

The Haryana Clinical Establishments (Registration and Regulation) Rules, 2018

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Rule

THE-HARYANA-CLINICAL-ESTABLISHMENTS-REGISTRATION-AND-R of 2018

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The Haryana Clinical Establishments (Registration and Regulation) Rules, 2018Published vide Notification No. S.O. 38/C.A. 23/2010/S. 54/2018, 13.7.2018Haryana GovernmentHealth DepartmentNo. S.O. 38/C.A. 23/2010/S. 54/2018. - In exercise of the power conferred by section 54 of the Clinical Establishments (Registration and Regulation) Act, 2010 (Central Act 23 of 2010), the Governor of Haryana hereby makes the following rules, namely:-

1. Short title and commencement.

(1)These rules may be called the Haryana Clinical Establishments (Registration and Regulation) Rules, 2018.(2)They shall come into force from the date of their publication in the Official Gazette.

2. Definitions.

(1)In these rules, unless the context otherwise requires,-(a)"Act" means the Clinical Establishments (Registration and Regulation) Act, 2010 (Central Act 23 of 2010);(b)"Chairman" means the Chairman of the State Council;(c)"Chairperson" means the Chairperson of the authority;(d)"Convenor" means the Convenor of the authority;(e)"member secretary" means the member secretary of the State Council.(2)The words and expression used herein and not defined in these rules but defined in the Act shall have the same meanings respectively assigned to them in the Act.

3. Time, place and convening of meeting of State Council.

(1) Every meeting of the State Council shall be presided over by the Chairman. The meetings of the State Council shall be held at such time and such place as the Chairman may decide. The State Council shall meet at least once in six months. (2) Notice of every meeting shall be issued by the member secretary to each member of the State Council at least ten days before the date of the meeting. The notice shall specify the place, date, time of the meeting and shall contain the statement of the business to be transacted at such meeting. (3) One-third of the total number of members of the State Council shall form a quorum and all actions of the State Council shall be decided by a majority of the members present and voting. (4) The Chairman may convene an urgent meeting for consideration of any matter which in his opinion requires immediate and urgent attention by the State Council. Such meeting may be called through electronic mail or telephonic message. (5) The proceedings of each meeting of the State Council shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairman. A copy of minute shall be submitted to the Chairman by the member secretary within ten days of the meeting and the minutes after having been approved by Chairman shall be sent to each member of the State Council within fifteen days of the meeting. If no objection to their correctness is received within ten days of their dispatch, any decisions therein shall be given effect to: Provided that the Chairman may, where in his opinion it is necessary or expedient to do so, direct that action be taken on the decision of the meeting immediately.

4. Casual vacancies.

(1) A member may, at any time, by writing under his hand, addressed to the Chairman resign from his office. (2) When a casual vacancy occurs by reason of death, resignation or otherwise of a member, a report shall be made forthwith by the Chairman to the State Government which shall take steps to have the vacancies filled by nomination or election, as the case may be.

5. Account and audit.

- The accounts of the State Council shall be subject to audit annually by Accountant General, Haryana and any expenditure incurred in connection with such audit shall be payable by the State Council.

6. Functions and powers of authority.

(1) The authority shall perform the following functions, namely:-(a) to grant, renew, suspend or cancel registration of any clinical establishments; (b) to enforce compliance of the provisions of the Act and rules made there under; (c) to investigate complaints of breach of the provisions of the Act or the rules made there under and to take immediate action; (d) to prepare and submit quarterly report containing details of number and nature of provisional and permanent registration certificate issued, including those cancelled, suspended or rejected to the State Council; (e) to report to the State Council on a quarterly basis on action taken against non-registered clinical establishments

operational in violation of the Act;(2)The authority shall, for the purposes of discharging its functions under this Act, have the same powers as are vested in a Civil court under the Code of Civil Procedure, 1908(Central Act 5 of 1908), in respect of the following matters, namely:-(a)summoning and enforcing the attendance of any person and examining him on oath;(b)requiring the discovery and production of any document or other electronic records or other material objective producible as evidence;(c)receiving evidence on affidavits;(d)requisitioning of any public record;(e)issuing commission for the examination of witnesses or documents;(f)reviewing its decisions, directions and orders;(g)dismissing an application for default or deciding it exparte.

7. Time, place and convening of meeting of authority.

(1)Every meeting of the authority shall be preside over by the Chairperson. The meetings of the authority shall be held at least once in three months at such time and at such place, as the Chairperson may decide.(2)Notice of every meeting shall be issued by the Convenor to each member of the authority at least ten days before the date of the meeting. The notice shall specify the place, date, time of the meeting and shall contain the statement of the business to be transacted at such meeting.(3)One-third of the total number of members of the authority shall form a quorum and all actions of the authority shall be decided by a majority of the members present and voting.(4)The Chairperson may convene an urgent meeting for consideration of any matter which in his opinion requires immediate and urgent attention by the authority. Such meeting may be called through electronic mail or telephonic message.(5)The proceedings of meetings of the authority shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson. A copy of minutes of each meeting of the authority shall be submitted to the Chairperson by the Convenor within ten days of the meeting and the minutes after having been approved by Chairperson shall be sent to each member of the authority within fifteen days of the meeting. If no objection to their correctness is received within ten 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 to do, direct that action be taken on the decision taken in the meeting.

8. Casual vacancies.

(1)A member may, at any time, by writing under his hand addressed to the Chairperson, resign from his office.(2)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 State Government which shall take steps to filled the vacancies by nomination or election, as the case may be.

9. Provisional certificate.

(1)The applicant shall apply to the authority for provisional certificate either in person, or by post or through web based online facility with the necessary information in a format as per Annexure 1. The fees for various sizes of clinical establishments shall be as follows, namely :-

Description	Fee for Provisional Registration (Rupees)
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51 to 100 beds	2000
101 to 300 beds	3000
301 to 500 beds	4000
Above 500 beds	5000

(2)The authority, or any person authorized in this behalf, shall provide the acknowledgment slip as per Annexure 2 immediately. Such acknowledgement slip shall be delivered by post or online, as the case may be.(3)The authority shall within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration containing particulars as per Annexure 3 either by post or electronically.(4)The fee shall be paid by a demand draft drawn /online transaction in favor of the authority concerned.(5)Clinical establishments owned, controlled and managed by the Central Government or State Government or local authority or department of Government, shall be exempt from payment of fees for registration.(6)In the event of any change of ownership or management, the clinical establishment shall intimate to the authority in writing within one month of such change.(7)In case the provisional certificate is lost or destroyed, mutilated or damaged, the owner shall apply to the authority, to issue a duplicate certificate upon payment of fee of five hundred rupees and contain such particulars as per Annexure 4.(8)The authority shall, within a period of forty-five days from the grant of provisional certificate, cause to be published it on the website of the Health Department, in the Official Gazette and two daily newspapers circulating in the area of which atleast one shall be in regional language for public at large.

10. Permanent certificate.

(1)The applicant shall apply to the authority for permanent certificate, in person, or by post or through web based online facility with the necessary information filled and with evidence of having met the requirements of minimum standards for different categories of clinical establishments in a form prescribed by the National Council (available at www.clinicalestablishment.gov.in). The fees for various sizes of clinical establishment shall be as follows, namely :-

Description	Fee for Permanent Registration(Rupees)
51 to 100 beds	8000
101 to 300 beds	12000
301 to 500 beds	16000
Above 500 beds	20000

(2)The authority, or any person authorized in this behalf, shall provide the acknowledgment slip as per Annexure 5 immediately. Such acknowledgement slip shall be delivered by post or online, as the case may be.(3)The authority shall, if it, allows an application of the clinical establishment, issue a certificate of permanent registration containing particulars as per Annexure 6.(4)Clinical establishments owned, controlled and managed by the Central Government or State Government or local authority or department of Government, shall be exempt from payment of fees for registration.(5)The fee shall be paid by a demand draft drawn /online transaction in favor of the registration authority concerned.(6)In the event of any change of ownership or management, the clinical establishment shall intimate to the authority in writing within one month of such

change.(7)In case the permanent certificate is lost or destroyed, mutilated or damaged, the owner shall apply to the authority, to issue a duplicate certificate upon payment of five hundred rupees and contain such particular as per Annexure 7.(8)The authority shall within fifteen days, after receiving the required evidence for permanent registration, by notice display the information as per Annexure 8 in the Official Gazette and two daily newspapers circulating in the area of which at least one shall be in regional language and website of the Health Department, for public at large inviting objections in this regard, if any, in writing, within thirty days from the date of publication of the notice.

11. Account and Audit.

(1)The authority shall maintain proper accounts and other relevant records and prepare and annual statement of account including the balance sheet.(2)The accounts of the authority shall be subject to audit annually by the Accountant General, Haryana and any expenditure incurred in connection with such audit shall be payable by the authority.

12. Renewal of registration.

(1)The clinical establishment shall apply for renewal of provisional registration within thirty days before the expiry of the validity of the certificate of provisional registration. In case the application for renewal is not submitted within the stipulated period, the authority shall allow for renewal of registration on payment of the renewal amount as specified in Annexure 9 and penalty of fifty rupees per day till the date of renewal.(2)A clinical establishment which has not applied for renewal of registration till the expiry of validity of certificate of permanent registration shall be liable to penalties as per Annexure 9 and penalty for delay in filing application for renewal at the rate of fifty rupees per day after the expiry of the valid registration:Provided that in case the renewal application has been submitted alongwith requisite fees and penalties as per Annexure 9, the clinical establishment shall be allowed to continue to function till the decision of the authority;

13. Manner of entry and search.

(1)Entry and search of the clinical establishment shall be done by the authority or team duly authorized by it or subject to such general or special orders as may be made by the authority. The team shall include the Civil Surgeon and President/ representative of the district Indian Medical Association.(2)The inspection team shall give notice to the establishment about the visit. The team shall examine premises used or proposed to be used for the clinical establishment and inspect the equipments, furniture and other accessories and enquire into the professional qualifications of the technical staff employed or to be employed and may make any such other enquires , as it consider necessary to verify the statements made in the application for registration and grant of license. All persons connected with the running of the establishment shall be bound to supply full and correct information to the inspection team.(3)The inspection team shall submit a report as per Annexure 10 within a week of the inspection to the authority and also forward a copy to the State Council.

14. Appeal.

(1) Any person or clinical establishment, aggrieved by the decision of the authority may file an appeal as per Annexure 11 to the State Council within three months from the date of decision along with a fee of five thousand rupees. (2) After receipt of the appeal, the State Council shall fix the time and date for hearing and inform the same to the appellant and other concerned by a registered letter/email/any other means giving at least fifteen days time before hearing of the case. (3) The appellant may represent by himself or authorized person or a legal practitioner and submit the relevant documentary materials if any in support of the appeal. (4) The State Council after thorough examination shall consider the appeal and communicate its decision preferably within ninety days from the date of filing the appeal. (5) If the State Council considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal. (6) The State Council shall have the authority to stay the operation of the order of the district authority till such time, as it deems necessary. The decisions of State Council shall be final and binding. (7) If no appeal is filed against the decision of the authority within three months from the date of the order, the orders of the authority shall be final. Annexure 1 [see rule 9 (1)] Application Form for Provisional Registration of Clinical Establishments

1. Name of the Establishment: / Doctor (in case of single practitioner) _____

2. Address:

Village/Town: _____ District: _____ State: _____
 _____ Pin code _____ Tel No (with STD code): _____
 Mobile: _____ Website (if any): _____

3. Name of the owner:

Address:

District: _____ State: _____ Pin code _____ Tel No (with STD code): _____
 Mobile: _____ Email ID : _____

of Person in charge and Qualifications: _____

4. Ownership

(a) Public Sector: Central Government State Government Local Government Public Sector
 Undertaking Any other (please specify): _____ (b) Private

Sector Individual Proprietorship Registered Partnership Registered Company Co-operative Society
Trust / Charitable Any other (please specify): _____

5. Systems of Medicine offered: (please tick whichever is applicable)

Allopathy Ayurveda Unani Siddha Homeopathy Yoga & Naturopathy

6. Services Provided: (please tick whichever is applicable)

Inpatient Outpatient Laboratory / Imaging Centre Any other (please specify): _____ Category of
Clinical Services: General Single Specialty Multi Specialty Super Specialty

7. Type of Establishment: (please tick whichever is applicable)

(a) Inpatient: Hospital Nursing Home Maternity Home Primary Health Centre Community Health
Centre Sanatorium Day Care Centre (b) Number of Beds: _____ (c) Outpatient: Single
practitioner Polyclinic Sub-Centre Physiotherapy Clinic Occupational Therapy Infertility clinic
Dental Clinic Dispensary Dialysis Centre Any other (please

specify): _____ (d) Laboratory: Pathology Haematology

Biochemistry Microbiology Genetics Collection Centre Any other (please

specify): _____ (e) Imaging Centre: please

specify: _____ Special diagnostics:

Please specify: _____ I hereby declare that

the statements above are correct and true to the best of my knowledge and shall abide by all the rules
and declarations under the Clinical Establishment (Registration and Regulation) Act, 2010. I

undertake that I shall intimate to the appropriate registering authority any change in the particulars
given above. Date: _____ Signature of the Authorized Signatory _____ Annexure 2 [see rule 9

(2)] Acknowledgement of Provisional Registration of Clinical Establishment The application in Form
_____ for Grant of Provisional Registration of the clinical establishment submitted by

_____ (Name and address of Owner) has been received by the
authority on _____ (date) and found to be Complete Or Incomplete This

acknowledgement does not confer any rights on the applicant for grant or renewal of

registration. Signature and Designation of Authority. SEAL Designation of the Issuing Authority

(Computer Generated) Place and Date: (Computer Generated) Annexure 3 [see rule 9 (3)] Provisional

Certificate For Registration of Clinical Establishment Provisional registration No: (Computer

Generated) Date of issue: (Computer Generated) Valid up to: (Computer Generated)

1. Name of the Clinical Establishment:

2. Address:

3. Owner of the Clinical Establishment:

4. Name of Person in Charge:

5. System of Medicine :

6. Type of Establishment:

Is hereby provisionally registered under the provisions of Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under. This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under. Designation of the Issuing Authority (Computer Generated) Place and Date: (Computer Generated) District Registration Authority Address with Contact details: Phone Number in Case of Grievances: Annexure 4[see rule 9 (7)] Duplicate Certificate for Clinical Establishment Provisional Registration No: (Computer Generated) Date of Issue: (Computer Generated) Valid up to: (Computer Generated)

1. Name of the Clinical Establishment :

2. Address :

3. Owner of the Clinical Establishment

: _____

4. Name of Person In Charge :

5. System of Medicine :

6. Type of Establishment :

is hereby provisionally registered under the provisions of `Clinical Establishments(Registration and Regulation) Act, 2010 and the Rules made there under .This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under.Designation of the Issuing Authority (Computer Generated)Place and Date (Computer Generated)District Registration AuthorityAddress:Phone Number in case of GrievancesAnnexure 5[see rule 10(2)]AcknowledgementRegistration of Clinical EstablishmentThe application in Form ____ for Renewal of Permanent registration of the clinical establishment submitted by _____ (Name and address of Owner) has been received by the authority on _____ (date) and found to beCompleteOrIncompleteThis acknowledgement does not confer any rights on the applicant for grant or renewal of registration.Signature and Designation of authority or authorized person of the appropriate authority.SEALDesignation of the Issuing Authority (Computer Generated)Place and Date: (Computer Generated)Annexure 6[see rule 10 (3)]Permanent Certificate for Registration of Clinical EstablishmentPermanent Registration No: (Computer Generated)Date of Issue : (Computer Generated)Valid up to : (Computer Generated)

1. Name of the Clinical Establishment :

2. Address :

3. Owner of the Clinical Establishment

: _____

4. Name of Person In Charge :

5. System of Medicine :

6. Type of Establishment :

is hereby permanently registered under the provisions of `Clinical Establishments(Registration and Regulation) Act, 2010 and the Rules made there under .This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and

Regulation) Act, 2010 and the Rules made there under. Designation of the Issuing Authority (Computer Generated) Place and Date (Computer Generated) District Registration Authority Address: Phone Number in case of Grievances Annexure 7 [see rule 10 (7)] Duplicate Certificate for Clinical Establishment Permanent Registration No: (Computer Generated) Date of Issue: (Computer Generated) Valid up to: (Computer Generated)

1. Name of the Clinical Establishment :

2. Address :

3. Owner of the Clinical Establishment

: _____

4. Name of Person In Charge :

5. System of Medicine :

6. Type of Establishment :

is hereby permanently registered under the provisions of `Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under . This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under. Designation of the Issuing Authority (Computer Generated) Place and Date (Computer Generated) District Registration Authority Address: Phone Number in case of Grievances Annexure 8 [(see rule 10(8))] Display of registration status for filing objections I, being the authority under the Clinical Establishments Act, 2010 after considering the applications received during the period; from to under Sec. 24 satisfying the provisions of the Clinical Establishments Act, 2010 and the Clinical Establishments Rules, 2018 made thereunder, hereby publish the list of Clinical Establishments; within the jurisdiction of district.

Serial No.	Name of Clinical Establishment with address	Ownership / In charge	System of medicine	Date on which application was submitted	Category & standards complied with
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Objections if any, in writing to the published list may be addressed in duplicate to

..... (address of the authority) within 30 days, from the date of this notification, as required under S.26 of the act. Place: Date: Signature: Name: (Seal of the authority) Annexure 9 (see rules 12) Fees to be Charged

Description	Provisional Registration	Permanent Registration
1	2 (In Rupees)	3 (In Rupees)
51 to 100 beds	2000	8000
101 to 300 beds	3000	12000
301 to 500 beds	4000	16000
Above 500 beds	5000	20000

Other Fees • For Renewal half the amount of registration fee (Provisional / Permanent) • For Late Application the amount would be double of the registration fee (Provisional / Permanent) • For Duplicate Certificate the amount would be Rs. 500/- • For change of ownership, management or name of establishment would be half the amount of registration fee (Provisional / Permanent) • For any appeal the amount would be Rs. 200/- * If a laboratory or diagnostic center is a part of an establishment providing Inpatient care, no separate registration is required.

Monetary penalties for Non Registration {(Section 41(i) }

1	2	3	4
Category of Clinical Establishment	1st Contravention (In Rupees)	2nd Contravention (In Rupees)	3rd Contravention (In Rupees)
51 to 100 Beds	20,000	80,000	2,00,000
101 to 300 Beds	30,000	1,20,000	3,00,000
301 to 500 Beds	40,000	1,60,000	4,00,000
>500 Beds	50,000	2,00,000	5,00,000

Regarding penalties under section 41 (2), the Authority to levy penalty as per the bed strength of the Clinical Establishment and type of personnel. Annexure 10 [see rule 13 (3)] Format for Submission of Inspection Report Number of visits made with dates Names and details of members of the inspection team Name of clinical establishment visited Address and contact details of clinical establishment visited Process followed for inspection (e.g. kindly outline who was met with, what records were

examined, etc) Salient Observations / Findings Conclusions Specific Recommendations: (1) To the Clinical Establishment (2) To the Authority *In case of lack of consensus amongst members of the inspection team, the same may be kindly indicated Signature (of all members of the inspection team) Date Place Annexure 11 [see rule 14 (1)] Application for Appeal To The State Council, Government of Sir, I, Dr....., of had applied for registration / is a valid license holder with registration number under Clinical Establishments Act, 2010 for my located at I was communicated by the district authority as per letter no. dated that either; (i) That my application was rejected (ii) That my registration is cancelled (iii) That I am restrained from carrying on with the running of clinical establishment (iv) That I am charged with a penalty for an offence under the act (v) Any other The above decision of the district authority appears to be not valid. I request you to consider my application as per the justifications mentioned below; (i) (ii) am willing to appear before you for a personal hearing, if necessary. I am enclosing herewith a draft of Rs. 5000/- (Five Thousand Rupees) Thanking you, Place: Date: Signature: Name: