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## **PART IV-B**

**Rules and Orders (Other than those published in Parts I, I-A, and I-L) made  
by the Government of Gujarat under the Gujarat Acts**

### **HEALTH AND FAMILY WELFARE DEPARTMENT**

#### **NOTIFICATION**

Sachivalaya, Gandhinagar, 26<sup>th</sup> September, 2022.

#### **GUJARAT CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2021**

**No.GHY-32-2022-GCA-102021-1314-A:** WHEREAS the Government of Gujarat is satisfied that circumstances exist which render it necessary to take immediate action to make rules and brought into force at once and to dispense with the previous publication thereof under the proviso to sub-section (1) of section 45 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj. 18 of 2021);

NOW, THEREFORE, in exercise of the powers conferred by sub-section (1) of section 45 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj. 18 of 2021), the Government of Gujarat hereby makes the following rules, namely :-

**1. Short title, commencement and extent :-** (1) These rules may be called the Gujarat Clinical Establishments (Registration and Regulation) Rules, 2022.

(2) They shall come into force from the date of their publication in the *Official Gazette*.

(3) They shall be applicable to all types of recognised systems of medicine.

**2. Definitions :-** (1) In these rules, unless the context otherwise requires,-

(a) "*Act*" means the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021.

(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 the State Council :-** (1) Every meeting of the State Council shall be presided over by the Chairperson. The meetings of the State Council shall be held at such time and such place as the Chairperson 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 Chairperson 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 Chairperson. A copy of minutes shall be submitted to the Chairperson by the Member Secretary within ten days of the meeting and the minutes after having been approved by Chairperson 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 Chairperson 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 Member Secretary 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 Member Secretary 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, Gujarat and any expenditure incurred in connection with such audit shall be payable by the State Council.

**6. Functions and powers of the 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;

**7. Time, place and convening of meeting of the authority:** - (1) Every meeting of the authority shall be presided 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 Member Secretary 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 each 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 Member Secretary 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 fill the vacancies by nomination or election, as the case may be.

**9. Provisional certificate of registration:** - (1) For the purpose of provisional registration certificate of the clinical establishment the applicant shall apply to the District Health Officer or Chief Medical Officer as the case may be either in person or by post or through web based online facility with the necessary information in a form as per Annexure 1 along with the fees to be charged for various size of clinical establishments based on number of beds as shown in Annexure 7.

(2) The fee shall be paid by a demand draft drawn /online transaction in favor of the authority concerned.

(3) The District Health Officer or Chief Medical Officer as the case may be, 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.

(4) The District Health Officer or Chief Medical Officer as the case may be 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.

(5) Clinical establishments owned, controlled and managed by the Central Government or State Government or Local Authority or Department of Government, shall be exempted 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 along with the fees mentioned in Annexure 7.

(7) The District Health Officer or Chief Medical Officer as the case may be 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 and Family Welfare Department, in the *Official Gazette* and two daily newspapers circulating in the area of which at least one shall be in regional language for public at large.

**10. Permanent certificate of registration:** - (1) For the purpose of registration certificate of the clinical establishment the applicant shall apply to the authority either in person or by post or through web based online facility with the necessary information filled and the fees for various size of clinical establishment as shown in Annexure 7.

- (2) The fee shall be paid by a demand draft drawn /online transaction in favor of the registration authority concerned.
- (3) The authority, or any person authorized in this behalf, shall provide the acknowledgment slip as per Annexure 4 immediately. Such acknowledgement slip shall be delivered by post or online, as the case may be.
- (4) The authority shall, if it, allows an application of the clinical establishment, issue a certificate of permanent registration containing particulars as per Annexure 5.
- (5) Clinical establishments owned, controlled and managed by the Central Government or State Government or Local Authority or Department of Government, shall be exempted 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) The authority shall within fifteen days, after receiving the required evidence for permanent registration, by notice, publish the information as per Annexure 6 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 and Family Welfare 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, Gujarat and any expenditure incurred in connection with such audit shall be payable by the authority.

**12. Renewal of registration:** - The clinical establishment shall apply for renewal of provisional registration within thirty days before the expiry of the validity of the provisional certificate. 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 7 and penalty of fifty rupees per day till the date of renewal.

**13. Appeal.** - (1) Any person or clinical establishment, aggrieved by the decision of the authority may file an appeal as per Annexure 8 to the State Council within three months from the date of decision along with a fee of ten 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 passing of 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:** / \_\_\_\_\_**2. Address:** \_\_\_\_\_

Village/Town: \_\_\_\_\_ District: \_\_\_\_\_

State: \_\_\_\_\_ Pin code \_\_\_\_\_

Tel No (with STD code): \_\_\_\_\_ Mobile: \_\_\_\_\_

Website (if any): \_\_\_\_\_

**3. Name of the owner:** \_\_\_\_\_**Address:** \_\_\_\_\_

Village/Town: \_\_\_\_\_ District: \_\_\_\_\_

State: \_\_\_\_\_ Pin code \_\_\_\_\_

Tel No (with STD code): \_\_\_\_\_ Mobile: \_\_\_\_\_

Email ID : \_\_\_\_\_

Name 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 and 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 my knowledge and shall abide by all the rules and declarations under The Gujarat Clinical Establishments Act, 2021. 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 (3)]

#### 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 (4)]

#### 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 the Gujarat Clinical Establishments Act, 2021 and the rules made there under.

This authorization is subject to the conditions as specified in the rules in force under the Gujarat Clinical Establishments Act, 2021 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 10(3)]

**Acknowledgement**

**Registration of Clinical Establishment**

The 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 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 or authorized person of the appropriate authority.

SEAL

Designation of the Issuing Authority (*Computer Generated*)

Place and Date: (*Computer Generated*)

**Annexure 5**

[see rule 10 (4)]

**Permanent Certificate for Registration of 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 the Gujarat Clinical Establishments Act, 2021 and the rules made there under .

This authorization is subject to the conditions as specified in the rules in force under the Gujarat Clinical Establishments Act, 2021 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 6**

[(see rule 10(7)]

**Display of registration status for filing objections**

I, .....being the authority under the Gujarat Clinical Establishments Act, 2021 after considering the applications received during the period; from..... to ..... under Section 21 satisfying the provisions The Gujarat Clinical Establishments Act, 2021 and the Gujarat Clinical Establishments (Registration and Regulation) Rules, 2022 made there under, 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 |
|------------|---|-----------------------|--------------------|---|------------------------------------|
|            |   |                       |                    |   |                                    |
|            |   |                       |                    |   |                                    |
|            |   |                       |                    |   |                                    |

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.

Place:

Signature:

Date:

Name:

(Seal of the authority)

**Annexure 7**

(see rules 9(6), 10(1) and 12)

**Fees to be Charged**

| Description  | Provisional Registration | Permanent Registration |
|--|--------------------------|------------------------|
| 1  | 2                        | 3                      |
|  | (In Rupees)              | (In Rupees)            |
| 51 to 100 beds   | 15000/-                  | 75000/-                |
| More than 100 beds   | 50000/-                  | 200000/-               |
| Other establishments   | 5000/-                   | 20000/-                |
| <b>Other Fees</b>  |                          |                        |
| <ul style="list-style-type: none"> <li>• For Renewal half the amount of registration fee (Provisional / Permanent)</li> <li>• For Late Application the amount would be double of the registration fee (Provisional / Permanent)</li> <li>• For change of ownership, management or name of establishment would be half the amount of registration fee(Provisional/Permanent)</li> </ul> <p>* If a laboratory or diagnostic center is a part of an establishment providing Inpatient care, no separate registration is required.</p> |                          |                        |

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 8**

[see rule 13 (1)]

**Application for Appeal**

To,  
The State Council,  
Government of Gujarat.

Sir,

I, Dr....., of ..... had applied for registration / is a valid license holder with registration number ..... under the Gujarat Clinical Establishments Act, 2021 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) .....
- (iii) .....

I am willing to appear before you for a personal hearing, if necessary. I am enclosing herewith a draft of Rs. 10000/- (Ten Thousand Rupees)

Thanking you,

Place:

Signature:

Date:

Name:

(Seal of the authority)

By order and in the name of the Governor of Gujarat,

**PRAKASH PATNI,**  
Joint Secretary to Government.

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