

The Clinical Establishments (Registration and Regulation) Rules, 2010

Draft Rules for the Central Government

These rules may be called The Clinical Establishments (Registration and Regulation) Rules (Central Government), 2010

These rules extend to the whole of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and in any other State which adopts this Act under clause (1) of Article 252 of the Constitution and the Union Territories of Chandigarh, NCT of Delhi, Dadra & Nagar Haveli, Puducherry, Andaman and Nicobar Islands, Daman and Diu and Lakshadweep

It shall come into force from the date of notification of these Rules in the Official Gazette.

The Rules shall be applicable to various categories of clinical establishments in a phased manner, as may be notified from time to time.

Definitions

In these rules, unless the context otherwise requires:

- a) 'Act' means the Clinical Establishments (Registration and Regulation) Act 2010
- b) 'Rules' means the Clinical Establishments (Registration and Regulation) Rules, 2010
- c) 'Authority'¹ means the district registering authority set up under Section 10 of the Act.
- d) 'Certificate' means certificate of registration issued under section 30;
- e) '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 recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or
 - (ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include a clinical establishment owned, controlled or managed by
 - (a) the Government or a department of the Government;
 - (b) a trust, whether public or private;
 - (c) a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;
 - (d) a local authority; and
 - (e) a single doctor,

but does not include the clinical establishments owned, controlled or managed by the Armed Forces constituted under the Army Act 1950, the Air Force Act 1950 and the Navy Act 1957.

- f) '*Emergency Medical Condition*' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in:
 - (i) placing the health of the individual or with respect to a pregnant women, the health of the woman or her unborn child, in serious jeopardy;
 - (ii) serious impairment to bodily functions; or
 - (iii) serious dysfunction of any organ or part of a body

- g) '*National Council*' means the National Council for clinical establishments established under section 3 of the Act
- h) '*Prescribed*' means prescribed by rules made under this Act by the Central Government or, as the case may be, the State Government;
- i) '*Recognised System of Medicine*' means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognised by the Central Government;
- j) '*Register*' means the register maintained by the authority, State Government and the Central Government under sections 37, 38 and 39 respectively of this Act containing the number of clinical establishments registered;
- k) '*Registration*' means to register under section 11 and the expression registration or registered shall be construed accordingly;
- l) '*Schedule*' means the Schedule appended to this Act;
- m) '*Standards*' means the conditions that the Central Government may prescribe under section 12, for the registration of clinical establishments from time to time;
- n) '*State Government, in relation to a Union Territory*', means the Administrator thereof appointed under article 239 of the Constitution; and
- o) To '*stabilise*' (with its grammatical variations and cognate expressions) means, with respect to an emergency medical condition specified in clause (f), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

The words and expressions used herein and not defined but defined in the Act shall have the same meanings respectively assigned to them in the Act.

The National Council for Clinical Establishments

Establishment of the National Council for Clinical Establishments

The Central Government by way of a Notification shall constitute a National Council for Clinical Establishments.

The establishment of the National Council shall be as defined in Section 3 of the Act

Appointment of Secretary of the National Council by the Central Government

The Central Government shall appoint an officer of the rank of Joint Secretary dealing with the subject of Clinical Establishments in the Ministry of Health & Family Welfare as the Secretary, National Council under Section 3 (10) of the Act.

The term of office of Secretary of the National Council shall be for a period of 3 years.

The Secretary of the council will be responsible for the control & management of the secretariat of the council and supervision of the other employees of the Council and perform such other duties as may be required of him/her by the Council for the purposes of the Act. He shall attend the meetings of the Council.

The Central Government will provide the National Council with such other secretarial and other staff as deemed necessary by it under Section 3 (10) of the Act.

The powers and duties of the other employees shall be such as may be laid down from time to time in the standing orders as may be framed for the purposes by the National Council.

Functions of the National Council for Clinical Establishments

The National Council shall:

- (a) Compile and publish a National Register of clinical establishments within two years from the date of the commencement of this Act;
- (b) Classify the clinical establishments into different categories;
- (c) Develop the minimum standards and their periodic review;
- (d) Determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the clinical establishments;
- (e) Collect the statistics in respect of clinical establishments
- (f) Perform any other function determined by the Central Government from time to time.

Sub - Committees of the National Council

The National Council shall at any time constitute sub-committees for such periods, not exceeding two years, for the consideration of particular matters related to :

- Categorization of clinical establishments;
- Development of minimum standards and personnel for various categories of clinical establishments and their periodic review;
- Compilation and publication of a National Register of clinical establishments;
- Collection of statistics from clinical establishments and
- Any other function determined by the Central Government from time to time.

A motion for the appointment of each sub-committee shall define the functions of each subcommittee, number and nature of members to be appointed thereon and timeline for completion of tasks. At the time of formation of each sub-committee, it should be ensured that there is adequate representation from across the country in each committee from experts in the relevant fields across the private sector, public sector and/its organizations, non-governmental sector, professional bodies, academia and research institutions amongst others.

The Chairperson of every such sub-committee shall be appointed by the National Council at the time of the appointment of the sub-committee.

The proceedings of the meetings of the sub-committees shall be preserved in the form of minutes which shall be authenticated after confirmation by the chairperson of the subcommittees.

Any decisions taken by the sub-committee/s shall be placed before the National Council at its next meeting for its consideration and approval.

The National Council of Clinical Establishments shall request the State / Union Territory Councils to provide inputs for the consideration of particular matters. If required, the State / Union Territory Council shall at the request of the National Council and / or as determined by the Central Government constitute sub-committee/s consisting of members of the state and UT council and field experts for such period not exceeding one year, for the particular matter.

Determination of standards of personnel, facilities and services (including standards for permanent registration); classification of clinical establishments by the National Council

The minimum standards of facilities and services and personnel for different categories of Clinical Establishments for permanent registration shall be submitted by the National Council to the Central Government to be notified from time to time under Section 5 (c) (d) read with Section 7, Section 12 (1) (i) (ii) and Section 13 (1) (2), Section 28 of the Act.

The Clinical Establishments of different systems of medicines under Section 13 (1) have been classified into the categories as prescribed in CG1 Annexe and the Central Government will have the power to add, delete or modify such categories, as it deems appropriate from time to time, based on the recommendations of the National Council established under this Act.

The National Council shall constitute sub-committees having adequate representation from across the country including experts in the relevant fields across the private sector, public sector and/its organizations, non-governmental sector, professional bodies, academia and research institutions amongst others for such period, not exceeding two years, for determination of minimum standards and personnel for different categories of Clinical Establishments under Section 5 (c) (d) read with Section 7, Section 12 (1) (i) (ii) and Section 13 (2) of the Act, in particular, the National Council shall have regard to local conditions while prescribing the standards of personnel, facilities and services for different categories of clinical establishments.

Once the standards are developed, the National Council shall prepare the application form for permanent registration, including format for submission of evidence that different categories of clinical establishments have met the requirements of minimum standards and personnel. The form and format developed shall come into effect after notification by the Central Government.

Conduct of business of meetings of the National Council

Every meeting of the National Council shall be presided over by the Chairperson

Time and Place of and Preparation of Business for Meetings of the National Council

The meetings of the National Council shall ordinarily be held at Delhi or at such other place in India and on such dates as may be fixed by the Council, The National Council shall meet every month till such time as standards are developed. Thereafter, the Council shall at the minimum meet every three months.

Notice of Meeting

Notice of every meeting other than a special meeting called shall be issued to each member of the Council not less than 15 days before the date of the meeting.

Quorum, Call for Meeting, Minutes

One - third of the total number of members of the National Council shall form a quorum and all actions of the Council shall be decided by a majority of the members present and voting.

The notice and agenda of every such meeting of the National Council shall ordinarily be given 15 days before the meeting by the Secretary of the National Council.

A copy the minutes of each meeting of the National Council shall be submitted to the Chairperson within 7 days of the meeting and after having been approved by him/her shall be sent to each member of the Council within 15 days of the meeting. If no objection to their correctness is received within 10 days of their dispatch, any decisions therein shall be given effect to, provided that the Chairperson may, where in his opinion it is necessary or expedient so to do, direct that action be taken on the decision taken in the meeting.

The proceedings of the meetings of the Council shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson.

Allowances for members of the National Council

The central government officials who are members of the National Council for Clinical Establishments under sub-section 3 (5) of the Act shall not be paid any allowances. The travel and daily allowance for state government officials shall be paid by the respective States / UTs. The non-official members of the Council shall be paid travel and daily allowance in accordance with the rules of the Central Government for Class I officials as applicable from time to time.

Resignation and filling of casual vacancies

A member desiring to resign his seat on the National Council shall send his resignation in writing to the Chairperson and every such resignation shall take effect from the date mentioned by him in this behalf or in case no such date is mentioned, from the date of the receipt of his letter by the Chairperson after confirmation from the member concerned about his resignation.

When a casual vacancy occurs by reason of death, resignation or otherwise of a member, a report shall be made forthwith by the Chairperson to the Central Government which shall take steps to have the vacancy filled by nomination or election, as the case may be.

Disqualification for Appointment of Member

A person shall be disqualified for being appointed as a member of the National Council if she/he

- a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government, involves moral turpitude; or
- b) is an undischarged insolvent; or
- c) is of unsound mind and stands so declared by a competent court; or

- d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or
- e) has, in the opinion of the Central Government, such financial or other interest in the Council as is likely to affect prejudicially the discharge by him of his functions as a member.

Register of Clinical Establishments

Every State Government shall maintain a State Register of Clinical Establishments in digital format containing the particulars as prescribed in CG3 Annexe under Section 38 of the Act

District Registering Authority

Qualification and the terms and conditions for the members of the authority

The Central Government prescribes that 3 members of the District Registering Authority under Section 10 sub-section (1) clause (c) shall be nominated by the District Collector /District Magistrate and they shall include one representative from the City Police Commissioner (or his/her nominee) or SP or SSP, (as the case may be); one representative from a reputed Non-Governmental Organization working in the district / State in the area o health and related issues for a minimum period of 3 years and one representative from i professional medical association or body, having jurisdiction in the district or at the state level (as the case may be)

The term of office for the representative from the NGO and the professional medica association or body shall be for a period of 3 years.

If a casual-vacancy occurs in the office of any other members, whether by reason of death, resignation or inability to discharge, functions owing to illness or any other incapacity, such vacancy shall be filled by the District Collector/District Magistrate by making a fresh appointment and the member so appointed shall hold office for the remaining term of office of the person in whose place s/ he is so appointed.

The State Government shall include the members in the District Registration Authority for each District as prescribed by the Central government in clause 52 (d) under section 10 (1) (c) of the Act

Procedures under which the powers of the authority may be exercised by the District Health Officer or Chief Medical Officer for the purpose of provisional registration of clinical establishment

The district registering authority shall have the power to grant, renew, enforce or cancel registration of any clinical establishment in accordance with the provisions and rules of the Clinical Establishments (Registration and Regulation) Act 2010 as per procedure prescribed under Section 14 (1) (2) (3) (4) (5); Section 15; Section 16 (1) (2); Section 17; Section 19; Section 22; Section 23 (1) (2) (3); Section 24; Section 25; Section 26; Section 29; Section 30 (1) (2) (3) (4); Section 32 (1) (2) (3); Section 33 (1) (2) (3) (4); Section 34 and Section 36.

The District Registering Authority shall be responsible for

- Grant, renewal, suspension or cancellation of registration for any clinical establishment
- Enforcing compliance with the provisions and rules of the Clinical Establishments (Registration and Regulation) Act 2010
- Investigation of complaints of breach to the provisions of this Act or the rules made thereunder and take immediate action;
- Preparation and submission of report to the State / Union Territory Council, on a quarterly basis containing details related to number and nature of provisional and permanent registration certificates issued; included those cancelled, suspended or rejected
- Reporting to the State / Union Territory Council on a quarterly basis on action taken against non-registered clinical establishments operation in violation of the Act

The District Health Officer or the Chief Medical Officer (by whatever name called) shall exercise the powers of the district health authority as per procedure outlined in the Act The Convener of the District Registering Authority may also perform such functions as maybe assigned to him / her by the Chairperson from time to time and the Rules framed by the State government.

Maintenance of records and reporting by clinical establishments

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. The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishments are prescribed in **CG 2 Annexe** as per Section 12 (1) (iii) of the Act

Copies of all records and statistics shall be kept with the clinical establishment concerned for at least 3 or 5 years or in accordance with any other relevant Act in force at the time under Section 12(1) (iii).

All clinical establishments shall be responsible for submission of information and statistics in time of emergency or disaster or epidemic situation.

The Central Government may notify from time to time, the nature of information that needs to be furnished by the Clinical Establishments along with the prescribed interval.

Other conditions for registration and continuation of clinical establishment

Each category of clinical establishments shall comply with the Standard Treatment Guidelines and maintain electronic medical records of every patient as may be notified by the Central Government from time to time

Each category of clinical establishments shall charge the rates for each type of procedure and service within the range of rates to be notified by the central government from time to time, for such procedures and services.

Every Clinical Establishment shall display the rates charged for each type of service provided and facilities available, for the benefit of the patients at a prominent place in the local dialect and as well as in English language. The minimum list of services for which rates are to be displayed are given in CG 4 Annexe.

In addition to the specific provisions of the Clinical Establishments (Registration & Regulation) Act 2010, all establishments shall comply and maintain information and statistics in keeping with other applicable Acts and Rules which are in force in the country.

Every category of clinical establishments, as may be notified by the Central Government from time to time, shall establish mechanisms for review and audit for the purpose of provision of rational practice and service and maintenance of high standards of quality.

Each category of clinical establishments, as may be notified by the Central Government shall carry out every prescription audits every 3 months.

Each category of clinical establishments, as may be notified by the Central Government from time to time, shall carry out audit to assess the cause of death including treatments given to explore better preventive and management strategies.

CG1 Annexe Classification of Clinical Establishments

Classification of Clinical Establishments would be as follows:

- 1) Rural/Urban
- 2) Government or Private
- 3) System of Medicine
- 4) Type of Establishment

Systems of Medicine

- Allopathy
- Ayurveda
- Unani
- Siddha
- Homeopathy
- Yoga & Naturopathy

Type of Establishment

Providing Out Patient Care

- Single practitioner
- Polyclinic
- Sub-Centre
- Physiotherapy Clinic
- Occupational Therapy
- Infertility
- Day Care Centre
- Dental clinic
- Dispensary
- Dialysis Centre
- Integrated Counseling and Testing Centre (ICTC)
- Wellness/fitness centre
- Any other

Providing In Patient Care

- Hospital
- Nursing Home
- Maternity Home
- Primary Health Centre
- Community Health Centre
- Sanatorium
- Any other

Providing Testing & Diagnostic Services:

Laboratory

- Pathology
- Haematology
- Biochemistry
- Microbiology
- Genetics
- Collection Centre
- Any other

Diagnostic and Imaging Centre

- X Ray centre
- Mammography centre
- Bone Densitometry centre
- Sonography centre
- Color Doppler centre
- CT Scan centre
- Magnetic Resonance Imaging (MRI) centre
- Positron Emission Tomography (PET) Scan centre
- Electro Myo Graphy (EMG) centre
- Any other

CG2 Annexe
RECORDS TO BE MAINTAINED BY CLINICAL ESTABLISHMENTS

The various medical records to be maintained by clinical establishment

- Out patient Register
- Inpatient Register
- Operation Theater register
- Labor room register
- MTP register (if registered under the MTP Act)
- Case sheets
- Medico legal register
- Laboratory Register
- Radiology and imaging register
- Discharge summary
- Medical certificate in duplicate
- Complaint register
- Birth register (Notified to such medical officer as authorized)
- Death register by Government in such format as prescribed by Government/ State level authority)
- Information in terms of government programmes / areas of work (eg maternal health, child health, immunization, family planning, Vector borne disease, NLEP, RNTCP, IDSP. NRHM initiatives-ASHA, JSY)
- Number of beds system-wise and specialty-wise in Clinical Establishments providing in patient care (e.g General Med/Surg Beds; Special Care Beds)
- Total Discharges:

CG3 Annexe
State / District Register for Clinical Establishment

Details of Information Required

(A) At State/District level:

Total number of establishments by

- Category
- System of medicine practiced
- Type of service provided
- Rural / urban / metro
- No of beds

Number of Clinical Establishments increased or decreased

Number of Inspections carried out.

Number of Pending applications with reasons

Action Taken against non-registered Establishments operating in violation of the Act

Complaints received by the State Council under the Act and Action taken pursuant thereto

(B) Detailed information

Details of each Clinical Establishment by

Name

Location containing details

Rural / Urban / Metropolitan

Village / Town

Taluka

District

State

Pincode

Phone Number

Email ID:

Ownership Details

Name of Owner

Educational Qualification

Person in Charge of Clinical Establishment

Educational Qualification

Urban / Rural Designation:

Longitude / Latitude: Systems of Medicine offered

Type of Establishments by category specified under Section ____ of the ____ rules

Nature of Services provided by category specified under Section ____ of the ____ rules

Number of beds system-wise and specialty-wise in Clinical Establishments providing in patient care

Total Employees:

Total Discharges:

Average length of stay (OP / IP)

Utilization Statistics

Details of Staff with Name, Qualification, Registration number, Number temporary or permanent

CG 4 Annexe

Minimum list of services for which rates are to be displayed

Name of the service	Type of Service	Charges (in Rs.)
Room Charges: (includes Room/ Bed charges, Nursing charges, Medical utilities charges)	General Services	
	Private rooms:	
	Semi Deluxe - Shared	
	Deluxe with AC	
Intensive care units: (Charges include the ICU Bed Charges, Medical Utilities, Monitoring and Nursing charges)	MICU & ICU	
	NEURO	
	POW	
	Neonatal ICU	
Pediatrics ICU		
OT Charges		
General Anesthesia Vz Hour	General ward	
	Twin/ Triple sharing	
General Anesthesia 1 Hour	General Ward	
	Twin/ Triple sharing	
Local Anesthesia	1/2 Hour	
	1 Hour	
Surgical procedures Charges (Package) (includes Surgeon charges+ Anesthetist charges* Nursing Home Charges and Inpatient Medicine Charges)	General Surgical Procedures	
	Ob & Gy procedures	
	Orthopedic Surgical procedures	
	Cardiac Surgical procedures	
Doctor Consultation charges: OP	Specialist	
	Super Specialist	
IP	Per Visits	
Emergency Visits	Per Visits	
Emergency care team charges	3 shift per day	
Diagnostic Charges		
Common diagnostic Tests X- ray per film		
Ultra Sound, General and Obstetric care	Abdomen	
	Female Pelvic	
	KUB	
CTScan: Multi slice/Spiral/CT scan	Brain Plain	
	Chest/ Abdomen/ Neck/ Spine	
MRI 0.5/1/1.5 (Magnetic Resonance Imaging)	Brain	
	Chest	
	Contast	
ECG/TMT/ECHO/EMG/EEG		
Upper GI Endoscopy/ Lower GI Endoscopy		
Lab Investigation:		
Random Blood sugar		
Serum Creatinine		
CBP/ESR/CUE		
Blood Group		
Blood for MP		
LFT		

Lipid profile		
HBSAG/VDRL/HIV		
Electrolytes T3, T4, TSH		
Any other items (not included above]		
Note: Other service charges for Inpatients such as drugs & disposables, investigations and concession, if any, shall be displayed at appropriate places for the benefit of the patient		