

No. A.12034/18/2019-MH.II/MS
Government of India
Ministry of Health & Family Welfare
Department of Health & Family Welfare
Medical Services Section


Nirman Bhawan, New Delhi
Dated 17th July, 2019

NOTICE

Subject: Placing the Draft 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 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 17th 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;

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.

Medical Diagnostic Laboratories

	Template	Basic Composite *	Medium	Advanced	Remarks
I	Definition	upto 30 samples	30-100 samples	> 100 samples	
II	Scope of Services	These test can be performed in mobile lab at field centres also	Apart from the test performed in Composite lab additional tests mentioned as under.	Apart from the test performed in Medium lab additional tests mentioned as under.	
a)	Biochemistry	Routine Biochemistry Test like Blood Sugar, KFT, LFT, Amylase, lipase, lipid profile, CSF & other biological fluid (glucose and protein), OGTT, Electrolytes, Ca/PO ₄ , HbA1c. Any dry chemistry based rapid test.	a) Routine Biochemistry, b) Hormone Bioassay, Tumor markers, plasma protein electrophoresis	a) Routine Biochemistry, b) Hormone Bioassay, Tumor markers, plasma protein electrophoresis, coagulation profile, Drug monitoring and toxicology assay, c) Molecular genetics, Inborn errors of metabolism	
b)	Hematology	Haemogram, BT, CT, PT, APTT, Blood grouping	Haemogram, BT, CT, PT, APTT, Blood grouping, Coagulation Assay	All other Haematology test also	
c)	Histopathology	NIL	May/ May not do	Histopathology Examination	
d)	Molecular Genetics	NIL	May/ May not do	molecular genetics	
e)	Cytopathology	NIL	PAP smear, FNAC, sputum & CSF cytology	PAP smear, FNAC, sputum cytology and other biological fluid cytology, D; Ultrasound and CT Guided FNAC	
f)	Immunohistopathology	NIL	NIL	Immunohistopathology	as per scope of lab
g)	Medical Microbiology & Immunology	Basic test like Rapid Test (point of care) tests for infection, Urine routine and microscopy, Hanging drop for V cholerae, Stool for ova, cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory.	a) Basic Test as in composite lab b) Serological tests for viruses, bacteria, fungi, parasites c) Culture Sensitivity tests, Bacterial/ fungal) d) Other special stains besides Gram's	a) Basic Test as in composite lab b) Serological tests for viruses, bacteria, fungi, parasites c) Culture Sensitivity tests, Bacterial/ fungal/ viruses) Gene based tests (Nucleic acid tests for infections like Real time PCR tests), Histopathology of Infectious diseases. and Desirable: Immunocytochemistry	

III	Infrastructure				
	1. Signage				
	Basic signage- A signage within or outside the facility should be made available containing the following information.	Yes	Yes	Yes	M
	a) Name of the incharge with qualification and registration number,	Yes	Yes	Yes	M
	b) Broad Services provided i.e. Hematology, Biochemistry, Clinical Pathology, Histology, Cytology Molecular Genetics- Whichever is applicable	Yes	Yes	Yes	M
	c) Timings of the different consultants	Yes	Yes	Yes	M
	d) Internet facility/ Telephone and mobile number for appointment	Yes	Yes	Yes	D
	Fee structure: To be displayed separately including type of investigation and charges i.e. Special and routine tests.	Yes	Yes	Yes	M
	Safety Signage's (wherever applicable)				
	Safety Hazard and Caution signs - Biomedical waste segregated in colored bins and bags as per Biomedical waste Management and Handling Rules 1998 including Radioactive materials, toxic chemicals, Microbial agents, Infected biological material.	Yes	Yes	Yes	M

Appropriate Fire exit signage's - Minimum one fire extinguisher	Yes*	Yes*	Yes**	As per norms*- Desirable **Mandatory
2. Space requirement-				
A. Registration and waiting room, Public Utilities, Safe drinking water etc.	Yes*	Yes**	Yes**	* D **M
B. Sample collection area	Yes		Yes	M
C. Laboratory with adequate diffuse and spot lighting	Yes		Yes	M
D. Toilet	Yes		Yes	M
E. Reporting and billing area	Yes		Yes	M
F. Staff room and doctor's duty room - Male and female different where 24 hours services available	Desirable	Desirable	Yes*	*M
G. Washing room	Yes		Yes	M
H. Preservation of the specimens and slides	Yes		Yes	M
I. Electrical facilities	Yes		Yes	M
J. Temperature control for specialized equipments like flow cytometry and chemiluminescence equipments ELISA test equipment etc.	Yes		Yes	M
K. Counselling room for HIV	yes		yes	if applicable
L. FNAC room for all patients for sample collection	yes		Yes	D
M. Dark room for Immunofluorescence	No		Yes	if applicable
N. Frozen Section facilities	No		Yes	if applicable

	4. Furniture & Fixtures	Yes	Yes	Yes	M
	5. Communication system - Telephone and mobile number for appointment	Yes	Yes	Yes	D
	6. Wash - Basins	Yes	Yes	Yes	M
IV	Human resource				
	Designation, minimum qualification of Technical Head of Lab / Specialist/ Signatories.	MBBS from a recognised institution (with atleast one year experience in laboratory work- Desirable	Incharge can be MD/DNB in Pathology/Biochemistry/ Medical Microbiology/Lab Medicine/Diploma in Clinical Pathology (DCP) with one year post diploma experience / MBBS with PhD in any of the 3 subjects/ Apart from incharge, if any special test of other speciality is done, it is desirable that specialist of that subject need be there on full time/part time or outsourced (Special tests means any other apart from routine basic biochemistry, haematology, or medical microbiology tests as listed in basic composite lab)	Incharge can be MD/DNB Pathology/Lab Medicine/ Biochemistry/ Medical Microbiology/ DCP with one year post diploma experience/MBBS with PhD in any of the 3 subjects/ Apart from incharge, if any special test of other speciality is done, it is desirable that specialist of that subject need be there on full time/part time or outsourced (Special tests means any other apart from routine basic biochemistry, haematology, or microbiology tests as listed above)	M
	Number of laboratory technicians with DMLT / MLT/BSc in lab sciences/ MSc in lab sciences/PhD in lab sciences qualification (govt / university)	1	2 LT	4 LT	M
	Support staff (Lab Assistant /Lab Attendant) Roster of salary of staff Periodic health check up and vaccination of staff	1			2 M

	Process of calibration of equipments and reagents	Yes	Yes	Yes	M
	Booklet of SOPs of all procedures available	Yes	Yes	Yes	M
	Grievance Registration and Disposal mechanism	Yes	Yes	Yes	M
	QUALITY CONTROL in the form of EQAS/ILC as the case may be	Yes	Yes	Yes	D
	policy of PROFICIENCY TESTING of tests performed.	Yes	Yes	Yes	D
		M- Mandatory	D- Desirable		