

Rajasthan Government Clinical Establishment (Registration and Regulation) Rules, 2013

RAJASTHAN

India

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Rule

RAJASTHAN-GOVERNMENT-CLINICAL-ESTABLISHMENT-REGISTRATION of 2013

- Published on 5 June 2013
- Commenced on 5 June 2013
- [This is the version of this document from 5 June 2013.]
- [Note: The original publication document is not available and this content could not be verified.]

Rajasthan Government Clinical Establishment (Registration and Regulation) Rules, 2013Published vide Notification No. G.S.R. 16, dated 5.6.2013G.S.R. 16. - In exercise of the power conferred by section 54 of the Clinical Establishment (Registration and Regulation) Act, 2010 (Central Act No. 23 of 2010), the State Government hereby makes the following rules, namely:-

1. Short title and commencement.

(1)These rules may be called the Rajasthan [***] [Deleted 'Government' by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).] Clinical Establishment (Registration and Regulation) Rules, 2013.(2)They shall come into force with immediate effect.

2. Definitions.

(1)In these rules, unless the context otherwise requires,-(a)"Act" means the Clinical Establishments (Registration and Regulation) Act 2010;(b)"Form" means form appended to these rules;(c)"Schedule" means Schedule appended to these rules; and(d)"Section" means section of the Act.(2)Words and expressions used and not defined in these rules, but defined in the Act, shall have the same meanings respective assigned to them in the Act.

3. Conduct of business of State Council.

(1) Every meeting of the State Council, constituted under section 8, shall be presided over by the Chairman. (2) The meetings of the State Council shall ordinarily be held at Jaipur on such dates as may be fixed by the Chairman. The State Council shall meet at least once in three months. (3) The notice and agenda of every meeting of the State Council shall be circulated by the Member Secretary to each member of the State Council ordinarily seven days before the meeting; (4) The Chairman may, at any time, at his discretion, convene a special meeting of the State Council at the shortest notice, normally not less than three days. (5) 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. (6) The proceedings of the meetings of the State Council shall be preserved in the form of minutes which shall be authenticated by the Chairman. (7) A copy of the minutes of each meeting of the State Council shall be submitted to the Chairman within seven days of the meeting and after having been approved by him/her 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, any decisions therein shall be given effect.

4. Conduct of business of District Registering Authority.

(1) Every meeting of the Authority, constituted under section 10, shall be presided over by the Chairperson. (2) The notice and agenda of every meeting of the Authority shall be circulated by the Convener to each member of the Authority ordinarily seven days before the meeting. (3) The Chairperson may, at any time, at his discretion, convene a special meeting of the Authority at the shortest notice normally not less than three days. (4) 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. (5) The proceedings of the meeting of the Authority shall be preserved in the form of minutes which shall be authenticated by the Chairperson. (6) A copy of the minutes of each meeting of the Authority shall be submitted to the Chairperson by the Convener within seven days of the meeting and after having been attested by him 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, any decisions therein shall be given effect.

5. Provisional registration.

(1) The application for provisional registration shall be made to the Authority, constituted under section 10, in Form-1 along with the fee specified in Schedule, either in person or by post or through web based online facility. (2) The Authority shall not undertake any enquiry prior to the grant of provisional registration and shall within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in Form-2. (3) The Authority shall, within a period of forty-five days from the grant of provisional registration, publish, in two local newspapers and on the website of the Authority, all particulars of clinical establishment, so registered provisionally, including the name of the clinical establishment, address ownership, name of person in charge, system of medicine offered, type and nature of Services offered and details of the medical staff (Doctors, Nurses, etc.).

6. Permanent Registration.

(1)The application for permanent registration shall be made to the Authority, constituted under section 10, in Form-3 along with the fee specified in Schedule, either in person or by post or through web based online facility with the necessary information filled and with evidence of having the requirements of minimum standards and personnel for different categories of clinical establishments.(2)As soon as the clinical establishment submits the required evidence of having complied with the prescribed minimum standards, the Authority shall publish notice, in From-4, in two local newspapers and on the website of the Authority, inviting objection from public at large within a period of thirty days. Such notice shall contain all particulars of clinical establishment including the name of the clinical establishment, address, ownership, name of person in charge, system of medicine offered, type and nature of services offered, details of the medical staff (Doctors, Nurse, etc).(3)If any person has any objection to the information publishes regarding the clinical establishment, he shall give in writing the reasons and evidence of objection or non-compliance to the Authority.(4)The Authority shall communicate to the clinical establishment this objections received, if any, for response within a period of forty five days.

7. Application for more than one category of services.

-If a clinical establishment is offering services in more than one category as classified by the Central Government under sub-section (1) of section 13 of the Act, it shall apply for a separate provisional or permanent registration for each category of services offered by the clinical establishment. However, if a laboratory or diagnostic center is a part of clinical establishment providing outpatient/inpatient care, no separate registration shall be required. [Application may also be received and disposed off through single window clearance system.] [Added by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).]

8. Acknowledgement of Application.

- The Authority, constituted under section 10, or any officer/employee authorised by him, shall, acknowledge receipt of the application for grant/renewal of Provisional/Permanent registration, in [the duly filled in acknowledgement slip in Form-5] [Substituted 'the acknowledgement slip in Form-5' by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).], same day if submitted in person or not later than the next working day, if received by post and in case of online application, acknowledgement shall be generated automatically by the system.

9. Certificate of registration.

(1)The Authority shall grant the applicant a certificate of permanent registration in Form-6 either by post or electronically after satisfying itself that the applicant has complied with all the requirements and criteria, including provisions of minimum standards and personnel required to run the clinical establishment.(2)In case of permanent registration, the Authority shall pass an order within the period allowed under section 29 of the Act,-(a)allowing the application for permanent registration;

or(b)disallowing the application:Provided that the authority shall record its justifications and reasons, if it disallows an application, for permanent registration.

10. [Information about expiry of registration. [Substituted by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).]

- The Authority shall inform through notice published on web site of the Authority inform the clinical establishment about date of expiry of its Provisional or Permanent registration, as the case may be. Such information shall be published, in case of Provisional Registration Certificate thirty days before date of expiry and in case of Permanent registration six months before the date of expiry.].

11. Fees to be charged.

(1)The various fees for provisional and permanent registration, renewal, late application, duplicate certificate, change of ownership, management or name of establishment shall be charged as specified in Schedule.(2)The clinical establishments owned, controlled and managed by the Government (Central State or Local Authority) or Department of Government, shall be exempted from payment of fees as mentioned in sub-rule (1).(3)The fee shall be paid by a demand draft drawn online transaction in favour of the Authority concerned as specified under sub-section(1) of section 14 or section 24 of the Act, as the case may be.(4)[All tax and fee etc. imposed by the Government or any other local authority shall be paid by the Clinical Establishment and after establishment of Clinical Establishment, if any additional amount of tax or fees etc. is payable the Authority shall coordinate in payment of such tax or fees etc.] [Added by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).].

12. Change of ownership or management.

- 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 along with the fees as specified in Schedule and certificate. for grant of a revised certificate of Provisional or Permanent registration, as the case may be, incorporating the changes.

13. Duplicate certificate.

- In the event of certificate of registration Provisional or Permanent, as the case may be, being lost destroyed, mutilated or damaged; the clinical establishment shall apply to the Authority to issue a duplicate certificate upon payment of fees as specified in Schedule.

14. Renewal of Registration.

(1)The clinical establishment shall apply for renewal of provisional registration 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 fee and late fee as specified in Schedule.(2)The clinical establishment shall apply for renewal of permanent registration six months before the expiry of the validity of the certificate of permanent 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 fee and late fee as specified in Schedule.

15. Information to be provided by Clinical establishment.

(1)The Clinical establishments 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 Authorities. The minimum medical records to be maintained and nature of information to be provided by the clinical establishments shall be as per the formats developed by the National Council.(2)Copies of all records and statistics shall be kept by the clinical establishment concerned at least for three years or in accordance with any other relevant law. All clinical establishments shall be responsible for submission of information and statistics in the time of emergency or disaster or epidemic situation.(3)[The State Government may notify, from time to time, the nature of information required to be furnished by the Clinical Establishments including other disease notified for this purpose. Such information shall be uploaded on the web site of the department in the manner and with in such interval as may be specified by the State Government.] [Substituted by Notification No. G.S.R 63, dated 17.3.2015 (w.e.f. 5.6.2013).]

16. Power to Enter.

(1)Entry and search of the clinical establishment may be made by the Authority or an officer or team duly authorised by it or subject to such general or special orders, issued by the Authority.(2)Such entry and search of clinical establishments may be made, if anyone is carrying on a clinical establishment without registration or does not adhere to the prescribed minimum standards or has reasonable cause to believe that the clinical establishment is being used for purposes other than it is registered or contravenes any of the provisions of this Act and rules.(3)The Authority or an officer or team duly authorised by it shall intimate the clinical establishment in writing about the date or visit and reasons for the inspection and shall examine all record, register, document, 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 shall make any such other enquires as they consider necessary to verify the statements made in the application for grant of certificate of registration.(4)The inspecting officer or inspecting team, as the case may be, shall submit its report in Form-8, within a period of seven days of inspection, to the Authority, with a copy to the State Council. In case the inspection is made by the Authority, it shall submit inspection report within a period of seven days of inspection, to the State Council in Form-7.

17. Penalty.

- For the purpose of adjudging monetary penalty under the Act, the Authority shall hold an inquiry and provide opportunity of being heard. While holding an inquiry the Authority shall summon and enforce the attendance of any person acquainted with the fact and circumstances of the case to give evidence or to produce any document which in the opinion of the Authority, may be useful for or relevant to the subject matter of the inquiry, and if, on such inquiry, the Authority is satisfied that the person has failed to comply with the provisions of the Act and liable for monetary penalty, it may by order impose the monetary penalty specified in the Act.

18. Appeals.

(1)Any person, aggrieved by an order of the Authority, -(i)refusing to grant or renew a certificate of registration or revoking a certificate of registration, may file an appeal in Form-8 to the State Council within thirty days from the date of receipt of such order along with a fee as specified in Schedule.(ii)passed under section 41 or 42, may file an appeal in Form-8 to the State Council within a period specified in the said section along with a fee as specified in Schedule.(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 giving at least fifteen days time for hearing of the case.(3)The appellant may represent by himself or authorised person or a Legal practitioner and submit the relevant documentary material if any in support of the appeal.(4)The State Council shall hear all the concerned, receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its decision preferably within 90 days from the date of filling 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 decisions of State Council shall be final and binding.From-1[See Rule 5]Application from for provisional Registration of Clinical Establishments

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

2. Address: _____ Village/Town: _____

Taluka: _____ District: _____

_____ State: _____

_____ Pin Code _____

_____ Tel. No. (with STD Code): _____

_____ Mobile: _____

_____ Website (if any): _____

3. Name Of The Owner: _____

Address: _____ **Village/town:** _____

_____ **Taluka:** _____

_____ **district:** _____

_____ **State:** _____

_____ **Pin Code** _____

_____ **Tel. No. (with STD Code):** _____

_____ **Mobile:** _____

_____ **Email Id:** _____

3a. Name of Person in charge and Qualification: _____

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):

_____ (a)Category of Clinical Services: General Single Specialty Multi
Specialty Super Specialty

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

Inpatient: Hospital Nursing Home Maternity Home Primary Health Centre Community Health
Center 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
Hematology Biochemistry Microbiology Genetics Collection Centre Any other (please specify):

_____ (e)Imaging Centre: please specify:Special

diagnostics: Please specify: _____ I hereby declare that the
statement above are correct and true to the best of my knowledge and shall abide by all the rules and

a 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 &Place: Signature of the Authorized Signatory

Form-2(See Rule 5)Provisional CertificateFor Registration Of Clinical EstablishmentProvisional 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 thereunder.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 thereunder.Designation & Signatureof the Issuing Authority (Computer Generated) Place & Date:.(Computer Generated)From-3[See Rule 6]Application from for Permanent Registration of Clinical EstablishmentsProvisional Registration No.

_____Date of issue of Provisional Registration:

_____Valid upto: _____

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

2. Address: _____

Village/Town:

Taluka: _____ **District:**

_____ **State:**

_____ **Pin Code**

_____ **Tel. No. (with STD Code):**
_____ **Mobile:**
_____ **Website (if any):**

3. Name of The Owner: _____
Address: _____ **Village/town:** _____
_____ **Taluka:** _____
_____ **District:** _____
_____ **State:** _____
_____ **Pin Code** _____
_____ **Tel. No. (with STD Code):** _____
_____ **Mobile:** _____
_____ **Email Id:** _____

3a. Name of Person in charge and Qualification: _____

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 Homeopatliy Yoga & Naturopathy

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

Inpatient Outpatient Laboratory Imaging Centre any other (please specify):
_____ (a)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 Center 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
Hematology Biochemistry Microbiology Genetics Collection Centre Any other (please specify):
_____ (e)Imaging Centre: please specify:Special

diagnostics: Please specify: _____ I hereby declare that the statement above are correct and true to the best of my knowledge and shall abide by all the rules and a 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.Detail information:- Any complain and adverse report by inspection team after issue of Provisional Registration.Enclosed: Photo copy of Provisional Registration.

Date & Place Signature of the Authorized Signatory

Form-4[See Rule 6]Display of registration status for filing objectionsI, being the authority under the Clinical Establishments Act, 2010 after considering the applications received during the period; from to under Section 24 satisfying the provisions of the Clinical Establishments (Registration & Regulation) Act, 2010 and the Establishments (Registration & Regulation) Rules, 2013 made their under, hereby publish the list of Clinical Establishment; 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 above list may be addressed in duplicate to (address of the authority) within 30 days., from the date of this notice, as required under section 26 of the Act.

Date:Place SignatureName:(Seal of the authority)

[Form-5] [Substituted by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).][See Rule 8]Acknowledgement Registration of Clinical EstablishmentThe application in Form for Grant/Renewal of Provisional/Permanent registration of the Clinical Establishment submitted by (Name and address or Owner) has been received by the District Registration 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 Registration Authority or authorized person in the Office of the Appropriate Authority.Designation & Signatureof the Issuing Authority (Computer Generated)SealReceipt numberPlace, Date and Time (Computer Generated)From-6[See Rule 6]Permanent CertificateFor 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 provisionally registered under the provisions of Clinical
Establishments (Registration and Regulation) Act, 2010 and the Rules made
thereunder.

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 thereunder. Designation & Signature of the Issuing Authority (Computer Generated) Seal Place & Date: (Computer Generated) District Registration Authority Authority Phone numbers in case of Grievances From 7 [See Rule 16] Format for Submission of Inspection Report Number of visit 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 District Registering 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: Form-8 [See Rule 18] Application for Appeal To The State Council. Government of Sir, I, Dr of had applied for registration / holder of registration certificate number under the Clinical Establishment (Registration and Regulation) 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 or the district authority appears to be not valid. I request you to consider my application as per the justifications mentioned below: (i) (ii) (iii) I am willing to appear before you for a personal hearings, if necessary. I am enclosing herewith a draft of Rs. 5000/-.

Thanking you, Place: Date: Signature Name:

[Schedule] [Substituted by Notification No. G.S.R. 63, dated 17.3.2015 (w.e.f. 5.6.2013).] [See rule 11] Fees to be Charged

Description	Urban Provisional	Urban Permanent	Rural Provisional	Rural Permanent	Metro Provisional	Metro Permanent
Out Patient Care	-	200	-	100	100	500
In Patient Care						
1 to 30 beds	-	200	-	100	100	500
30 to 100 beds	100	500	50	250	200	1000
Above 100 beds	200	1000	100	300	300	1500
Testing & Diagnostic:	100	500	50	250	200	1000
Laboratories		1000	100	300	300	1500
Diagnostic & Imaging Centre	200					

Other Fees: (i) For Renewal half the amount of registration fee (Provisional/Permanent) (ii) For Late Application, along with the renewal fee, Rs. 50/- per day late fee upto the date of filling application for renewal of the registration (Provisional/Permanent) shall be charged. (iii) For Duplicate Certificate, the amount shall be Rs. 100/-. (iv) For change of ownership, management or name of establishment, shall be Rs. 100/-. (v) For any appeal the amount shall be Rs. 1000/-. Note. - If a laboratory or diagnostic center is a part of a establishment providing outpatient/Inpatient care no separate registration is required.