

West Bengal Clinical Establishments (Registration And Regulation) Act, 2010

26 of 2010

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West Bengal Clinical Establishments (Registration And Regulation) Act, 2010

26 of 2010

An Act to provide for the registration and regulation of clinical establishments of the State and for matters connected there with or incidental there to.

WHEREAS it is expedient, in the public interest, to provide for

registration and regulation of clinical establishments and to prescribe the minimum standards of facilities and services to be provided by them;

It is here by enacted in the Sixty-first Year of the Republic of India, by the Legislature of West Bengal, as follows:-

CHAPTER 1 Preliminary

1. Short title, extent, commencement and application :-

(1) This Act may be called the West Bengal Clinical Establishments (Registration and Regulation) Act, 2010.

(2) It extends to the whole of the State of West Bengal.

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

(4) It shall apply to all clinical establishments other than -

(a) any clinical establishment maintained by, or under the control of, the State Government, Central Government or local Self-Government or any local authority; or

(b) any clinical establishment or asylum established or licensed under the Mental Health Act, 1987; or

(c) 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, the Air Force Act, 1950 and the Navy Act, 1957.

2. Definitions :-

In this Act, unless there is any repugnant in the subject or the context,-

(a) "adjudicating authority" means the authority appointed under section 34.;

(b) "appellate authority" means the authority appointed under section 26;

(c) "clinical establishment" means the whole or part of institution, facility with or without bed or beds, building or premises of any Hospital, Maternity Home, Nursing Home, Dispensary, Clinic, Polyclinic, Immunization or Vaccination Centre, Sanatorium, Physical Therapy Establishment, Clinical Laboratory, Fertility Regulation Clinic, Wellness Clinic or an establishment analogous to any of them by whatever name called, used or intended to be used for the health care related services established and administered or maintained by any person or body of persons, whether incorporated or not; and shall include-

(i) a clinical establishment for profit or not for profit, owned, controlled or managed by,-

(a) a trust, whether public or private;

(b) a Corporation (including a co-operative society), not owned by the Government, registered under a Central Act, or State Act; and

(ii) a single doctor establishment or medical clinic.

Explanation. - "medical clinic" shall mean a place used or intended to be used for consultation and treatment by a registered medical practitioner;

(d) "clinical laboratory" means any establishment or premises used or intended to be used for the -

(i) pathological, bacteriological, genetic, radiological, chemical, biological or other tests, examination, analysis or collection of sample and specimen or other diagnostic or investigative services, procedure or intervention, or

(ii) preparation of cultures, vaccines, sera or other biological or microbiological products,

with the aid of laboratory or other medical equipment for the purpose of diagnosis, treatment or research of diseases;

(e) "health care" means testing, treatment, care, procedures and any other service or intervention towards the nursing, preventive, promotive, curative, rehabilitative, palliative, diagnostic research or other health related purpose or combinations thereof in any recognized system of medicine for the convalescence, illness, sickness, injury, infirmity, deformity, abnormality or pregnancy or any other physiological condition whether of body or mind, and also includes any of these as a result of participation in a medical research programme;

(f) "improvement notice" means a notice issued under section 23;

(g) "license" means license issued under this Act to keep or carry on a clinical establishment consequent upon registration;

(h) "licensing authority" means the District registering authority under section 5;

(i) "maternity home" means any establishment or premises used or intended to be used for the reception or accommodation for women for the purpose of confinement and ante-natal and post-natal care in connection with childbirth, sterilization, medical termination of pregnancy, or anything connected therewith;

(j) "notification" means a notification published in the Official Gazette;

(k) "nursing home" means any establishment or premises used or intended to be used for the reception or accommodation for persons suffering from sickness, illness, injury or infirmity whether of body or mind for the purpose of observation, nursing, treatment and other health care and includes a maternity home;

(l) "physical therapy establishment" means any establishment or premises used or intended to be used for the massaging, electrotherapy, hydrotherapy, remedial gymnastics or similar services, for the purpose of treatment of diseases or of infirmity or for improvement of health, or for purpose of relaxation or for any other purpose whatsoever, whether or not analogous to the purpose hereinbefore mentioned in this clause;

(m) "prescribed" means prescribed by rules made under this Act;

(n) "prohibition order" means an order issued under section 21;

(o) "recognized system of medicine" means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani Systems of medicines or any other system of medicine recognized by the Government;

(p) "registration" means registration done under this Act;

(q) "register" means the register maintained by the licensing authority, or the State Registrar under sections 9, or 10 of this Act, as the case may be, containing the number of clinical establishments registered and the expressions "registered" and "registration" shall be construed accordingly;

(r) "registered medical practitioner" means a medical practitioner

registered under the relevant Medical Act and shall include a person who possesses any of the recognized medical qualifications and who has been enrolled in the register of the respective Medical Council, viz., Allopathy, Dental, Homeopathic and Board of Indian Medicine or any such council, Board or any other statutory body recognized by the Government of West Bengal;

(s) "registered nurse" or "registered midwife" means a nurse or midwife registered under the Bengal Nurses Act, 1934.

(t) "Tribunal" means the West Bengal Clinical Establishments Tribunal constituted under section 35;

(u) "rules" means rules made under this Act;

(v) "section" means the section of this Act;

(w) "service provider" means a medical doctor, nurse, midwife, other paramedical professional, social worker or other appropriately trained and qualified person with specific skills relevant to particular health care services, and any reference to "service provider" shall mean the same unless specifically stated otherwise;

(x) "service recipient" means person who seeks, accesses or receives any health care, as outpatient or inpatient, from any clinical establishment, or service provider, including for profit and not for profit;

(y) "standards" means the requirements that the State Government may prescribe under section 7, for the registration of clinical establishments;

(z) "State Government" means the State Government of West Bengal;

(za) "trade practice" in relation to a clinical establishment means any practice relating to the provision of services by a clinical establishment, and includes -

(i) anything done by the clinical establishment which controls or affects the price charged for services rendered by the clinical establishment, or the method of providing services by the clinical establishment;

(ii) a single or isolated action of any person in relation to any trade.

3. Power to seek advice or assistance :-

The State Government may associate with itself any person or body whose assistance or advice it may desire in carrying out any of the provisions of this Act.

CHAPTER 2 Registration and Standards

4. State Registrar of clinical establishments :-

(1) The State Government shall, by notification, designate the Director of Health Services (by whatever name called) or any other officer subordinate to him as the State Registrar of clinical establishments.

(2) It shall be the responsibility of the State Registrar of clinical establishments to compile and update the State register of clinical establishments.

5. Authority for registration and license :-

(1) The Chief Medical Officer of Health of a district other than the district of Kolkata shall be the Registering Authority as well as licensing authority in respect of clinical establishment situated within the district.

(2) An officer not below the rank of Assistant Director of Health Services as designated by the State Government shall be the Registering Authority as well as licensing authority in respect of clinical establishment situated within the district of Kolkata.

Explanation.- For the purpose of this section, the word Kolkata' shall have the same meaning as defined in clause(9) of section 2 of the Kolkata Municipal Corporation Act, 1980.

6. Registration and license for clinical establishments :-

No person shall keep or carry on a clinical establishment without being duly registered by the registering authority in respect thereof and except under and in accordance with the terms of a license granted therefor.

Explanation-I.- For the purpose of this section person includes a body, group or association of individuals, and organization, a firm, a trust or society (whether registered or not) or a company registered under the law for the time being in force.

Explanation-II. - For the purposes of this section, "carry on" means to provide the service recipient in a clinical establishment with any kind of services including consultation, treatment, diagnosis, or nursing care.

7. Conditions for registration and license :-

(1) The licensing authority, if satisfied that the applicant and the clinical establishment has fulfilled such standards as may be prescribed, shall register the clinical establishment and shall grant a license in duplicate in respect of the clinical establishment in such form as may be prescribed.

(2) No license shall be granted in respect of a clinical establishment unless it has -

(a) provided such minimum standard of accommodation as may be prescribed;

(b) engaged such minimum number, and norms, of service providers including registered medical practitioner, registered nurse, other paramedical staff and other categories of employees with such qualification as may be prescribed;

(c) made arrangements for such minimum standard of services including emergency care and referral services as may be prescribed;

(d) installed such equipments and machineries as may be prescribed;

(e) made such arrangements for disposal of biomedical wastes as may be prescribed;

(f) made provisions for maintenance of such records and registers in such form and containing such particulars as may be prescribed;

(g) fulfilled any other condition that may be prescribed.

(3) Every license granted under sub-section (1) shall be subject to the following terms and conditions:-

(a) continued fulfillment of the condition laid down in sub-section (2);

(b) that necessary precaution shall be observed so guarding that the clinical establishment is not being used for unsocial or immoral purpose or both;

(c) that the clinical establishment shall not resort to any unethical

or unfair trade practices including unfair pricing for different services;

(d) that such measures shall be taken to keep the clinical establishment in such satisfactory, sanitary and hygienic condition as may be prescribed;

(e) that such information is to be displayed and in such manner as may be prescribed ;

(f) that such reports in such form containing such particulars and such necessary documents shall be submitted to such authorities at such intervals or on demand, as may be prescribed;

(g) that such medical and other reports, records and documents shall be made available to the licensing authority or the service recipient or his representative on demand as may be prescribed;

(h) that report shall be submitted to the licensing authority as soon as a person who has been received or accommodated or both in the clinical establishment is found to be suffering from any such infectious or dangerous disease or other condition as may be notified;

(i) that every case of a victim of accident, injury, or trauma, received or accommodated or both thereto shall be reported to the police station, within the jurisdiction of which such clinical establishment is located;

(j) that no person shall be subject to any discrimination in any form or manner, by the clinical establishment in access to facilities, goods, care and services including admission, on any of the grounds of nationality, sex, physical or mental disability, occupation, religion, sect, language, caste, political or other opinion, actual or perceived health status and disease condition like Human Immunodeficiency Virus (HIV) infection or Acquired

Immunodeficiency Syndrome (AIDS) or such other diseases as may be prescribed or such other arbitrary grounds;

(k) that no person shall be denied, under any circumstances, including inability to pay the requisite fee or charges, such emergency life-saving medical treatment and critical care by the clinical establishment as may be prescribed:

Provided that the clinical establishment has the right to recover the cost from the service recipient or his representative in due course of time;

(1) that the clinical establishment shall actively participate in the implementation of all National and State Health Programmes including prevention of spread of communicable diseases in such manner as the State Government may specify from time to time and furnish periodical reports thereon to the authorities concerned; and

(m) any other terms and conditions which may be prescribed.

(4) Every license granted under sub-section (1) shall, unless suspended or cancelled earlier under this Act, remain in force and be valid for such period with effect from the date on which it is granted as may be prescribed.

8. Power of State Government to relax terms and conditions of registration & license :-

Notwithstanding anything contained in sub-section (2) and sub-section (3) of section 7, the State Government may, for reasons to be recorded in writing, relax for such clinical establishment or in such circumstances as may be prescribed, all or any of the terms and conditions to which a license granted under sub-section (1) of section 7 shall be subject.

9. Register of clinical establishments :-

(1) The licensing authority shall maintain in digital or in such form and containing such particulars, as may be prescribed by the State Government, a register to be known as the district register of clinical establishments in respect of clinical establishments of the district.

(2) Each licensing authority shall supply in digital or in such other prescribed format to the State Registrar 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 up-to-date.

10. Maintenance of State register of clinical establishments
:-

The State Registrar shall maintain in digital or in such other form and containing such particulars, as may be prescribed by the State Government, a register to be known as the State register of clinical establishments in respect of clinical establishments of the State.

11. Classification of clinical establishments :-

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

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

CHAPTER 3 Procedure for registration and licensing

12. Application for registration and licensing :-

(1) Every person intending to open, keep or carry on a clinical establishment shall submit an application in the prescribed proforma along with the prescribed fee to the licensing authority for the purposes of registration in respect of a clinical establishment

under section 6 and for the grant of a license thereof subject to the provision of section 7 or for the renewal of the registration and license under section 19.

(2) Every application made under sub-section (1) shall contain such particulars and shall be accompanied by such evidence of the clinical establishment having complied with the prescribed minimum standards in such manner, as may be prescribed.

(3) Any change in address or situation of or of staff belonging to, or any other particulars mentioned under sub-section (2) shall be communicated by the applicant or the person carrying on the clinical establishment to the licensing authority not later than thirty days after such change with specific mention as to the exact date when such change occurred.

(4) No applicant under sub-section (1) shall try to obtain the license by means of misrepresentation of facts, fraudulent practices, falsifying documents, or using unfair means.

13. Grant or rejection of application :-

On receipt of application made under sub-section (1) of section 12, the licensing authority shall, if it is satisfied after causing such enquires as may be necessary and after following the criteria as may be prescribed, pass an order within the prescribed period from the date of receipt of application, either -

(a) granting the application for registration and license or renewal of registration and license; or

(b) rejecting the application, and shall send a copy of the order to the applicant by registered post or in such other manner as may be prescribed:

Provided that if the licensing authority rejects an application for registration and license or renewal of registration and license, it

shall record its reasons therefore.

14. Grounds for rejection :-

(1) The licensing authority may reject the application made under subsection (1) of section 12 if he is satisfied-

(a) that the applicant or the clinical establishment does not fulfill the conditions laid down in sub-section (2) and (3) of section 7; or

(b) that the applicant does not fulfil the condition laid down in sub-sections (1) and (2) of section 12; or

(c) that the applicant is trying to obtain the license in contravention to the sub-section (4) of section 12; or

(d) that the real objective of the applicant is to use or allow the clinical establishment to be used for antisocial or immoral purposes; or

(e) in the case of a nursing home other than a maternity home that such nursing home is not or will not be under the charge of a registered medical practitioner resident therein round the clock and that the nursing of persons received and accommodated therein is not or will not be under the superintendence of a registered nurse resident therein round the clock; or

(f) in the case of a maternity home that such maternity home is not or will not be under the charge of a registered medical practitioner resident therein round the clock and that the attendance on every woman before, at or after child birth or sterilization or medical termination of pregnancy or on any child born is not or will not be under the superintendence of a registered midwife resident therein round the clock; or

(g) that for reasons connected with the location, constructions, accommodation, staffing or equipment, the clinical establishment is not fit to be used as a clinical establishment of such a description as the clinical establishment mentioned in the application.

(2) The licensing authority may, before rejecting an application communicate to the applicant the deficiencies on the grounds of which the application can be rejected and issue him an improvement notice as per provision of section 23 directing him to rectify the deficiencies within such time as he may deem fit.

(3) If within such time as deemed fit by the licensing authority or within such further time as may be allowed by him, the applicant is unable to rectify the deficiencies, the licensing authority may reject the application.

(4) The licensing authority shall in every case where the application is rejected, record the grounds for rejection:

Provided that no application shall be rejected, unless the applicant has been given an opportunity of showing cause in support of his application.

15. Fresh application for registration and license :-

The rejection of an application shall not debar a clinical establishment from applying afresh for registration and license under section 12, and after providing such evidence, as may be required, of having rectified the deficiencies on the grounds of which the earlier application was disallowed.

16. Display of license :-

One license in original 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.

17. Copy of license :-

In case the license is lost, destroyed, mutilated or damaged, the licensing authority shall issue a copy of license on the request of the clinical establishment and on the payment of such fees, as may be prescribed.

18. License to be non-transferable :-

In the event of change of ownership or proprietorship or change of management or on ceasing to function as a clinical establishment, the license shall be surrendered to the licensing authority and the owner or proprietor or management of the clinical establishment shall apply afresh for grant of license.

19. Renewal of registration and license :-

(1) Application for renewal of registration and license shall be made at least a period of thirty days before the date of expiry of the validity of the registration and license:

Provided that in case the application for renewal is made-(a) after the said period but before the date of expiry of the validity of the registration and license; or

(b) after expiry of the validity of the registration and license, the licensing authority shall allow renewal of registration and license on payment of such enhanced fee for each day and on such terms and conditions, as may be prescribed.

(2) In the event of failure of the licensing authority to communicate the fact of granting or rejection of application for renewal of registration and license after the expiry of the prescribed period from the date of receipt of such application, the license shall be deemed to have been renewed and the person can keep or carry on the clinical establishment in accordance with the provision of this Act until such communication is received.

20. Cancellation of registration and license :-

(1) If, at any time after any clinical establishment has been registered and licensed, the licensing authority is satisfied,-

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

(b) that any of the grounds which would have entitled the licensing authority to refuse the application for registration and license, exist; or

(c) that the person entrusted with the management of the clinical establishment has violated any of the directions including improvement notice of the licensing authority or the Tribunal; or

(d) that the person entrusted with the management of the clinical establishment has contravened any of the provisions of this Act or rules made thereunder, the licensing authority, notwithstanding anything contained in section 23, may issue a show cause notice as to why its registration and license under this Act should not be cancelled for the reasons to be mentioned in the notice.

(2) If after giving a reasonable opportunity of being heard to the clinical establishments, the licensing authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, he may, without prejudice to any other action that he may take against such clinical establishment, cancel its registration and license.

21. Prohibition orders :-

(1) If, -

(a) any clinical establishment is convicted of an offence under this Act; or

(b) the clinical establishment is being kept or carried on without a valid license; or

(c) the license of the clinical establishment is cancelled; or

(d) the licensing authority is satisfied that an imminent danger to the health and safety of any member of the public or patient exist with respect to that clinical establishment, the licensing authority may, after giving the clinical establishment an opportunity of being heard, by an order, impose the following prohibitions, namely:-

(i) a prohibition on the use of the process or treatment for the purposes of the service delivery by the clinical establishment;

(ii) a prohibition on the use of the premises or equipment for the purposes of the service delivery by the clinical establishment.

(2) As soon as practicable after the making of an order under sub-section (1), the concerned licensing authority shall-

(a) serve a copy of the order on the clinical establishment by registered post or by any such manner as may be prescribed; and

(b) affix a copy of the order at a conspicuous place on such premises used for the purposes of the clinical establishment.

(3) Every order made under sub-section (1) shall take immediate effect:

Provided that the licensing authority, after issuance of Prohibition order for reasons to be recorded in writing shall take steps to inform the police authority to restrain immediately the clinical establishment from carrying on health care related services.

Explanation.- Police authority means an officer not below the rank of Inspector-in-Charge or Officer-in-Charge of the local Police Station area where the clinical establishment is situated.

(4) Every order made under sub-section (1) shall contain a direction that no person shall be freshly admitted in the clinical establishment either as an in-patient or an out-patient and the inpatients of the clinical establishment shall be transferred immediately to such other clinical establishment as the patient or his representative opts or where it is not practicable to transfer the inpatients to the clinical establishment so opted, to the nearest Government Hospital, which shall be specified in that order and it shall also contain directions as to the care and custody of such inpatients pending such transfer.

(5) A prohibition order shall cease to have effect upon the licensing authority being satisfied, on an application made by the clinical establishment not less than six months after the prohibition order has been passed, that the clinical establishment has taken sufficient measures justifying the lifting of the prohibition order.

(6) The concerned licensing authority shall issue a certificate to the effect that the clinical establishment has taken sufficient measures justifying lifting of the prohibition order, within seven days of his being satisfied on an application made by the clinical establishment for such a certificate or the said officer shall-

(a) determine, as soon as is reasonably practicable and in any event within fourteen days, whether or not he is so satisfied; and

(b) if he determines that he is not so satisfied, give notice to the clinical establishment of the reasons for that determination.

22. Inspection of clinical establishments :-

(1) The licensing authority or an officer authorized by him, shall have the power to cause an inspection or inquiry in respect of any

clinical establishment, its building, laboratories and equipment and also of the services rendered by the clinical establishment or any other matter connected with the clinical establishment, and that establishment shall be entitled to be represented thereat.

(2) (a) Every officer authorized under sub-section (1) shall conduct the inspection and submit a report to the prescribed authority within seven days of completion of any inspection by him in such manner as may be prescribed.

(b) He shall record his observation or inspection note in the inspection book to be kept at the clinical establishment for this purpose.

23. Improvement notices :-

(1) If the licensing authority has reasonable ground for believing that any clinical establishment has failed to comply with any provision of this act, he may, after ascertaining the opinion of the clinical establishment thereon, by a notice served on that clinical establishment-

(a) state the grounds for believing that the clinical establishment has failed to comply with the rules;

(b) specify the matters which constitute the clinical establishments failure so to comply;

(c) specify the measures which, in the opinion of the said authority, the clinical establishment must take, in order to secure compliance; and

(d) require the clinical establishment to take those measures, or measures which are at least equivalent to them, within a reasonable period (not being less than fourteen days) as may be specified in the notice.

(2) The clinical establishment shall report to the licensing 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.

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

(4) If the clinical establishment fails to comply with an improvement notice, his license may be suspended for such period to be mentioned in the order.

(5) Every order made under sub-section (4) shall contain a direction that no person shall be freshly admitted in the clinical establishment as an inpatient or an outpatient.

(6) If the clinical establishment, during the period mentioned in the order of suspension-

(a) still fails to comply with the improvement notice, the licensing authority may after giving the licensee an opportunity to show cause, cancel the license granted to him; or

(b) complies with the improvement notice to the satisfaction of the licensing authority, he may revoke the suspension order within a reasonable period not exceeding fourteen days.

24. Power to enter :-

(1) Subject to such rules as may be made under this Act, any

officer of the State Government authorized by the State Government in this behalf-

(a) may make such inquiries, as he deems necessary in order to ascertain whether the place or the establishment is being used as a clinical establishment;

(b) may make such examination of place or establishment and inspect any equipment, sample, article or document found therein and seize and take out there from any such equipment, sample, article or document, as he deems necessary for the purpose of examination, analysis, investigation or evidence and retain them in such manner and for such period as may be prescribed;

(c) may, if there is any reasonable cause to suspect that anyone is carrying on a clinical establishment without registration and license, enter and search in the manner prescribed with or without the assistance of a police officer not below the rank of sub-inspector, at any reasonable time, and the clinical establishment, shall offer reasonable facilities for inspection or inquiry and be entitled to be represented thereat:

Provided that no such person shall enter the clinical establishment without giving notice in writing of his intention to do so.

(2) No person shall obstruct an officer authorized under sub-section (1) in the exercise of any power conferred by that sub-section or make any false or reckless statement in answer to a question put by such officer in exercise of the power conferred on him under clause (a) of that sub-section.

(3) Save as in this Act otherwise expressly provided, provision of the Code of Criminal Procedure, 1973 relating to search, seizure, summon, investigation and prosecution shall apply, as far as may be, to all action taken by the Officer authorized under sub-section(1).

25. Fees for registration and license for different categories of clinical establishments :-

The licensing authority may charge such fees for registration and license for different categories of clinical establishments, as may be prescribed:

Provided that the State Government may, if it considers necessary to do so in the public interest, by order, subject to such terms and conditions as may be specified therein, exempt clinical establishment from payment wholly of any such fee or reduce the amount of any such fee payable by any clinical establishment as may be prescribed.

26. Appeal to the Appellate Authority :-

(1) Any person, aggrieved by-

(i) the failure of the licensing authority in communicating the allowing or rejection of application for registration and license to clinical establishment after the expiry of prescribed period; or

(ii) an order of the licensing authority refusing to allow registration or to grant or renew a license; or

(iii) canceling or suspending a license; or

(iv) an improvement notice; or

(v) prohibition order; may, prefer an appeal to such authority not below the rank of Special Secretary, Department of Health & Family Welfare of the State Government being the Appellate authority as may be prescribed.

(2) Every appeal under sub-section (1) shall be made in such manner, in such form within such period from the date of the order and be accompanied by such fee as may be prescribed:

Provided that the Appellate authority 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.

(3) The decision of the Appellate authority shall be final and binding.

(4) No civil court shall have any jurisdiction to entertain any suit or other proceedings challenging the decision of the licensing authority refusing to allow registration of the clinical establishment or to grant or renew a license or canceling or suspending a license or issuing a prohibition order or, an improvement notice under sections 13, 14, 20, 21, and section 23 as well as the decision of the Appellate authority.

CHAPTER 4 Contravention and Penalty

27. Penalty for non-registration and licensing :-

(1) Whoever carries on a clinical establishment without registration and license shall be liable to a penalty which may extend to fifty thousand rupees, along with a further penalty of five hundred rupees for each day of operation of the clinical establishment without license subject to maximum of two lakh rupees.

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

28. Disobedience of order, obstruction and refusal of information :-

(1) Whoever willfully 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 penalty which may extend to two lakh rupees.

(2) Whoever being required by or under this Act to supply any information willfully 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 penalty which may extend to fifty thousand rupees.

(3) Whoever being required by or under this Act to maintain and supply records, reports, registers and other documents willfully tamper, destroy, falsify such documents shall be liable to a penalty which may extend to two lakh rupees.

29. Minor & major deficiencies :-

(1) Whoever contravenes any provision of this Act or any rule made thereunder resulting in such minor deficiencies, that do not pose any imminent danger to the health and safety of any patient or public and can be rectified within a reasonable time, shall be liable to a penalty which may extend to fifty thousand rupees.

(2) Whoever contravenes any provision of this Act or any rule made thereunder resulting in such major deficiencies, that pose an imminent danger to the health and safety of any member of the public or patient and which cannot be rectified within a reasonable time, shall be liable to a penalty which may extend to five lakh rupees.

Explanation.- For the purpose of this section Minor deficiencies and major deficiencies shall have such meaning as may be prescribed.

30. Penalty for Contravention :-

Whoever contravenes any provision of this Act or any rule made thereunder shall, if no penalty is provided elsewhere, be liable to a

penalty which may extend to ten thousand rupees for the first contravention and fifty thousand rupees for any subsequent contravention.

31. 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 penalty:

Provide that nothing contained in this sub-section shall render any such person liable to any penalty 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 penalty.

Explanation.- for the purposes of this section, -

(a) company includes a firm or society; and

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

32. General provision relating to Penalties :-

(1) While adjudging the quantum of penalty under this Chapter, the Adjudicating Authority or the Tribunal, as the case may be, shall have due regard to the following:-

(a) the amount of gain or unfair advantage, wherever quantifiable, made as a result of the contravention;

(b) the amount of loss caused or likely to cause to any person as a result of the contravention;

(c) the repetitive nature of the contravention;

(d) whether the contravention is without his knowledge; and

(e) any other relevant factor.

(2) The penalties which may be imposed for contravention of any provision of this Act or any rule made thereunder shall be without prejudice to the power of the licensing authority to suspend or cancel the license.

33. Compensation in case of injury or death of the service recipient :-

(1) Without prejudice to the other provisions of this Chapter, if any clinical establishment whether by itself or by any other person on its behalf, while providing services causes injury to the service recipient or his death, due to negligence or any deficiency in providing service, it shall be lawful for the Tribunal, on substantiation of charges, to direct it to pay compensation to the victim or the legal representative of the victim, a sum-

(a) not less than five lakh rupees in case of death;

(b) not exceeding three lakh rupees in case of grievous injury; and

(c) not exceeding one lakh rupees, in all other cases of injury:

Provided that the compensation shall be paid at the earliest and in no case later than six months from the date of occurrence of the incident:

Provided further that in case of death, an interim relief shall be paid to the next of the kin within thirty days of the incident.

(2) Where any person is held guilty of a contravention leading to grievous injury or death, the Tribunal may cause the name and place of residence of the person held guilty, the offence and the penalty imposed to be published at the offender's expense in such newspapers or in such other manner as the Tribunal may direct and the expenses of such publication shall be deemed to be part of the cost attending the conviction and shall be recoverable in the same manner as a fine.

(3) The Tribunal may also order for cancellation of license, closure of the clinical establishment, forfeiture of establishment and property in case of grievous injury or death of the service recipient.

CHAPTER 5 Adjudication and Tribunal

34. Adjudication :-

(1) For the purposes of adjudication under this Chapter, an officer not below the rank of Additional District Magistrate of the district where the alleged offence is committed shall be notified by the State Government as the Adjudicating authority for adjudication in the manner as may be prescribed:

Provided that for the district of Kolkata an officer not below the rank of Joint Secretary to the State Government as may be

appointed by notification by the State Government shall be the Adjudicating authority.

Explanation.- For the purposes of this section, the word Kolkata shall have the same meaning as defined in clause (9) of section 2 of the Kolkata Municipal Corporation Act, 1980.

(2) The Adjudicating authority, on receipt of a complaint from the licensing authority that any person has committed a contravention under sections 27, 28, subsection (1) of section 29, and section 30 of this Act, shall, after giving the person a reasonable opportunity for making representation in the matter, and if, on such inquiry, he is satisfied that the person has committed the contravention of provisions of this Act or the rules or the regulations made thereunder, impose such penalty as he thinks fit in accordance with the provisions of this Act.

(3) The Adjudicating Authority shall have the powers of a civil court and-

(a) all proceedings before him shall be deemed to be judicial proceedings within the meaning of sections 193 and 228 of the Indian Penal Code, 1860;

(b) shall be deemed to be a court for the purposes of sections 345 and 346 of the Code of Criminal Procedure, 1973.

(4) While adjudicating the quantum of penalty under this Chapter, the Adjudicating authority shall have due regard to the guidelines specified in section 32.

35. Formation of West Bengal Clinical Establishment Tribunal :-

(1) The State Government may constitute by notification for the purposes of this Act, a Tribunal for the State to be known as the

West Bengal Clinical Establishment Tribunal (hereinafter referred to as the Tribunal).

(2) The Tribunal shall consist of not more than three Members, including the Chairperson.

(3) The Chairperson and members of the Tribunal shall be appointed by the State Government.

36. Qualification for appointment of Chairperson and members of Tribunal :-

(1) The Chairperson and the Members of the Tribunal shall be persons of ability, integrity and standing who have adequate knowledge of, and have shown capacity in, dealing with problems relating to health administration, finance, economics, law or management, ethics or public health Acts.

(2) Notwithstanding anything contained in sub-section (1), the State Government may appoint any person as the Chairperson from amongst persons who is, or has been, a Judge of a High Court:

Provided that no appointment under this sub-section shall be made except after consultation with the Chief Justice of that High Court.

(3) The Chairperson or any other Member of the Tribunal shall not hold any other office.

37. Term of office and conditions of service of Chairperson and members :-

(1) The Chairperson or other member shall hold office for a term of not more than three years from the date on which he enters upon his office:

Provided that the Chairperson or other member of the Tribunal shall not be eligible for reappointment in the same capacity as the Chairperson or a member in that Tribunal in which he had earlier held office as such:

Provided further that no Chairperson or member shall hold office as such after he has attained the age of sixty-five years.

(2) The salary, allowances payable to and other terms and condition of service of the Chairperson and members shall be such, as may be prescribed:

Provided that the salary, allowances and other terms and conditions of service of Chairperson and the members, shall not be varied to their disadvantage after appointment.

(3) Notwithstanding anything contained in sub-section (1), the Chairperson or any Member may-

(a) relinquish his office by giving in writing to the State Government a notice of not less than three months; or

(b) be removed from his office in accordance with the provisions of section 38.

38. Removal of Member :-

(1) The Chairperson or Member shall not be removed from office except in accordance with the provision of this section.

(2) The State Government may, by order, remove from office the Chairperson or any Member if he-

(a) has been adjudged an insolvent; or

(b) has been convicted of an offence which, in the opinion of the State Government, involves moral turpitude; or

(c) has become physically or mentally incapable of acting as a Member; or

(d) has acquired such financial or other interest as is likely to affect prejudicially his functions as a Member; or

(e) has so abused his position as to render his continuance in office prejudicial to the public interest; or

(f) has been guilty of proved misbehaviour.

(3) No member or chairperson shall be removed under clauses (d) and (e) of subsection (2) unless he has been given a reasonable opportunity of being heard in the matter.

39. Officers and other employees of Tribunal :-

(1) The Tribunal may, with the approval of the State Government, appoint Officers and such other employees as may be considered by it for the due discharge of its functions.

(2) The salaries and allowances payable to, and other terms and conditions of service of, the officers and other employees shall be such as may be prescribed.

(3) The Tribunal may, with the approval of the State Government, appoint consultants required to assist it in the discharge of its functions on such terms and conditions as may be specified, by regulations.

40. Functions of Tribunal :-

(1) The Tribunal shall discharge the following functions namely: -

(a) to decide any dispute between proprietors of clinical establishment and service recipient in relation to-

(i) services as provided by clinical establishment;

(ii) bills as charged by clinical establishment, and to award reasonable amount of compensation payable by the clinical establishment to the service recipients:

Provided that any complain of medical negligence against medical professionals will be dealt with by respective State Medical Councils;

(b) to decide whether the charges for services and investigations by clinical establishments are fair & reasonable in case where there is any dispute between the clinical establishment and the service recipient or his representative:

Provided that dispute between Insurance agency and clinical establishment regarding charges or rates of services investigations shall not be decided by the Tribunal.

(2) The Tribunal shall hear the appeal preferred by the aggrieved clinical establishment against the order of penalty made by the Adjudicating authority under sub-section (2) of section 34.

(3) Every appeal under sub-section (2) shall be made in such manner, in such form within such period from the date of the order and be accompanied by such fee as may be prescribed:

Provided that the Tribunal may admit the appeal after the expiry of such period if it is satisfied that the aggrieved clinical establishment was prevented by sufficient cause from filing it in appropriate time.

(4) The Tribunal shall adjudicate any complaint made by the aggrieved party against any clinical establishment regarding-

(a) alleged irrational and unethical trade practice; and

(b) alleged contravention of any provision of this Act or any rule made thereunder resulting in major deficiencies that may pose any imminent danger to the health and safety of any patient or public, under sub-section (2) of section 29.

41. Procedure and Powers of the Tribunal :-

(1) The Tribunal shall not be bound by the procedure laid down by the Code of Civil Procedure, 1908 but shall be guided by the principles of natural justice and, subject to the other provisions of this Act and the rules made thereunder, the Tribunal shall have powers to regulate its own procedure including the place at which it shall have its sittings.

(2) The Tribunal shall, for the purposes of discharging its functions under this Act, have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908, in respect of the following matters, namely:-(a) summoning and enforcing the attendance of any person and examining him on oath;

(b) requiring the discovery and production of any document or other electronic records or other material object producible as evidence;

(c) receiving evidence on affidavits;

(d) requisitioning of any public record;

(e) issuing commission for the examination of witnesses or documents;

(f) reviewing its decisions, directions and orders;

(g) dismissing an application for default or deciding it exparte;

(h) any other matter which may be prescribed.

(3). Every proceedings before the Tribunal shall be deemed to be judicial proceedings within the meaning of sections 193 and 228 of the Indian Penal Code, 1860 and the Tribunal shall be deemed to be a civil court for the purposes of sections 345 and 346 of the Code of Criminal Procedure, 1973.

(4) The appellant may either appear in person or authorise one or more legal practitioners or any of its officers to represent his case before the Tribunal.

(5) The provisions of the Limitation Act, 1963, shall, except as otherwise provided in this Act, apply to an appeal made to the Tribunal.

(6) The Tribunal shall have the powers to pass such interim order in any proceedings, hearing or matter before the Tribunal, as that Tribunal may consider appropriate.

(7) While adjudicating the quantum of penalty under this Chapter, the Tribunal shall have due regard to the guidelines specified in section 32.

42. Appeal to the High Court :-

Any person aggrieved by any decision or order of the Tribunal may file an appeal to the High Court within sixty days from the date of communication of the decision or order of the Tribunal to him on any question of fact or law arising out of such order:

Provided that the High Court may, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the said period, allow it to be filed within a further period not exceeding sixty days.

43. Enforcement of orders :-

(1) Where an order made under this Act by the Tribunal is not complied with, the Tribunal may order the property of the clinical establishment, not complying with such order to be attached.

(2) No attachment made under sub-section (1) shall remain in force for more than three months at the end of which, if the non-compliance continues, the property attached may be sold and out of the proceeds thereof, the Tribunal may pay the compensation awarded by it to the complainant or service recipient and shall pay the balance if any, to the clinical establishment thereof.

44. Civil court not to have jurisdiction :-

No civil court shall have jurisdiction to entertain any suit or proceeding in respect of any matter which an Adjudicating authority or the Tribunal is empowered by or under this Act to determine and no injunction shall be granted by any court or other authority in respect of any action taken or to be taken in pursuance of any power conferred by or under this Act.

45. Grants and loans by State Government :-

The State Government may, after due appropriation made by Legislature of a State in this behalf, make to the Tribunal grants and loans of such sums of money as that Government may consider necessary.

46. Establishment of Fund by State Government :-

(1) There shall be constituted a Fund to be called the State Clinical Establishment Tribunal Fund and there shall be credited thereto -

(a) any grants and loans made to the Tribunal by the State Government under section 45;

(b) all proceeds of the attachment received by the Tribunal under sub-section (2) of section 43;

(c) all sums received by the Tribunal from such other sources as may be decided upon by the State Government.

(2) The Fund shall be applied for meeting-

(a) the salary, allowances and other remuneration of Chairperson, Members, Secretary, Officers and other employees of the Tribunal;

(b) the expenses of the Tribunal in discharge of its functions under section 40;

(c) the expenses on objects and for purposes authorized by this Act;

(d) the payment of compensation out of the sell proceeds under sub-section (2) of section 43.

(3) The State Government may, in consultation with the Comptroller and Auditor-General of India, notify the manner of applying Fund for meeting the expenses specified in clause (b) or clause (c) of sub-section (2).

47. Accounts and audit of Tribunal :-

(1) The Tribunal shall maintain proper accounts and other relevant records and prepare annual statement of accounts in such form as may be notified by the State Government in consultation with the Comptroller and Auditor -General of India.

(2) The accounts of the Tribunal shall be audited by the Comptroller and Auditor -General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Tribunal to the Comptroller and Auditor -General of India.

(3) The Comptroller and Auditor -General of India and any person appointed by him in connection with the audit of the accounts of the Tribunal under this Act shall have the same rights and privileges and authority in connection with audit as the Comptroller and Auditor -General of India generally has in connection with the audit of Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Tribunal.

(4) The accounts of the Tribunal, as certified by the Comptroller and Auditor -General of India or any other person appointed by him in this behalf, together with the audit report thereon shall be forwarded annually to the State Government and that Government shall cause the same to be laid, as soon as may be after it is received, before the State Legislature.

48. Annual report of Tribunal :-

(1) The Tribunal shall prepare once every year in such form and at such time as may be notified, an annual report giving a summary of its activities during the previous year and copies of the report shall be forwarded to the State Government.

(2) A copy of the report received under sub-section (1) shall be laid, as soon as may be after it is received, before the State Legislature.

49. Budget of Tribunal :-

The Tribunal shall prepare, in such form and at such time in each financial year as may be notified, its budget for the next financial year, showing the estimated receipts and expenditure of that Tribunal and forward the same to the State Government.

50. Power of the Tribunal to make regulations :-

The Tribunal may, with the previous approval of the State Government, by notification, make regulations not inconsistent with this Act and the rules made thereunder to provide for all matters for which provision is necessary or expedient for the purpose of giving effect to the provisions of this Act.

51. Directions by State Government :-

(1) In the discharge of its functions, the Tribunal shall be guided by such directions in matters of policy involving public interest as the State Government may give to it in writing.

(2) If any question arises as to whether any such direction relates to a matter of policy involving public interest, the decision of the State Government thereon shall be final.

CHAPTER 6 Miscellaneous

52. Indemnity :-

(1) No suit, prosecution or other legal proceedings whatsoever shall lie against any authority or any officer authorized 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 the 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.

53. Credit of fees and fines :-

Any fees received or fines paid under this Act and rules framed thereunder shall be credited to the consolidated Fund of the State.

54. Power to give directions :-

Without prejudice to the foregoing provisions of this Act, the licensing authority 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.

55. Employees of the authority, etc., to be public servants :-

Every employee of the adjudicating authority, licensing authority and appellate authority including Tribunal 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, 1860.

56. Power to remove difficulties :-

(1) If any difficulty arises in giving effect to the provisions of this Act, the State Government may, by 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 it is made, be laid before the State Legislative Assembly.

57. Power of State Government to make rules :-

(1) The State Government may, by notification, make rules for carrying out all or any of the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:-

(a) the standards which an applicant and a clinical establishment shall fulfill for registration and license under sub-section (1) of section 7;

(b) the form in which a license shall be granted under sub-section (1) of section 7;

(c) the minimum standard of accommodation which shall be provided under clause (a) of sub-section (2) of section 7;

(d) the minimum number and norms in respect of health service providers and other persons under clause (b) of sub-section (2) of section 7;

(e) the minimum qualification in respect of health service providers and other persons under clause (b) of sub-section (2) of section 7;

(f) the minimum standard of services including emergency care, and referral services which are to be provided under clause (c) of sub-section (2) of section 7;

(g) the equipments and machineries which are to be provided under clause (d) of sub-section (2) of section 7;

(h) the arrangements for disposal of biomedical wastes which are to be provided under clause (e) of sub-section (2) of section 7;

(i) the records and registers, the format and the particulars which are to be maintained under clause (f) of sub-section (2) of section

7;

(j) any other terms and conditions subject to which the license shall be granted under clause (g) of sub-section (2) of section 7;

(k) the measures which shall be taken to keep the clinical establishment in the satisfactory sanitary and hygienic condition under clause (d) of subsection (3) of section 7;

(l) the conditions which are satisfactory sanitary and hygienic under clause (d) of sub-section (3) of section 7;

(m) the information which are to be displayed under clause (e) of sub-section (3) of section 7;

(n) the manner in which the information are to be displayed under clause (e) of sub-section (3) of section 7;

(o) the reports, their format, the particulars containing therein, and the necessary documents which are to be submitted under clause (f) of subsection (3) of section 7;

(p) the authorities to whom the reports are to be submitted under clause (f) of sub-section (3) of section 7;

(q) the interval at which the reports are to be submitted under clause (f) of sub-section (3) of section 7;

(r) the medical and other reports, records and documents which are to be made available under clause (g) of sub-section (3) of section 7;

(s) the grounds of discrimination and the diseases under clause (j) of subsection (3) of section 7;

(t) the emergency medical treatment, first-aid and critical care to be provided under clause (k) of sub-section (3) of section 7;

(u) any other terms and conditions subject to which the license shall be granted under clause (m) of sub-section (3) of section 7;

(v) the period for which registration and license shall be valid under subsection (4) of section 7;

(w) the circumstances in which the State Government may relax all or any of the terms and conditions under section 8;

(x) the form and particulars to be contained in the register to be maintained under sub-section (1) of section 9;

(y) the format and manner of supply to the State Registrar the entry made in the register of clinical establishments under sub-section (2) of section 9;

(z) the form and particulars to be contained in the register to be maintained under section 10;

(aa) the categories into which the clinical establishment shall be classified under sub-section (1) of section 11;

(ab) the different standards for classification of clinical establishments under sub-section (2) of section 11;

(ac) the proforma of application and the fee to be paid for registration and license under subsection (1) of section 12;

(ad) the particulars and the accompanied evidence under sub-

section (2) of section 12;

(ae) the criteria and time period to be followed before passing an order under section 13;

(af) the manner by which the copy of order to be sent to the applicant under section 13;

(ag) the fees to be paid by the clinical establishment to get a copy of license under section 17;

(ah) the enhanced fees to be charged for renewal after expiry of registration and license under sub-section (1) of section 19;

(ai) the terms and conditions for renewal after expiry of registration and license under sub-section (1) of section 19;

(aj) the period from the date of receipt of application under sub-section (2) of section 19;

(ak) the period to be mentioned in the order under sub-section (2) of section 21;

(al) the manner by which the copy of order to be served under clause (a) of sub-section (2) of section 22;

(am) the manner of seizure and period of retention under clause (b) of subsection (1) and the manner of entry and search under clause (c) of subsection (1) of section 24;

(an) the fees to be charged by the licensing authority for different categories of clinical establishments under section 25;

(ao) the terms and conditions for exemption of fees payable by any clinical establishment under proviso of section 25;

(ap) the authority to Act as Appellate authority under sub-section (1) of section 26;

(aq) the manner and the period within which an appeal may be preferred to the Appellate authority under sub-section (2) of section 26;

(ar) the form and the fees to be paid for an appeal under sub-section (2) of section 26;

(as) the meaning of minor and major deficiencies under section 29;

(at) the manner for adjudication under sub-section (1) of section 34;

(au) the manner of lodging appeal by anyone to the Tribunal under subsection (3) of section 40;

(av) any other matter in respect of powers of the Tribunal under clause (h) of sub-section (2) of section 41;

(aw) any other matter which is required to be or may be prescribed by the State Government.

(3) All rules made under this Act shall be laid for not less than fourteen days before the State Legislature as soon as possible after they are made and shall be subject to such modification as the State Legislature may make during the session in which they are so laid. Any modification of the said rules made by the State Legislature shall be published in the Official Gazette, and shall, unless some later date is appointed by the State Government, come into force on the date of such publication.

58. Effect of Act on other laws :-

The provisions of this act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force and to extent of such inconsistency that other law shall be deemed to have no effect.

59. Repeal and Savings :-

(1) The West Bengal Clinical Establishments Act, 1950 is hereby repealed.

(2) Notwithstanding such repeal, anything done, including any rule, notification, inspection, order or notice made or issued or any license, permission, authorization or exemption granted or any document or instrument executed or any direction given under the repealed Act shall, insofar as it is not inconsistent with the provisions of this Act, be deemed to have been done or taken under the corresponding provisions of this Act.

(3) Notwithstanding anything contained in this Act, any proceeding pending in any court at the commencement of this Act may be continued in that court as if this Act has not been passed.

(4) Notwithstanding anything contained in sub-section (2), the clinical establishment for which license was granted before the commencement of this Act shall be governed by the provisions of repealed Act till the expiry of the terms of existing license.