

The Gujarat Clinical Establishments (Registration and Regulation) Act, 2021

GUJARAT

India

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Act 18 of 2021

- Published on 22 May 2021
- Not commenced
- [This is the version of this document from 22 May 2021.]
- [Note: The original publication document is not available and this content could not be verified.]

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

1. Short title, extent and commencement.

(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.

2. Definitions.

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 women, 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

3. State Council of Clinical Establishment.

(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. Providing information to National Council.

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.

5. Authority for registration.

(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:—(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.

6. Registration for Clinical Establishments.

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

7. Conditions for registration.

(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. Classification of Clinical Establishments.

(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. (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. Application for provisional certificate of registration.

(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. (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).

10. Provisional certificate.

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.

11. No inquiry prior to provisional registration.

(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.

12. Validity o provisional registration.

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.

13. Display of certificate of registration.

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.

14. Duplicate certificate.

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.

15. Certificate to be non-transferable.

(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. Publication of expiry of registration.

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.

17. Renewal of registration.

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.

18. Time-limit for provisional registration.

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,—(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 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.

19. Application for permanent registration.

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.

20. Verification of application.

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

21. Display of information for filing objections.

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.

22. Communications of objections.

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.

23. Standard for permanent registration.

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

24. Allowing or disallowing of registration.

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. Certificate of permanent registration.

(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.(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. Fresh application for permanent registration.

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.

27. Cancellation of registration.

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

28. Inspection of registered clinical establishments.

(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. Power to enter.

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.

30. Levy of fee by State Government.

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

31. Appeal.

(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: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

32. Register of clinical establishments.

(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.

33. Maintenance of State Register of clinical establishments.

(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. Penalty.

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.

35. Monetary penalty for non-registration.

(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.(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.

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

(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. Penalty for minor deficiencies.

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.

38. Contravention by companies.

(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.

39. Offences by Government Clinical Establishments.

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

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.

Chapter VI

MISCELLANEOUS

41. Protection of action taken in good faith.

(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. (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.

42. Furnishing of returns, etc.

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.

43. Power to give directions.

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.

44. Employees of Authority, etc. to be public servants.

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).

45. Power to make rules.

(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. Power to remove difficulties.

(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: 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.

47. Repeal and saving.

(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. (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.