nitroglycerine	As per I.P.	Minimum 10 Ampoules/ Vials
7.	Inj. Sodium Bicarbonate	As per I.P.	Minimum 10 Ampoules/ Vials
8.	Inj. Hydrocortisone	As per I.P.	Minimum 10 Ampoules/ Vials
9.	Inhaler Beclomethasone (250 micro/dose)	As per I.P.	Minimum 10 Ampoules/ Vials
10.	Inhaler Salbutamol (200 micrograms)	As per I.P.	Minimum 10 Ampoules/ Vials
11.	Inj. Frusemide	As per I.P.	Minimum 10 Ampoules/ Vials
12.	Inj. Diazepam/Midazolam	As per I.P.	Minimum 10 Ampoules/ Vials
13.	Inj. Deriphyllin	As per I.P.	Minimum 10 Ampoules/ Vials
14.	Inj. Phenytoin sodium	As per I.P.	Minimum 10 Ampoules/ Vials
15.	Inj. Avil	As per I.P.	Minimum 10 Ampoules/ Vials
16.	Inj. Ondansetrone	As per I.P.	Minimum 10 Ampoules/ Vials
17.	Inj. KCl	As per I.P.	Minimum 10 Ampoules/ Vials
18.	Inj. Lignocaine 2%	As per I.P.	Minimum 10 Ampoules/ Vials
19.	Inj. Amiodarone	As per I.P.	Minimum 10 Ampoules/ Vials
20.	Inj. Magnesium sulphate	As per I.P.	Minimum 10 Ampoules/ Vials
21.	Inj. Mannitol	As per I.P.	Minimum 10 Ampoules/ Vials
22.	Inj. Morphine/Inj. Pethidine	As per I.P.	Minimum 10 Ampoules/ Vials
23.	Inj. Noradrenaline bititrate	As per I.P.	Minimum 10 Ampoules/ Vials
24.	Inj. Fentanyl	As per I.P.	Minimum 10 Ampoules/ Vials
25.	water for Injection	As per I.P.	Minimum 10 Ampoules/ Vials
26.	Inj. Sodium Valporate	As per I.P.	Minimum 10 Ampoules/ Vials
27.	Inj. Voveran	As per I.P.	Minimum 10 Ampoules/ Vials
28.	Inj. Paracetamol	As per I.P.	Minimum 10 Ampoules/ Vials
29.	Mannitol Injection	As per I.P.	Minimum 10 Ampoules/ Vials
30.	Metoprolol Injection	As per I.P.	Minimum 10 Ampoules/ Vials
31.	N/2 saline Injection	As per I.P.	Minimum 10 Ampoules/ Vials
32.	Oxygen Inhalation	As per I.P.	Minimum 10 Ampoules/ Vials
33.	Oxytocin Injection	As per I.P.	Minimum 10 Ampoules/ Vials

II. Disinfectants: As applicable in adequate quantity

Sr. no	Disinfectants
1.	Hypochlorite 4%-6%
2.	Ortho-phthalaldehyde (OPA)
3.	70% ethanol plus10ppm Bitrex
4.	Formaldehyde solutions (1%–2%)

5.	Glutaraldehyde
6.	Hydrogen peroxide
7.	Quaternary ammonium compounds
8.	Phenolic germicides

III. Linen

Sr. no	Linen	Quantity
1.	Bed sheets	As per requirement
2.	Bedspreads	As per requirement
3.	Blankets	one per bed
4.	Curtain cloth windows and doors	As per requirement
5.	Overcoat for consultant	one per consultant
6.	Mats (Nylon)	As per requirement
7.	Mattress (foam) adults	As per requirement
8.	Pediatric Mattress	one per bed
9.	towels	As per requirement
10.	Pillow covers	As per requirement
11.	Pillows	As per requirement
12.	Table cloth	adequate quantity
13.	Uniform / Apron	As per requirement

IV. Stationary as per the scope of services

Sr. no.	Items
1.	Consents Forms
2.	Consultant Reference Form
3.	Continuation sheets
4.	Diet Sheets
5.	Initial Assessment Form
6.	Pathological Books
7.	Registers
8.	Registration Card
9.	Sentinel Event Form
10.	Supplementary Sheets
11.	X-ray Forms

Annexure 4

Legal/Statutory Requirements

This includes the minimum statutory compliance applicable as per the central or state government along with licensing body, wherever applicable.

Sr. no.	Name of the Act	Department/Area	Licensing body
1.	Registration under Shops and Establishment Act	Organization	Jurisdictional Authorities like Panchayat/ Nagarpalika/ Mahanagarpalika/ Municipality/ Municipal Corporation
2.	Registration under Clinical Establishment Act	Organization	Jurisdictional Authorities like Panchayat/ Nagarpalika/ Mahanagarpalika/ Municipality/ Municipal Corporation
3.	Agreement for Common Biomedical Waste Collection, Transportation, Treatment, Storage and Disposal Facility	Organization	Local Pollution Control Board
4.	Registration under Air (prevention and control of pollution) Act, 1981.	Organization	Local Pollution Control Board
5.	Building Permit (From the Municipality).	To be obtained from	Jurisdictional Revenue Authorities like Panchayat/ Nagarpalika/ Mahanagarpalika/ Municipality/ Municipal Corporation
6.	Certificate u/s 80-G of IT Act	Organization	If applicable.
7.	ESIS registration in case of >20 employees	Organization	Employee State Insurance Company
8.	Excise permit to store Spirit.	Organization	Excise department
9.	Generator Exhaust air Quality Report	Generator	Authorized Air Testing Laboratory
10.	License to sale or distribute drugs Form 20, 21, 21C	Pharmacy	FDA
11.	License for lift	Lift	Mobile Electric

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			Vehicles Department
12.	License to play music for public use	Organization	Indian
13.	No objection certificate from the Chief Fire Officer.	Organization	Fire Department
14.	Obtaining clearances for weighing equipments in all the centre units under The Standards of Weights and Measures Act, 1976.	Weights and measures	Department of Weights and Measures
15.	Occupation Certificate	To be obtained from	Jurisdictional Revenue Authorities like Panchayat/ Nagarpalika/ Mahanagarpalika/ Municipality/ Municipal Corporation
16.	PNDT Act, 1996.	Sonography	Health Department of Regulatory Body assigned with the responsibility
17.	SMPV License for Storage of Liquid Oxygen, Form III (License to compressed gas in pressure vessel or vessels)	Medical Gases in Pressurized Vessels	Licensing Authority
18.	TAN Number	Organization	Income Tax Department
19.	PAN Number	Organization	Income Tax Department
20.	Vehicle Registration certificates for Ambulance	Ambulance and Vehicles owned by the organization	Road Traffic Authority
21.	Water Prevention and control of pollution Act	Organization	Pollution Control Board

Annexure 5

Record Maintenance and reporting

1. Standard on record maintenance

Sr. no	Records
1.	Customer Records
2.	Customer reports records
3.	Reports of investigations
4.	Consents

2. Standard on content of medical record.

Sr. no.	Name Of Forms
1.	Customer Registration Details
2.	Consent
3.	Initial Assessment Record including Pain Assessment and Nutritional screening
4.	Advise or Treatment record
5.	Imaging Report Format for each imaging modality
6.	Laboratory Report Forms for each category of investigation

3. Standard on reporting of various notifiable diseases as per scope of services of Clinical establishment

As per scope of services or by the scope of concerned government/ municipal department