



सत्यमेव जयते

The Gujarat Government Gazette

EXTRAORDINARY
PUBLISHED BY AUTHORITY

Vol. LXIV]

THURSDAY, FEBRUARY 9, 2023 / MAGHA 20, 1944

Separate paging is given to this Part in order that it may be filed as a Separate Compilation.

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, 9th February, 2023

GUJARAT CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2021.

No. GHY/2023/4/GOI/132010/13/A :- In exercise of the powers conferred by sub section (1) of section 5 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (18 of 2021), The Government of Gujarat hereby constitute an Authority to be called the District Registering Authority for each district for registration of clinical establishments, consisting of following ex-officio members, The other members will be added in due course:-

1.	District Collector, <i>ex-officio</i> -	Chairperson
2.	Chief District Medical Officer (CDMO) cum Civil Surgeon / Medical Superintendent / Superintendent, <i>ex-officio</i> -	Member Secretary
3.	Chief District Health Officer of the concerned District, <i>ex-officio</i> -	Member

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

PRAKASH PATNI,
Joint Secretary to Government.

IV-B Ex.-20

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Signature Not Verified

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Separate paging is given to this Part in order that it may be filed as a Separate Compilation.

PART IV

Acts of Gujarat Legislature and Ordinances promulgated and Regulations made by the Governor

The following Act of the Gujarat Legislature, having been assented to by the Governor on the 13th May, 2021 is hereby published for general information.

K. M. LALA,
Secretary to the Government of Gujarat,
Legislative and Parliamentary Affairs Department.

GUJARAT ACT NO. 18 OF 2021

(First published, after having received the assent of the Governor, in the "Gujarat Government Gazette", on the 22nd May, 2021).

AN ACT

to provide for the registration and regulation of clinical establishments in the State of Gujarat and for matters connected therewith or incidental thereto.

WHEREAS it is considered expedient to provide for the registration and regulation of clinical establishments with a view to prescribing the standards of facilities and services which may be provided by them so that mandate of article 47 of the Constitution for improvement in public health may be achieved;

It is hereby enacted by in the Seventy-second Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

**Short title,
extent and
commencement.**

1. (1) This Act may be called the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021.

(2) It extends to the whole of the State of Gujarat.

(3) It shall come into force on such date as the State Government may, by notification in the *Official Gazette*, appoint:

Provided that different dates may be appointed for different categories of clinical establishments and for different recognised systems of medicine.

Definitions.

2. In this Act, unless the context otherwise requires,—

(a) “Authority” means the District Registering Authority constituted under section 5;

(b) “certificate” means a certificate of registration issued under this Act;

(c) “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.

Explanation.—For the purpose of this clause “Armed Forces” means the forces constituted under the Army Act, 1950 (46 of 1950), the Air Force Act, 1950 (45 of 1950) and the Navy Act, 1957 (62 of 1957);

(d) “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 woman, the health of the woman or her unborn child, in serious jeopardy; or
- (ii) serious impairment to bodily functions; or
- (iii) serious dysfunction of any organ or part of a body;

(e) “prescribed” means prescribed by rules made under this Act;

(f) “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;

(g) “register” means the register maintained by the Authority, State Government and the Central Government under sections 32 and 33, respectively containing the number of clinical establishments registered;

(h) “registration” means to register under section 6 and the expression registration or registered shall be construed accordingly;

(i) “standards” means the conditions that the State Government may prescribe under section 23, for the registration of clinical establishments; and

(j) “to stabilize (with its grammatical variations and cognate expressions)” means, with respect to an emergency medical condition specified in clause (d), 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.

CHAPTER II

REGISTRATION AND STANDARDS FOR CLINICAL ESTABLISHMENTS

**State Council of
Clinical
Establishment.**

3. (1) The State Government shall, by notification in the *Official Gazette*, constitute a State Council for clinical establishments.

(2) The State Council shall consist of the following members, namely:—

- (a) Minister of Health and Family Welfare, *ex-officio*, who shall be the Chairperson;
- (b) Additional Chief Secretary/Principal Secretary/Secretary, Health and Family Welfare Department—*ex-officio*, who shall be the Member-Secretary;
- (c) Commissioner of Health Services and Medical Education—*ex-officio* Member;
- (d) Additional Secretary/Joint Secretary/Deputy Secretary, Medical Services—*ex-officio*, Member;
- (e) Additional Director, Medical Services—*ex-officio*, Member;
- (f) Directors/ Additional Directors of different streams of Indian Systems of Medicine—*ex-officio* Members;
- (g) one representative of the Gujarat Medical Council;
- (h) one representative of the Gujarat Nursing Council;

- (i) two representatives of the Council working in State medical field, nominated by the State Government;
- (j) four Members of Parliament/Members of Legislative Assembly-who shall be the Doctor by profession.

(3) The State Council shall perform the following functions, namely:—

- (a) to determine the standards of Clinical Establishments and to specify the rights of patient;
- (b) implementation of this Act in the State;
- (c) compiling and updating the State Registers of clinical establishment;
- (d) representing the State in the National Council;
- (e) hearing of appeals against the orders of the Authority; and
- (f) publication on annual basis a report of implementation of standards.

4. It shall be the responsibility of the State Council to compile and update the State Register of clinical establishments of the State and further to send monthly returns in digital format for updating the National Register.

Providing information to National Council.

5. (1) The State Government shall, by notification in the *Official Gazette*, constitute an Authority to be called the District Registering Authority for each district for registration of clinical establishments, with the following members, namely:—

Authority for registration.

- (a) the District Collector — *ex-officio* Chairperson;
- (b) the Chief District Medical Officer /Associate Civil Surgeon/Medical Superintendent —Member -Secretary;
- (c) Chief District Health Officer of the concerned District;
- (d) Representative of the Grant-in-Aid Organisation which runs a Hospital in the concerned District (if any);
- (e) the expert in the concerned subject-nominated by the District Collector (if required);

- (f) one representative of the local Medical Association (if any) -nominated by the District Collector;
- (g) one Dean of the Medical Faculty of the University having jurisdiction in the concerned District;
- (h) four representatives concerned with the Ayush, Physiotherapy, Dental and Homeopathy- nominated by the District Collector;
- (i) Local Member of Parliament/Member of Legislative Assembly-if he is a Doctor (in Allopathic or Ayurveda) by profession.

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under section 9 and 19, the District Health Officer or the Chief Medical Officer, as the case may be, shall exercise the powers of the Authority as per the procedure as may be prescribed.

**Registration for
Clinical
Establishments.**

6. No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act.

**Conditions for
registration.**

7. (1) For registration and continuation, every clinical establishment shall fulfill the following conditions, namely:—

- (i) the standards of facilities and services as may be prescribed;
- (ii) the requirement of personnel as may be prescribed;
- (iii) provisions for maintenance of records and reporting as may be prescribed;
- (iv) such other conditions as may be prescribed.

(2) The clinical establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment.

8. (1) The clinical establishment of different systems shall be classified into such categories, as may be prescribed by the State Government, from time to time.

**Classification of
Clinical
Establishments.**

(2) The different standards may be prescribed for classification of different categories referred to in sub-section (1):

Provided that in prescribing the standards for clinical establishments, the State Government shall have regard to the local conditions.

CHAPTER III PROCEDURE FOR REGISTRATION

9. (1) For the purposes of registration of the clinical establishment under section 6, an application in the prescribed proforma along with the prescribed fee shall be made to the Authority.

**Application for
provisional
certificate of
registration.**

(2) The application shall be filed in person or by post or online.

(3) The application shall be accompanied by such details as may be prescribed.

(4) If any clinical establishment is in existence at the time of the commencement of this Act, an application for its registration shall be made within one year from the date of the commencement of this Act and a clinical establishment which comes into existence after the commencement of this Act, shall apply for permanent registration within a period of six months from the date of its establishment.

(5) If any clinical establishment is already registered under any existing law requiring registration of such establishments, even then it shall apply for registration as referred to in sub-section (1).

- Provisional certificate.** **10.** The Authority shall, within a period of fifteen days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in such form and containing such particulars and such information, as may be prescribed.
- No inquiry prior to provisional registration.** **11.** (1) The Authority shall not conduct any inquiry prior to the grant of provisional registration.
(2) Notwithstanding the grant of the provisional certificate of registration, the Authority shall, within a period of forty-five days from the grant of provisional registration, cause to be published in such manner, as may be prescribed, all particulars of the clinical establishment so registered provisionally.
- Validity of provisional registration.** **12.** Subject to the provisions of section 18, every provisional registration shall be valid to the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable.
- Display of certificate of registration.** **13.** The certificate shall be kept affixed in a conspicuous place in the clinical establishment in such manner so as to be visible to every one visiting such establishment.
- Duplicate certificate.** **14.** In case the certificate is lost, destroyed, mutilated or damaged, the Authority shall issue a duplicate certificate on the request of the clinical establishment on payment of such fees as may be prescribed.
- Certificate to be non-transferable.** **15.** (1) The certificate of registration shall be non-transferable.
(2) In the event of change of ownership or management, the clinical establishment shall inform the authority of such change in such manner as may be prescribed.

(3) In the event of change of category, or location, or on ceasing to function as a clinical establishment, the certificate of registration in respect of such clinical establishment shall be surrendered to the Authority and the clinical establishment shall apply afresh for grant of certificate of registration.

16. The Authority shall cause to be published within such time and in such manner, as may be prescribed, the names of clinical establishments whose registration has expired.

**Publication of
expiry of
registration.**

17. The application for renewal of registration shall be made thirty days before the expiry of the validity of the certificate of provisional registration and, in case the application for renewal is made after the expiry of the provisional registration, the Authority shall allow renewal of registration on payment of such enhanced fees, as may be prescribed.

**Renewal of
registration.**

18. Where the clinical establishments in respect of which standards have been notified by the State Government, the provisional registration shall not be granted or renewed beyond,—

**Time-limit for
provisional
registration.**

- (i) the period of one year from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act;
- (ii) the period of one year from the date of notification of the standards for clinical establishments which come into existence after the commencement of this Act but before the date of notification of the notification of the standards; and
- (iii) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified.

Application for permanent registration.

19. The application for permanent registration by a clinical establishment shall be made to the Authority in such form and be accompanied by such fees, as may be prescribed.

Verification of application.

20. The clinical establishment shall submit evidence of having complied with the prescribed minimum standards in such manner, as may be prescribed.

Display of information for filing objections.

21. As soon as the clinical establishment submits the required evidence of having complied with the prescribed standards, the Authority shall cause to be displayed for information of the public at large and for filing objections, if any, in such manner, as may be prescribed, all evidences submitted by the clinical establishment of having complied with the prescribed minimum standards for a period of thirty days before processing for grant of permanent registration.

Communications of objections.

22. If objections are received within a period as referred to in section 21, such objections shall be communicated to the clinical establishment for response within a period of forty-five days.

Standard for permanent registration.

23. The permanent registration shall be granted only when a clinical establishment fulfils such standards for registration prescribed by the State Government.

Allowing or disallowing of registration.

24. The Authority shall pass an order immediately after the expiry of the prescribed period and within the next thirty days thereafter either—

(a) allowing the application for permanent registration; or

(b) disallowing the application:

Provided that the Authority shall record its reasons, if it disallows an application for permanent registration.

25. (1) The Authority shall, if it, allows an application of the clinical establishment, issue a certificate of permanent registration in such form and containing such particulars, as may be prescribed.

Certificate of permanent registration..

(2) The certificate shall be valid for a period of five years from the date of issue.

(3) For the purposes of sub-section (1), the provisions of sections 13, 14, 15 and 16 shall also apply.

(4) The applications for renewal of permanent registration shall be made within six months before the expiry of the validity of the certificate of permanent registration and, in case the application of renewal is not submitted within the stipulated period, the Authority may allow renewal of registration on payment of such enhanced fees as may be prescribed.

26. The disallowing of an application for permanent registration shall not debar a clinical establishment from applying afresh for permanent registration under section 19 and after providing such evidence, as may be required, of having rectified the deficiencies on which grounds the earlier application was disallowed.

Fresh application for permanent registration.

27. (1) If, at any time after any clinical establishment has been registered, the Authority is satisfied that,—

Cancellation of registration.

(a) the conditions of the registration are not being complied with;
or

(b) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act,

it may issue a notice to the clinical establishment to show cause within a period of one month as to why its registration under this Act should not be cancelled for the reasons to be mentioned in the notice.

(2) If after giving a reasonable opportunity to the clinical establishment, the Authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, by an order, without prejudice to any other action that it may take against such clinical establishment, cancel its registration.

(3) Every order made under sub-section (2) shall take effect—

(a) where no appeal has been preferred against such order immediately on the expiry of the period prescribed for such appeal; and

(b) where such appeal has been preferred and it has been dismissed from the date of the order of such dismissal:

Provided that the Authority, after cancellation of registration for reasons to be recorded in writing, may restrain immediately the clinical establishment from carrying on if there is imminent danger to the health and safety of patients.

**Inspection of
registered
clinical
establishments.**

28. (1) The Authority or an officer authorised by it shall have the right to cause an inspection of, or inquiry in respect of any registered clinical establishment, its building, laboratories and equipment and also of the work conducted or done by the clinical establishment, to be made by such multi-member inspection team as it may direct and to cause an inquiry to be made in respect of any other matter connected with the clinical establishment and that establishment shall be entitled to be represented thereat.

(2) The Authority shall communicate its views to the clinical establishment with reference to the results of such inspection or inquiry and may, after ascertaining the opinion of the clinical establishment thereon, advise that establishment upon the action to be taken.

(3) The clinical establishment shall report to the Authority, the action, if any, which is proposed to be taken or has been taken upon the results of such inspection or inquiry and such report shall be furnished within such time, as the authority may direct.

(4) Where the clinical establishment does not, within a reasonable time, take action to the satisfaction of the Authority, it may, after considering any explanation furnished or representation made by the clinical establishment, issue such directions within such time as indicated in the direction, as that Authority deems fit, and the clinical establishment shall comply with such directions.

29. The Authority or an officer authorised by it may, if there is any reason to suspect that anyone is carrying on a clinical establishment without registration, enter and search in the manner prescribed, at any reasonable time and the clinical establishment, shall offer reasonable facilities for inspection or inquiry and be entitled to be represented thereat.

Power to enter.

30. The State Government may charge fees for different categories of clinical establishments, as may be prescribed.

Levy of fee by State Government.

31. (1) Any person, aggrieved by an order of the Authority refusing to grant or renew a certificate of registration or revoking a certificate of registration may, in such manner and within such period as may be prescribed, prefer an appeal to the State Council:

Appeal.

Provided that the State Council may entertain an appeal preferred after the expiry of the prescribed period if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

(2) Every appeal under sub-section (1) shall be made in such form and be accompanied by such fee as may be prescribed.

CHAPTER IV REGISTER OF CLINICAL ESTABLISHMENTS

**Register of
clinical
establishments.**

32. (1) The Authority shall within a period of two years from its establishment, compile, publish and maintain in digital format a register of clinical establishments, registered by it and it shall enter the particulars of the certificate so issued in a register to be maintained in such form and manner, as may be prescribed.

(2) Each Authority, including any other authority constituted for the registration of clinical establishments under any other law for the time being in force, shall supply in digital format to the State Council of clinical establishments a copy of every entry made in the register of clinical establishments in such manner, as may be prescribed to ensure that the State Register is constantly up-to-date with the registers maintained by the registering authority in the State.

**Maintenance of
State Register
of clinical
establishments.**

33. (1) The State Council shall maintain in digital and in such form and containing such particulars, as may be prescribed, a register to be known as the State Register of clinical establishments in respect of clinical establishments.

(2) The State Council shall supply in digital format to the National Council, a copy of the State Register of clinical establishments and shall inform the National Council, all additions to and other amendments in such register made, for a particular month by the 15th day of the following month.

CHAPTER V
PENALTIES

34. Whoever contravenes any of the provisions of this Act shall, if no penalty is provided elsewhere, be punishable for the first offence with fine which may extend to ten thousand rupees, for the second offence with fine which may extend to fifty thousand rupees and for any subsequent offence with fine which may extend to one lakh rupees. **Penalty.**

35. (1) Whoever carries on a clinical establishment without registration shall, on first contravention, be liable to a monetary penalty up to twenty-five thousand rupees, for second contravention with a monetary penalty which may extend to fifty thousand rupees and for any subsequent contravention with a monetary penalty which may extend to one lakh rupees. **Monetary penalty for non-registration.**

(2) Whoever knowingly serves in a clinical establishment which is not duly registered under this Act, shall be liable to a monetary penalty which may extend to fifty thousand rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), the Authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry, the Authority shall have the power to summon and enforce the attendance of any person acquainted with the facts 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, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the monetary penalty

specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8) of section 36.

(5) While determining the quantum of monetary penalty, the Authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the Authority may prefer an appeal to the State Council within a period of three months from the date of receipt of such decision.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

**Disobedience of
direction,
obstruction and
refusal of
information.**

36. (1) Whoever wilfully disobeys any direction lawfully given by any person or authority empowered under this Act to give such direction, or obstructs any person or authority in the discharge of any functions which such person or authority is required or empowered under this Act to discharge, shall be liable to a monetary penalty which may extend to five lakh rupees.

(2) Whoever being required by or under this Act to supply any information wilfully withholds such information or gives information which he knows to be false or which he does not believe to be true, shall be liable to a monetary penalty which may extend to five lakh rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), the Authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry, the Authority shall have power to summon and enforce the attendance of any person acquainted with the facts 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, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the monetary penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8).

(5) While determining the quantum of monetary penalty, the Authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the Authority may prefer an appeal to the State Council within a period of three months from the date of receipt of such decision.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

(8) The monetary penalty levied under sections 35 and under this section shall be credited to such account as the State Government may by order specify in this behalf.

37. Whoever contravenes any of the provisions of this Act or any rule made thereunder resulting in deficiencies that do not pose any imminent danger to the health and safety of any patient and can be rectified within a reasonable time, shall be punishable with fine which may extend to ten thousand rupees.

**Penalty for
minor
deficiencies.**

**Contravention
by companies.**

38. (1) Where a person committing contravention of any of the provisions of this Act or of any rule made thereunder is a company, every person who, at the time the contravention was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the contravention and shall be liable to fine:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment if he proves that the contravention was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such contravention.

(2) Notwithstanding anything contained in sub-section (1), where a contravention of any of the provisions of this Act or of any rule made thereunder has been committed by a company and it is proved that the contravention has taken place with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that contravention and shall be liable to fine.

Explanation.—For the purpose of this section,—

(a) “company” means a body corporate and includes a firm or other association of individuals; and

(b) “director”, in relation to a firm, means a partner in the firm.

**Offences by
Government
Clinical
Establishments.**

39. (1) Where an offence under this Act has been committed by any Clinical Establishment of Government within a period of six months after the commencement of this Act, the Head of the Clinical Establishment shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render such Head of the Clinical Establishment liable to any punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Clinical Establishment of Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the Head of the Clinical Establishment, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

40. Whoever fails to pay the fine, the State Council of clinical establishment may prepare a certificate signed by an officer authorised by it specifying the fine due from such person and send it to the Collector of the District in which such person owns any property or resides or carries on his business and the said Collector, on receipt of such certificate, shall proceed to recover from such person the amount specified thereunder, as if it were an arrear of land revenue.

**Recovery of fine
as an arrear of
land revenue.**

CHAPTER VI

MISCELLANEOUS

41. (1) No suit, prosecution or other legal proceedings shall lie against any member of the Authority or any member of the State Council or any officer authorised in this behalf in respect of anything, which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder.

**Protection of
action taken in
good faith.**

(2) No suit or other legal proceedings shall lie against a State Government in respect of any loss or damage caused or likely to be caused by anything which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder.

Furnishing of returns, etc.

42. Every clinical establishment shall, within such time or within such extended time, as may be prescribed in that behalf, furnish to the Authority such returns or the statistics and other information in such manner, as may be prescribed.

Power to give directions.

43. Without prejudice to the foregoing provisions of this Act, the State Government shall have the power to issue such directions, including furnishing returns, statistics and other information for the proper functioning of clinical establishments and such directions shall be binding.

Employees of Authority, etc. to be public servants.

44. Every employee of the Authority and the State Council shall be deemed to, when acting or purporting to act in pursuance of any of the provisions of this Act, be public servants within the meaning of section 21 of the Indian Penal Code (45 of 1860).

Power to make rules.

45. (1) The State Government may, by notification in the *Official Gazette*, subject to the condition of previous publication, make rules for carrying out the purposes of this Act:

Provided that if the State Government is satisfied that the circumstances exist which render it necessary to take immediate action, it may dispense with the previous publication of any rule to be made under this Act.

(2) All rules made under this section shall be laid for not less than thirty days before the State Legislature as soon as possible after they are made, and shall be subject to rescission by the State Legislature or to such modifications as the State Legislature may make, during the session in which they are so laid or the session immediately following.

(3) Any rescission or modification so made by the State Legislature shall be published in the *Official Gazette* and shall thereupon take effect.

46. (1) If any difficulty arises in giving effect to the provisions of this Act, the State Government may, by an Order published in the *Official Gazette*, make such provisions not inconsistent with the provisions of this Act as may appear to it to be necessary or expedient for removal of the difficulty:

Power to remove difficulties.

Provided that no such order shall be made after the expiry of a period of two years from the date of commencement of this Act.

(2) Every order made under this section shall, as soon as may be after it is made, be laid before State Legislature.

**Bom XV of
1949.**

47. (1) On the commencement of this Act, the Gujarat Nursing Homes Registration Act, 1949 in its application to the State of Gujarat shall stand repealed.

Repeal and saving.

(2) Notwithstanding such repeal of the said Act, anything done or any action taken (including any rule or order made, notification issued or appointment made) by or under that Act shall, in so far as it is not inconsistent with the provisions of this Act, be deemed to have been done or taken by or under this Act and shall continue to be in force until superseded by anything done or any action taken under the provisions of this Act.

Extra No. 214



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VOL. LXIII]

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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, 26th 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 ofdistrict.

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/-
Other Fees		
<ul style="list-style-type: none"> • 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 change of ownership, management or name of establishment would be half the amount of registration fee(Provisional/Permanent) <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.



Signature Not Verified

Signed by: BHOLUSINGH G THAKUR
Date: 2022.10.11 13:07:15 +05:30
Reason: Validate Document
Location: Government Central Press,
Gandhinagar