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**GOVERNMENT OF ASSAM
HEALTH & FAMILY WELFARE DEPARTMENT
DISPUR ::: GUWAHATI - 6**

**ORDERS BY THE GOVERNOR
NOTIFICATION**

Dated, Dispur the 3rd November, 2016

No. HLA. 1652/2003/Pt-IV/540 : In exercise of the power conferred by section 8 of the Clinical Establishment (Registration and Regulation) Act, 2010 (Central Act No. 23 of 2010), the State Government hereby constitutes the Assam State Council for Clinical Establishments consisting of the following, namely:-

- | | | | |
|-----|--|---|-------------------|
| 1. | Senior most Secretary, Health & Family Welfare Department | - | Chairman |
| 2. | Director of Health Services, Assam | - | Member- Secretary |
| 5. | Director of AYUSH, Assam | - | Member |
| 7. | One representative each to be elected by the Executive Committee of: | | |
| | i) Assam Medical Council | - | Member |
| | ii) Assam State Dental Council | - | Member |
| | iii) Assam Nurses Midwives' & Health Visitors' Council | - | Member |
| | iv) Assam Pharmacy Council | - | Member |
| 8. | One representative each to be elected by the Executive Committee of Assam State Council of Indian Medicine representing following systems of medicine: | | |
| | i) Ayurveda | - | Member |
| | ii) Sidha | - | Member |
| | iii) Unani | - | Member |
| 9. | One representative to be elected by the State Council of the Indian Medical Association | - | Member |
| 10. | One representative from the line of paramedical systems nominated by the State Government | - | Member |
| 11. | Two representatives from State level consumer groups or reputed non-Government organisations working in field of health nominated by the State Government. | - | Members |

Note:

1. The nominated member of the State Council shall hold office for a term of three years, but shall be eligible for re-nomination for maximum of one more term of three years.
2. The elected member of the State Council shall hold office for three years but shall be eligible for re-election.

Provided that the person nominated or elected, as the case may be, shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the State Council.

The State Council shall perform the following functions, namely:-

- a) compiling and updating the State Registers of clinical establishment;
- b) sending monthly returns for updating the National Register;
- c) representing the State in the National Council;
- d) hearing of appeals against the orders of the authority; and
- e) publication on annual basis a report on the State of implementation of standards within the State.



(Samir K. Sinha, IAS)

Commissioner & Secretary to the Govt. of Assam
Health & Family Welfare Department

Memo No. HLA. 1652/2003/Pt-IV/540 -A

Dated Dispur

3rd November, 2016

Copy to :

1. The Secretary, Legislative Department, Dispur

2. The Secretary, Judicial Department and Legal Remembrancer, Assam.
3. The Secretary, Health & Family Welfare Department.
4. All Deputy Commissioners/ Sub-Divisional Officers.
5. All Principal Secretaries of the Autonomous Councils, Assam
6. Commissioner of Police, Guwahati/ All Superintendents of Police.
7. The Mission Director, National Health Mission, Assam.
8. The Director of Medical Education, Assam for necessary action.
9. The Director of Health Services, Assam for necessary action.
10. The Director of Health Services (Family Welfare), Assam
11. The Director of AYUSH, Assam
12. The Project Director, Assam State Aids Control Society.
13. Additional Deputy Director General, Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services, Room No. 560 A, Nirman Bhawan, New Delhi-110108.
14. The P.S. to Hon'ble Minister, Health & Family Welfare, Assam.
15. The P.S. to Chief Secretary, Assam.
16. The P.S. to Director General of Police, Assam
17. All Joint Director of Health Services, Assam for necessary action.
18. Managing Directors/ Directors/ Medical Superintendents/ Hospital (I/C) etc. of all Hospitals (including private) in the State of Assam.
19. Member concerned.
20. Any other concerned.
21. Guard File.

By order etc.,

Deputy Secretary to the Government of Assam
Health & Family Welfare Department

Note:

1. Designated member of the State Council shall hold office for a term of three years but shall be eligible for re-nomination for a maximum of two more terms of three years.
2. The elected member of the State Council shall hold office for three years but shall be eligible for re-nomination.

Provided that the person nominated or elected as the member shall hold office for so long as he/she continues to be a member of the office or, in case of election, he/she continues to be a member of the State Council.

The State Council shall perform the following functions:-

- (a) preparing and updating the State Register of clinical establishments;
- (b) sending monthly returns to update the National Register;
- (c) representing the State in the National Council;
- (d) issuing of orders against the orders of the authority; and
- (e) submission of annual report on the State to the Government of Assam.

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GOVERNMENT OF ASSAM
HEALTH & FAMILY WELFARE DEPARTMENT
DISPUR ::: GUWAHATI - 6

ORDERS BY THE GOVERNOR
NOTIFICATION

Dated, Dispur the 3rd November, 2016

No. HLA. 1652/2003/Pt-IV/542: In exercise of the power conferred by section 10 of the Clinical Establishment (Registration and Regulation) Act, 2010 (Central Act No. 23 of 2010), the State Government hereby constitutes the District Registering Authority for each district consisting of the following members, nameily:-

- Deputy Commissioner (District Magistrate) - Chairperson
- Joint Director of Health Services (District Health Officer) - Convenor
- Commissioner of Police/ Superintendent of Police or his nominee not below rank of Deputy Superintendent of Police. - Member
- Senior level officer of Local Self Government to be nominated by the Deputy Commissioner. - Member
- One representative from a professional medical association or body having presence preferably in the district or within the State, as the case may be, to be nominated by the Deputy Commissioner, for a tenure of two years. - Member

(Samir K. Sinha, IAS)
Commissioner & Secretary to the Govt. of Assam
Health & Family Welfare Department

No. HLA. 1652/2003/Pt-IV/542 -A

Dated Dispur 3rd November, 2016

Copy to:

1. The Secretary, Legislative Department, Dispur
2. The Secretary, Judicial Department and Legal Remembrancer, Assam.
3. The Secretary, Health & Family Welfare Department.
4. All Deputy Commissioners/ Sub-Divisional Officers.
5. All Principal Secretaries of the Autonomous Councils, Assam
6. Commissioner of Police, Guwahati/ All Superintendents of Police.
7. The Mission Director, National Health Mission, Assam.
8. The Director of Medical Education, Assam for necessary action.
9. The Director of Health Services, Assam for necessary action.
10. The Director of Health Services (Family Welfare), Assam
11. The Director of AYUSH, Assam
12. The Project Director, Assam State Aids Control Society.
13. Additional Deputy Director General, Government of India, Ministry of Health and Family Welfare, Directorate General of Health Services, Room No. 560 A, Nirman Bhawan, New Delhi-110108.
14. The P.S. to Hon'ble Minister, Health & Family Welfare, Assam.
15. The P.S. to Chief Secretary, Assam.
16. The P.S. to Director General of Police, Assam
17. All Joint Director of Health Services, Assam for necessary action.

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- 18. Managing Directors/ Directors/ Medical Superintendents/ Hospital (I/C) etc. of all Hospitals (including private) in the State of Assam
- 19. Member concerned.
- 20. Any other concerned.
- 21. Guard File.

ORDER BY THE GOVERNOR
ASSAM

By order etc.,

Deputy Secretary to the Government of Assam
Health & Family Welfare Department

1. Deputy Commissioner of District Headquarters

2. Joint Director of Health Services (Medical) H&FW Deptt.

3. Joint Director of Police Superintendent of Police

4. Joint Director of Local Self Government

5. Representative from a professional medical body having experience preferably in the State of Assam, as the candidate may be selected by the Deputy Commissioner.

(Signed) K. Deka (AE)

Commissioner & Secretary to the Govt. of Assam
Health & Family Welfare Department

Date: 27 November 2010

- 1. The Secretary, Law & Legal Services Deptt.
- 2. The Secretary, Judicial Department and Legal Services, Assam
- 3. The Secretary, Health & Family Welfare Department
- 4. The Joint Director, Health & Family Welfare Department
- 5. All Principals, Superintendents of the AC-Community Clinics, Assam
- 6. The Joint Director of Police, Government of Assam
- 7. The Joint Director, National Health Service, Assam
- 8. The Director of Medical Education, Assam for necessary action
- 9. The Director of Health Services, Assam for necessary action
- 10. The Director of Health Services (Family Welfare), Assam
- 11. The Director of AC, Assam
- 12. The Joint Director, Assam State Health Control Society



THE ASSAM GAZETTE

অসাধাৰণ

EXTRAORDINARY

প্ৰাপ্ত কৰ্তৃত্বৰ দ্বাৰা প্ৰকাশিত

PUBLISHED BY THE AUTHORITY

নং 328 দিশপুৰ, মঙ্গলবাৰ, 18 অক্টোবৰ, 2016, 26 আহিন, 1938 (শক)

No. 328 Dispur, Tuesday, 18th October, 2016, 26th Asvina, 1938 (S.E.)

GOVERNMENT OF ASSAM

ORDERS BY THE GOVERNOR

HEALTH AND FAMILY WELFARE DEPARTMENT

NOTIFICATION

The 14th October, 2016

No. HLA.1652/2003/Pt.-IV/468.- In exercise of the powers conferred under section 54 of the Clinical Establishment (Registration and Regulation) Act, 2010 (No. 23 of 2010), the Governor of Assam is hereby pleased to make the following rules for regulating and registration of the clinical establishments to provide better medical and health care to the people of Assam, namely:-

1. Short title, extent and commencement. —

- (1) These rules may be called the Assam Clinical Establishments (Registration and Regulation) Rules, 2016.
- (2) They shall extend to the whole of the State of Assam State, and are applicable to all the Clinical Establishments in the State.
- (3) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions. —

In these rules, unless the context otherwise requires, —

- (a) "Act" means the Clinical Establishments (Registration and Regulation) Act 2010 (No. 23 of 2010);
- (b) "Rules" means the Assam Clinical Establishments (Registration and Regulation) Rules, 2016;
- (c) "State Council" means the Assam State Council for Clinical Establishments constituted under section 8 of the Act;
- (d) The words and expressions used herein and not defined, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. Conduct of Business. —

Every meeting of the State Council shall be presided over by the Chairperson.

(1) Time and place for meeting of the Assam State Council —

The meetings of the State Council shall ordinarily be held at Dispur at such dates as may be fixed by the Council. The Council shall meet at least once in three months.

(2) Notice of Meeting —

Notice of every meeting other than a special meeting called shall be issued by the Member Secretary to each member of the State Council not less than a week before the date of the meeting.

(3) Quorum, Call for Meeting, Minutes —

(a) One-third of the total number of members of the State Council shall form a quorum, and all actions of the State Council shall be decided by a majority of the members present and voting. The notice and agenda of every such meeting of the State Council shall ordinarily be given 7/10 days before the meeting by the Member Secretary of the State Council. The in-charge Joint / Deputy Secretary will be the ex-officio Member Secretary of the State Council.

(b) A copy the minutes of each meeting of the State Council shall be submitted to the Chairperson within 7 days of the meeting and after having been approved by him / her shall be sent to each member of the State Council within 15 days of the meeting. If no objection to their correctness is received within 10 days of their dispatch, any decisions therein shall be given effect to:

Provided that the Chairperson may, where in his opinion, it is necessary or expedient so to do, direct that action be taken on the decision taken in the meeting.

(c) The proceedings of the meetings of the State Council shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson.

(4) Resignation and filling of casual vacancies —

A member desiring to resign his / her seat on the Council shall send his resignation in writing to the Chairperson and every such resignation shall take effect from the date mentioned by him in this behalf or in case no such date is mentioned, from the date of the receipt of his / her letter by the Chairperson after confirmation from the member concerned about his / her resignation.

When a casual vacancy occurs by reason of death, resignation or otherwise of a member, a report shall be made forthwith by the Chairperson to the State Government, which shall take steps to have the vacancy filled by nomination or election, as the case may be.

(5) Finance and Accounts

The accounts of the State Council shall be audited annually by a Chartered Accountant, who is to be appointed from a panel approved by the Comptroller and Auditor General of India. Any expenditure incurred in connection with such audit shall be payable by the State Council.

4. Other Powers of the District Authority to be exercise by the District Health Officer under section 10(2) of the Act. —

(1) The district authority shall for the purposes of discharging its functions under the Act, have the same powers that 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 document;
- (f) Reviewing its decisions, directions or orders;
- (g) Dismissing an application for default or deciding it ex parte;
- (h) Any other matter which may be necessary.

(2) Time, Place and Preparation of Business for Meeting of the District Registering Authority —

The meeting of the District Registering Authority shall be held at least once in a month at stipulated date and time.

(3) Conduct of Business —

Every meeting of the District Registering Authority shall be presided over by the Chairperson. Additional Chief Medical Officer of the District shall be the Member Secretary of the District Registering Authority.

(4) Notice of Meeting —

Notice of every meeting other than a special meeting shall be issued by the Convener to each member not less than one week before the date of the meeting.

(5) Quorum, Minutes —

(a) One-third of the total number of the members of the District Registering Authority shall form a quorum and all action of the Authority shall be decided by a majority of the members present and voting.

(b) The proceedings of the meetings of the District Registering Authority shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson.

(c) A copy of the minutes of each meeting of the District Registering Authority shall be submitted to the Chairperson by the Member Secretary within 5-7 days of the meeting and after having been attested by him shall be sent to each member of the Council within 15 days of the meeting. If no objection to their correctness is received within 10 days of their dispatch, any decisions therein shall be given effect to, provided that the Chairperson may, where in his opinion it is necessary or expedient so to do, direct that action be taken on the decision taken in the meeting.

5. Registration of Clinical Establishments.

(1) Application for Registration:

The applicant shall apply to the District Registering Authority for provisional registration, either in person, or by post, or through web based online facility with the necessary information in a format as per **Form-I** under section 14 (1) and 14 (3) of the Act.

(2) The applicant shall apply to the District Registering Authority for permanent registration, in person, or by post or through web based online facility with the necessary information as per **Form-I** and with evidence of having met the requirements of minimum standards and personnel for different categories of Clinical Establishments in a format that shall be prescribed by the National Council under section 24 and 25 of the Act.

Category	Description of the Clinical Establishment
Out Patient Care	
1.	Clinic / Consultation Rooms (Solo Practitioners)
2.	Poly Clinic (Group of Practitioners)
In Patient Care	
3.	1 to 30 Beds Hospital / Nursing Home / Palliative Care Unit
4.	Hospital / Nursing Home / Palliative Care Unit 31 to 100 beds
5.	Hospital / Nursing Home / Palliative Care Unit above 100 beds
Testing & Diagnostic Laboratories / Diagnostic & Imaging Centres	
6.	Diagnostic Laboratories
7.	Diagnostic and / or Imaging Centres (CT, USG, MRI, ECHO etc.)
8.	Physiotherapy Units

***If a laboratory or diagnostic center is a part of an establishment providing out-patient /in-patient care, no separate registration is required. USG/ mapping centers are also to be registered under PCPNDT Act.**

(3) If an establishment is offering services in more than one category as specified under these rules, the establishment will need to apply for a separate provisional or permanent registration for each category of establishment under Section 14 (1) and Section 30 of the Act. However, if a laboratory or diagnostic center is a part of an establishment providing outpatient / inpatient care, no separate registration will be required.

6. Acknowledgement of Application. —

The Registration Authority, or any person in his office authorized in this behalf, shall, acknowledge the receipt of the application for registration, in the acknowledgement slip provided as per **Form II** immediately, if delivered at the office of the authority, or not later than the next working day, if received by post and by online, the acknowledgement in such case is to be generated automatically through the online system.

7. Grant of Provisional Registration. —

The authority shall not undertake any enquiry prior to the grant of provisional registration and shall within a period of **ten days** from the date of receipt of such application, grant to the applicant a Certificate of Provisional registration containing particulars and information either by post or electronically as per **Form-III** as per provision of section 15.

8. Displaying of Provisional Certificate of Registration. —

The Provisional certificate of registration of the clinical establishment shall be displayed prominently at the reception / entrance of the establishment as per provision of section 18 of the Act.

9. Certificate of Permanent registration. —

(1) Under Section 24 and section 30, the clinical establishment shall issue a Certificate of Permanent Registration as provided in Form-IV.

(2) In case of permanent registration, under section 29 of the Act, the authority shall pass order after the expiry of a period of 2 months.

10. Fees to be charged. —

(1) The various fees charged for provisional and permanent registration, renewal, late application, duplicate certificate, change of ownership, management or name of establishment is prescribed in Annexure I as per provision of Section 14 (1), section 19, section 20 (2), section 22; section 24, section 35 of the Act :

Provided that the Clinical establishments owned, controlled and managed by the government (central, State or local authority) or department of Government, shall be exempted from payment of fees for registration.

(2) The fees prescribed for various categories of clinical establishments may be revised by the State Council through a notification issued by the State Government.

(3) The fee shall be paid by a demand draft drawn/online transaction in favour of the Registration Authority concerned as specified under section 14 (1) and section 30 of the Act.

(4) The fees collected by the Authorities for registration of the Clinical Establishments shall be deposited by the Authority concerned in a Nationalized scheduled bank account opened in the name of the official designation of the Registration Authority concerned and shall be utilized by the Authority for the activities connected like payment of honorarium to the non-government member viz; Rs.1000/- to State Council Member and Rs.500/- to District Registering Authority member and other activities concerned with the implementation of the provisions of the Act and these rules as approved by the District Registration Authority.

11. Manner of Publishing of particulars of Clinical Establishment and after provisional registration. —

(1) The District Registering Authority shall publish in the public domain either through two local newspapers or any other public forums and on the website, which the District Registering Authority will launch, the name of the Clinical Establishment, its Address, ownership, name of person in charge, system of medicine offered, type and nature of services offered and details of the medical staff (Doctors, Nurses, etc.) as required under Section 16 (2) of the Act.

(2) The District Registering Authority shall within a period of 7 days cause to be published in the public domain either through two local newspapers or any other public forums and on the website, which the District Registering Authority will launch, the name of the clinical establishment, address, ownership, name of person in Charge, system of medicine offered, type and nature of services offered, details of the medical staff (Doctors, Nurses, etc.) and the details and information in relation of compliance of prescribed minimum standards for the particular category of the Clinical Establishment as per provision of section 26 of the Act.

12. Ownership change, or loss of certificate. —

In the event of any change of ownership of management, the clinical establishment shall intimate to the District Registration in writing within one month of such change along with the fee prescribed in Annexure I for issue of a revised certificate of Provisional or Permanent registration, as the case maybe, incorporating the changes and on surrendering the old certificate under section 20 (2) of the Act.

13. The Authority shall publish the name of the clinical establishment whose registration has been expired under section 21 of the Act in the public domain either through two local newspapers or any other public forums and on the Website of the District registration authority within 15 (fifteen) days of such expiry.**14. Renewal fee for Registration after stipulated time. —**

- (1) The application for renewal if is not submitted within the stipulated period, the authority shall allow for renewal of registration on payment of the renewal amount as prescribed in Annexure I with a penalty of Rs. 100 per day till the date of application for renewal is accepted by the Authority as under section 22 of the Act.

15. Registers to be maintained for furnishing of returns and display of information. —

- (1) Every District Registration 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 containing particulars as developed by National Council under section 37 and 38 of the Act.
- (2) Every District Registration Authority including any other authority set up for the registration of clinical establishments under the 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 District Register of Clinical Establishments for a particular month by the 15th day of the following month in keeping with Section 37 (2) of the Act.
- (3) The District Registration Authority shall cause to be displayed the above information in public domain for a period of 30 days for filing objections before granting permanent registration as per Annexure II under section 26 of the Act.

16. The manner of submitting evidence of Clinical Establishment for compliance of minimum standard under section 25 of the Act . —

- (1) The Clinical Establishments shall submit to the authority evidence for compliance of minimum medical standards in the form of maintenance of medical records of patients treated by it and the records of health information and statistics in respect of national programs and furnish the same to the district authorities in form of three monthly reports. The minimum medical records to be maintained and nature of information to be provided by the Clinical Establishments will be as per the formats developed by the National Council as at Annexure IV under Section 25 of the Act.
- (2) Copies of all records and statistics shall be kept with the Clinical Establishments concerned for at least 3 years or in accordance with any other relevant Act in force at the time under Section 12 (1) (iii) of the Act. All Clinical Establishments shall be responsible for submission of information and statistics in the time of emergency or disaster or epidemic situation.
- (3) The Government may notify from time to time, the nature of information that needs to be furnished by the Clinical Establishments including other disease notified for this purpose along with the prescribed interval.

- (4) In addition to the specific provisions of the Clinical Establishments (Registration & Regulation) Act 2010, all Clinical Establishments shall comply and maintain information and statistics in keeping with other applicable Acts and Rules which are in force in the country.
- (5) The Clinical Establishments shall display the rates charged for each type of service provided by them, for the benefit of the patients at the reception counter both in the relevant vernacular (Assamese / Bengali / Bodo) and English. The list of services provided along with the rates charged shall be sent to the Registering Authority by 1st June of every year for record.
- (6) The details of services and rates shall be explained to the patients or their attendants at the time of admission without any ambiguity.
- (7) The Clinical Establishments shall indicate the name, qualification and registration number allotted to doctors by the State Medical Council / Medical Council of India in all the prescriptions and certificates given to the patients.
- (8) Every doctor shall display the registration number allotted to him / her by the State Medical Council / Medical Council of India in clinic and in all prescriptions, certificates, money receipts etc., given to the patients.

17. Manner of entering and search of premises of clinical establishment for inspection. —

- (1) A District Registering Authority or a team of officers duly authorized by it or subject to such general or special orders as may be made by the authority under section 33 and 34 of the Act can enter into a Clinical Establishment.
- (2) The District Authority shall search the clinical establishments for enquiring whether the Clinical Establishment is carrying the establishment without registration or contravene any of the provisions or rule and inspect any record, register, document, equipment and articles as deemed necessary under the provisions of section 33 and 34 of the Act.
- (3) The inspection team shall intimate the establishment in writing about the date of visit and reasons for the inspection. The team shall examine all portions of the premises used or proposed to be used for the clinical establishment and inspect the equipments, furniture and other accessories and enquire into the professional qualifications of the technical staff employed or to be employed and shall make any such other enquiries as they consider necessary to verify the statements regarding the application for registration and grant of license. All persons connected with the running of the establishment shall be bound to supply full and correct information to the inspection team.
- (4) The officer and / or inspection team so constituted by the Registering Authority shall submit a report as per Annexure III within a week of the inspection to the District Registration Authority with a copy to the State Council as per provision under section 33 of the Act.

18. Appeals .—

- (1) Any person or clinical establishment, if aggrieved by the decision of the Authority under section 31, section 41(7) and section 42(6) of the Act, may file an appeal in the Form V to the State Council.
- (2) The appeal shall be sent to the State Council by registered post or in person.
- (3) Every appeal shall be accompanied by a fee of rupees Two thousand under section 32 of the Act.
- (4) The State Council may entertain the appeal after the expiry of 20 days if they feel the applicant has sufficient cause for appeal under section 36(1) of the Act.

- (5) After receipt of the appeal, the State Council shall fix the time and date for meeting and inform the same to the appellant and others concerned by a registered letter given at least 15 days time for hearing of the case.
- (6) The appellant may represent by himself or authorized person or a Legal practitioner and submit the relevant documentary material if any in support of the appeal.
- (7) The State Council shall hear all the concerned, receive the relevant oral / documentary evidence submitted by them, consider the appeal and communicate its decision preferably within 90 days from the date of filling the Appeal.
- (8) If the State Council considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal. The state council will have the authority to stay the operation of the order of the district authority till such time as it deems necessary. The decisions of State Council shall be final and binding.
- (9) If no appeal is filed against the decision of the Registering Authority in the prescribed period (i.e.,) within 30 days from the date of receipt of the order, the orders of the Authority shall be final.
- (10) The appeal fees collected by the authorities shall be deposited by the Authority concerned in a Nationalized bank account opened in the name of the official designation of the State Council concerned and shall be utilized by the Council and authority for the activities connected with the implementation of the provisions of the Act as approved by the Council.

19. Penalties. —

- (1) Under the provisions of Sections 41 (1) (2) (3) and Section 42 (1) (2) (3) the Act, whoever carries on a clinical establishment without registration or whoever willfully disobeys any direction, or obstructs any person or authority or withholds any such information or provides false information shall be liable for a monetary penalty.
- (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 twenty five thousand rupees.
- (3) The penalty fees collected by the authorities shall be deposited by the Authority concerned in a Nationalized bank account opened in the name of the official designation of the State Council concerned and shall be utilized by the Council and authority for the activities connected with the implementation of provisions of the Act and as approved by the Council.

20. Interpretation of the Rules. —

If there is any doubt or dispute regarding the application or the interpretation of the Rules, the decision of the State Government thereon shall be final.

21. Uploading on website. —

The District Registering Authority will upload the information about provisional registration, inspection report and permanent registration on the website to be developed by the State Council.

**APPLICATION FORM FOR PROVISIONAL / PERMANENT REGISTRATION OF
CLINICAL ESTABLISHMENT**

Form - I

(See rule 5 (1) (2), section - 10, 14, 24, 25 of the Act)

Name of the Clinical Establishment / Doctor (in case of single practitioner) _____

1. Address: _____

Village / Town / City: _____ Block : _____

District: _____ State : _____ Pin code _____

Tel No. (With STD Code): _____ Mobile : _____ Email _____

Website (if any): _____

2. Name of the owner: _____

Address: _____

Village / Town / City: _____ Block : _____

District: _____ State : _____ Pin code _____

Tel No. (With STD Code): _____ Mobile : _____ Email _____

3. Name of the person in charge: _____

Qualification (S): _____

Registration Number : _____

Name of Central/ State Council (with which registered) : _____

Tel No. (With STD Code) : _____ Mobile : _____ Email _____

4. Ownership

a) Government / Public Sector: Central Government State Government Local

Government Sector Undertaking Any other (Please specify) : _____

b) Private Sector : Individual Proprietorship Registered Partnership Registered

Company Co-Operative Society Trust / Charitable Any other (Please specify): _____

5. System of Medicine: (please tick whichever is applicable)

Allopathy Ayurveda Unani Siddha Homoeopathy Yoga Naturopathy

6. Type of Establishment: (please tick whichever is applicable)**Providing Out Patient Care**

- Single practitioner Polyclinic Sub-Centre Physiotherapy Clinic
 Occupational Therapy Infertility Dental clinic
 Dispensary Dialysis Centre
 Integrated Counseling and Testing Centre (ICTC) Wellness/fitness centre
 Any other (please specify): _____

Providing In Patient Care

- Hospital Nursing Home Maternity Home Primary Health Centre
 Community Health Centre Sanatorium
 Any other (please specify):^A _____

Providing Testing & Diagnostic Services:**Laboratory**

- Pathology Haematology Biochemistry Microbiology Genetics Collection Centre
 Any other (please specify): _____

Diagnostic and Imaging Centre

- X Ray centre Mammography Bone Densitometry Sonography
 Color Doppler CT Scan Magnetic Resonance Imaging (MRI)
 Positron Emission Tomography (PET) Scan
 Electro Myo Graphy (EMG)
 Any other (please specify): _____

Any other (please specify): _____

7. Nature of Services (please tick whichever is applicable)**For all Systems of Medicine**

- General Single Specialty Multi Specialty Super Specialty Mobile
 Any other, please specify: _____

a) Allopathy

- General Practice Out-patient In-patient Day care centre
 Emergency / Casualty ICU ICCU
 Special Care Services for challenged persons Blood Bank
 Organ /Tissue Bank
 Any other please specify: _____

b) Ayurveda

- Ausadh Chikitsa Shalya Chikitsa Shodhan Chikitsa Rasayana Pathya Vyavastha
 Any other please specify: _____

c) Unani

- Matab Jarahat Ilaj-bit-Tadbeer Hifzan-e-Sehat
 Any other please specify: _____

d) Siddha

- Maruthuvam Sirappu Maruthuvam Varmam Thokknam & Yoga
 Any other please specify:.....

e) Homeopathy

- General Homeopathy
- Any other please specify: _____

f) Naturopathy

- External Therapies with natural modalities
- Internal Therapies
- Any other please specify: _____

g) Yoga please specify: _____

INFRASTRUCTURE DETAILS

8. Area of the establishment (in sq. meters):

a) Total Area: _____ b) Constructed area: _____

9. Out Patient Department:

9.1 Total no. of OPD Clinics: _____

9.2 Specialty-wise distribution of OPD Clinic

S.No.	Specialty	No. of Rooms

10. In Patient Department:

10.1 Total number of beds:

10.2 Specialty-wise distribution of beds, please specify:

S.No.	Specialty	No. of Beds

11. Whether Clinical Waste Disposal License obtained from Panchayat/Municipality/Municipal Corporation etc?

- Yes
- No
- Applied For

12. Whether clearance from Pollution Control Board/Authority obtained?

- Yes
- No
- Applied For

HUMAN RESOURCES**13. Total number of Staff (as on date of application):**

No. of permanent staff: _____ No. of temporary staff: _____

Please furnish the following details:-

Category of staff	Name	Qualification	Registration Number (where applicable)	Nature of service Temporary/ Permanent
Doctors				
Nursing staff				
Para-medical staff				
Pharmacists				
Support staff				
Others, please specify				*

Separate annexure may be attached.*

14. Payment options for Registration Fees:
 Online payment Demand Draft Postal Order

 Any other (please specify): _____

Amount (in Rs): _____

Details: _____

Receipt No. _____

I, on behalf of myself and the company/society/association/body hereby declare that the statements above are correct and true to the best my knowledge and I shall abide by all the rules and declarations under the Clinical Establishment (Registration and Regulation) Act 2010.

I undertake that I shall intimate to the appropriate registering authority any change in the particulars given above.

Place:

Date:

 Signature of the Authorized Signatory
 Office Seal

Form - II

[See rule 6]

ACKNOWLEDGEMENT

REGISTRATION OF CLINICAL ESTABLISHMENT

The application in Form _____ for Grant / Renewal of Provisional/ Permanent registration of the Clinical Establishment submitted by _____ (Name and address of owner) has been received by the District Registration Authority on _____ (date) and found to be

Complete

Or

Incomplete

This acknowledgement does not confer any rights on the applicant for grant of renewal of registration.

Signature and Designation of Registration Authority or authorized person in the office the Appropriate Authority.

SEAL

Designation of the Issuing Authority

Place & Date

FORM - III

[See rule 7 Section 15, 17, 54 (2) (c) of the Act]

**PROVISIONAL CERTIFICATE
FOR REGISTRATION OF CLINICAL ESTABLISHMENT**

Provisional registration No.:

Date of Issue:

Valid up to:

1. Name of the Clinical Establishment : _____
2. Address : _____

3. Owner of the Clinical Establishment : _____
4. Name of Person in charge : _____
5. System of Medicine : _____
6. Type of Establishment : _____

Is hereby provisionally registered under the provisions of Clinical Establishments (Registration and Regulation) Act 2010 and the Assam Clinical Establishments (Registration and Regulation) Rules 2016 made there under.

This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act 2010 and the Assam Clinical Establishments (Registration and Regulation) Rules 2016 made there under

Designation of the Issuing Authority

Place & Date

District Registration Authority.

Address :

Phone number in case of Grievances.

FORM - IV

PERMANENT CERTIFICATE

FOR REGISTRATION OF CLINICAL ESTABLISHMENT

(under Rule 9, Sec 24, 30 of the Act)

Permanent Registration No.:

Date of Issue:

Valid up to:

1. Name of the Clinical Establishment : _____
2. Address : _____

3. Owner of the Clinical Establishment : _____
4. Name of Person in-charge : _____
5. System of Medicine : _____
6. Type of Establishment : _____

Is hereby permanently registered under the provisions of Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under.

This authorization is subject to the conditions as specified in the rules in force under the Clinical Establishments (Registration and Regulation) Act, 2010 and the Rules made there under

Place and Date

Designation of the Issuing Authority

District Registration Authority.

Address :

Application Document 2010-11

Phone number in case of Grievances.

FORM - V

[See Rule 18, 36(2), Section 54(n) (q) (v) of the Act]

Application for Appeal

To
The State Council
Government of

Sir,
I, Dr. of
had applied for registration / is a valid license holder with registration number
..... under clinical establishment act 2010 for my
..... located at I
was communicated by the district authority as per letter no
Date that either.

- 1) That my application was rejected.
- 2) That my registration is cancelled.
- 3) That I am restrained from carrying on with the running of clinical establishment.
- 4) That I am charge with a penalty for an offence under the act.
- 5) Any other

The above decision of the district authority appears to be not valid. I request you to consider my application as per the justifications mentioned below.

- i)
- ii)
- iii)

I am willing to appear before you for a personal hearing, if necessary. I am enclosing herewith a draft of Rs. 1000/-

Thanking you.

Place:
Date:

Signature
Name:

Annexure – I**FEES TO BE CHARGED**

[See Rules 10, Section 14, 19, 20 (2), 22, 24, 35, 54 (2a) (e) (h) (i) (p) (r) of the Act.]

Description	Urban		Rural		Metro	
	Provisional	Permanent	Provisional	Permanent	Provisional	Permanent
Out Patient Care/ Single doctor Clinic	500	1000	100	500	1500	3000
In patient care 1 to 30 beds	1000	3000	1000	2000	3000	5000
30 to 100 beds Above 100 beds	2000	5000	1000	5000	5000	10000
	3000	10000	2000	7000	5000	20000
Testing & Diagnostic Centre	500	3000	500	2000	1000	5000
Diagnostic with Imaging Centre	1000	5000	1000	2000	3000	10000

Other Fees

- For Renewal half the amount of registration fee (Provisional/ Permanent)
- For Late Application the amount would be double of the registration fee (Provisional/ Permanent)
- For Duplicate Certificate the amount would be Rs. 500/-
- On change of ownership, management or name of establishment would be Rs. 100/-
- For an appeal the amount would be Rs. 2000.

If a laboratory or diagnostic centre is a part of an establishment providing outpatient / Inpatient care no separate registration is required.

Annexure – II[See Rules 15. (3), Section 26, 54 (k) of the Act.]

Display of registration status for filing objection.

I, being the authority under the Clinical Establishments Act, 2010 after considering the applications received during the period; from to Under Sec. 24 satisfying the provisions of the clinical establishment act, 2010 and the Assam Clinical Establishments (Registration and Regulation) Rules 2016 made there under, hereby published the list of Clinical Establishments; within the jurisdiction of District.

Sl. No.	Name of Clinical Establishment with address.	Ownership / in charge	System of medicine	Date on which application was submitted	Category & standards complied with

Objections if any, in writing to the published list may be addressed in duplicate to (address of the authority) within 30 days, from the date of this notification, as required under S. 26 of the Act.

Place :

Signature:

Date :

(Seal of the authority)

Name :

Annexure – III

[See Rules 17, Section 33, 34, 54 (o) of the Act]

Suggested Format for submission of Inspection Report.

Number of visits made with dates :

Names and details of members of the inspection team :

Name of clinical establishment visited :

Address and contact details of clinical establishment visited :

Process followed for inspection (e.g. kindly outline who was met with, what records were examined, etc.)

Salient Observation / Finding :

Conclusion :

Specific Recommendation :

- 1) To the Clinical Establishment.
- 2) To the District Registering Authority.

➤ In case of lack of consensus amongst members of the inspection team, the same may be kindly indicated.

Signature (of all members of the Inspection team)

Date :

Place:

Annexure - IV**(Sec 45 of the Act.)****Information and Statistics to be collected from Clinical Establishments under the
Clinical Establishment Act.****A. General Information:**

Name of the Clinical Establishment _____

Registration Number of the Clinical Establishment _____

Address _____

Village / Town / City _____ Block _____

District _____ State _____ Pincode _____

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

Email ID _____ Website (if any): _____

Name of Contract person _____

Contract Details (Cell/ Landline/ email) _____

Clinical establishment Type :

 General practice Specialty practice Super-Specialty practice Psychiatric practice Obstetrics – Gynae Practice Pediatric practice**B. Category-wise Reporting forms for following categories (separate form for
each category to be filled up)**

General Hospitals

Stand Alone Super Specialty Hospital

Multiple Super Specialty Hospital

Stand Alone Specialty Hospital

Multiple Specialty Hospital

One Man Clinic

Polyclinic

Out Patient and In Patient information (as applicable)**I. General Information.**

S. No.	Description	Male	Female
1	Total OPD patients		
2	Total IPD Patients		
3	Total Deaths		
4	Number of Maternal Deaths		
5	Live Births		
6	Still Births		
7	No of Neonatal Deaths (within 24 hours of Birth) No. of Deaths of children (0 to 28 days) No of Deaths of children 0 to 1 year No of Deaths of children under 5 years of age		

II. Communicable Diseases:

S. No.	Disease	Old patient	New patient
1	Malaria		
2	Pulmonary Tuberculosis		
3	Dengue Hemorrhage fever		
4	Chikungunya		
5	Meningitis		
6	Typhoid		
7	Diphtheria		
8	Whooping cough		
9	Tetanus		
10	Measles		
11	Poliomyelitis		
12	Japanese Encephalitis		
13	Cholera		
14	Syphilis		
15	Gonorrhoea		
16	Leprosy (Multi bacillary)		
17	Leprosy (Pauci bacillary)		
18	Gastroenteritis		

19	Leptospirosis		
20	Hepatitis		
21	Conjunctivitis		
22	Trachoma		
23	Rabies		
24	Dog Bite (including Domestic / Wild animal)		
25	Snake Bite		

III. Non Communicable Diseases:

S. No.	Disease	Old patient	New patient
1	Diabetes* (moderate and above)		
2	Hypertension**		
3	Ischemic Heart Disease		
4	Mental Illness		
5	Osteoarthritis		
6	Stroke		

*** Criteria for diagnosing Diabetes**

Diagnosis	Fasting Glucose (mg/dl)	2-hour Post- Glucose Load (mg/dl)
Diabetes Mellitus	≥ 126	≥ 200
Impaired Glucose Tolerance	< 110	> 140 to < 200
Impaired Fasting Glucose	≥ 110 to < 126	

*WHO Definition 1999

****Hypertension**

Blood pressure record of $> 140/90$ mm Hg

v. **Specialty / Department wise Reports : Specific Information**

Name of Specialty	Name of Disease/ Procedure	No. of Cases
Ophthalmology	Cataract operations done	
	Glaucoma cases	
	Corneal Transplants done	
Mental Health	No. of Psychosis cases under treatment	
Gynae and Obstetrics	No. of deliveries conducted (including Caesarian deliveries)	
	No. of Still Births	
	No. of Maternal Deaths	
Neurology	No. of Stokes	
	Epilepsy	
CTVS		
Cardiology		
Gastroenterology	No. of Cirrhosis cases	
Trauma Hospital	No. of Major Head Injuries	
	Coma cases	
	No. of Brain Stem Death Certified	
Cancer Hospital	Type of Cancers	
Nephrology	Chronic Kidney Diseases (indicate Grade)	
	CRF	
	No. of Patients on Dialysis	

C. **Information to be collected from Diagnostic Medical Laboratory under Clinical Establishment Act.****Category of Laboratory:**

- General
- General with single specialty
- General with multi-specialty

1) No of tests performed in the following departments:

S. No.	Department	Tests Number
1	Hematology	
2	Biochemistry	
3	Immunology	
4	Serology	
5	Pathology	
6	Cytology & Histopathology	
7	Molecular Biology	
8	Virology	
9	Genetics	

2) Number of tests done and reported positive for the following communicable diseases:

S. No.	Department	Tests Number	Tests Number
1	HIV		
2	Tuberculosis		
3	Malaria faiciparum		
4	Dengue		
5	Chikungunya		
6	Japanese Encephalities		
7	Others		
(i)	HAV		
(ii)	HBV		
(iii)	HCV		
(iv)	HDV		
(v)	Malaria vivax		
(vi)	Leptospirosis		
(vii)	H ₁ N ₁ / Influenza		
(viii)	Meningococcal Meningitis		
(ix)	Shigella		
(x)	Typhoid		
(xi)	Paratyphoid A		
(xii)	Paratyphoid B		
(xiii)	Plague		
(xiv)	Cholera		
(xv)	Syphillis		
(xvi)	Gonorrhea		

SAMIR K. SINHA,

Commissioner & Secretary to the Government of Assam,
Health & Family Welfare Department.