GOVERNMENT OF INDIA
LAKSHADWEEP ADMINISTRATION
(DIRECTORATE OF HEALTH SERVICES)
KAVARATTI-682555


To,

The Director,
Printing and Stationary,
U.T.of Lakshadweep,
Kavaratti-682555.

Sub:- DHS- UT of Lakshadweep- Implementation of Clinical Establishment(Registration and Regulation) Act 2010- Notification –Regarding:-

Sir,

Notification dated 09.02.2017 regarding Clinical Establishment(Registration and Regulation) Act 2010 is enclosed for publishing in an extra ordinary Gazette.

Yours faithfully

Encl .As above.

(DR.K.SHAMSUDHEEN)
DIRECTOR HEALTH SERVICES

COPY TO.
1.THE CHAIRMAN AND MEMBER OF THE UT OF LAKSHADWEEP U. T COUNCIL CUM DISTRICT REGISTERING AUTHORITY.
2.THE CONVENOR AND MEMBERS OF THE LAKSHADWEEP DISTRICT REGISTRATION AUTORITY.
3.THE ADDITIONAL DEPUTY DIRECTOR GENERAL, GOI, MINISTRY OF HEALTH AND FAMILY WELFARE, DIRECTORATE GENERAL OF HEALTH SERVICES ROOM NO. 560 A NIRMAN BHAWAN, NEW DELHI-110108.
4.P.A TO ADMINISTRATOR
5. P.A TO SECRETARY (HEALTH).
6.DC/SDO/AO IN ALL ISLANDS
7. DHO, KAVARATTI/MEDICAL OFFICERS IN ALL ISLANDS.
The Lakshadweep Gazette
Government of India
EXTRAORDINARY

F.No. 39-1/2011-DHS Date: 02/2017

NOTIFICATION

In exercise of the powers conferred by Section 54 of The Clinical Establishments (Registration and Regulation) Act, 2010 of the Central Government, the Administrator of UT of Lakshadweep is pleased to make the following rules namely:

1. Short title and Commencement:
   (i) These rules may be called the UT of Lakshadweep Clinical Establishments (Registration and Regulation) Rules, 2016.
   (ii) These rules extend to the whole of the UT of Lakshadweep and are applicable to all the Clinical Establishments in the UT of Lakshadweep.
   (iii) These Rules shall come into force on the date of their publication in the Lakshadweep Official Gazette.
   (iv) The Rules shall be applicable to various categories of Clinical Establishments in a phased manner, as may be notified from time to time.

2. Definition:
   In this Act, unless the context otherwise requires:-
   (a) "Act" means the Clinical Establishments (Registration and Regulation) Act 2010.
   (b) "Rules" means the Clinical Establishments (Registration and Regulation) Rules, 2011.
   (c) "Authority" means the Lakshadweep district registering authority set up under section 10;
   (d) "Certificate" means certificate of registration issued under section 30;
   (e) "Clinical Establishment" means-
      (i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury deformity, abnormality or pregnancy in a recognized system of medicine established.

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(ii) a place established as an independent entity of part of an establishment referred to in sub-clause (i) in connection with the diagnosis or treatment of diseases where pathological, bacteriological genetic radiological chemical biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not,

And shall include a clinical establishment owned, controlled or managed by

1. the Government or a department of the Government;
2. a trust, whether public or private;
3. a corporation (including a society) registered under a Central, Provincial or UT Act, whether or not owned by the Government;
4. a local authority; and
5. a single doctor,

But does not include the clinical establishment owned controlled or managed by the Armed Forces constituted under the Army Act, 1950, the Air Force Act 1950 and the Navy Act 1957.

(f) "Emergency Medical Condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in-

1. placing the health of the individual or with respect to a pregnant women, the health of the woman or her unborn child, in serious jeopardy; or
2. serious impairment to bodily functions;
3. serious dysfunction of any organ or part of a body.

(g) "National Council" means the National Council for clinical establishments established under section 3;

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

(i) "Prescribed" means prescribed by rules made under this Act by the Central Government or as the case may be, the UT Administration;

(j) "Recognized" system of medicine "means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognized by the Central Government;

(k) "Register" means the register maintained by the authority, UT Administration and the Central Government under sections 37,38 and 39 respectively of this Act containing the number of clinical establishment registered;

(l) "Registration" means to register under section 11 and the expression registration
or registered shall be construed accordingly;

(m) "Schedule" means the Schedule appended to this Act;

(n) "Standards" means the conditions that the Central Government may prescribe under section 12 for the registration of clinical establishment;

(o) "UT Administration", in relation to a Union territory, means the Administrator thereof appointed under article 239 of the Constitution and

(p) "To stabilize (with its grammatical variations and cognate expressions)" means with respect to an emergency medical condition specified in clause (d) to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

3 Establishment of U.T Council for Clinical Establishments:

The UT Administration shall by notification constitute UT Council for Clinical Establishments.

The Institutional arrangements are under:

Chairman : Secretary (Health)
Member Secretary : Director of Health services
Members : 1) Four Elected representatives of Indian Medical Association (IMA)
           2) Two female elected members of reputed Health NGO

4 Functions of the UT Council:

1. The UT Council shall perform the following functions, namely:-
   (a) Compiling and updating the State Registers of clinical establishment;
   (b) Sending quarterly returns for updating the National Register (including in the digital format);
   (c) Representing the UT in the National Council;
   (d) Hearing of appeals against the orders of the authority;
   (e) Publication on annual basis, of a report on the state of implementation of standards in the UT;
Monitor the implementation of the provisions of the Act and rules in the State;
recommend to the Government, any modifications required in the rules in accordance with changes in technology or social conditions;
perform any other function as may be outlined by the National council of Clinical Establishments
Any other function as may be prescribed by the Central Government.

5 Disqualification for appointment as member
A person shall be disqualified for being appointed as a member of the UT Council if he-

a) Has been convicted and sentenced to imprisonment for an offence which, in the opinion of the UT Administration, involves moral turpitude or
b) Is an undischarged insolvent; or
c) Is of unsound mind and stands so declared by a competent court or
d) Has been removed or dismissed from the service of the Government or corporation owned or controlled by the Government or
e) Has in the opinion of the UT Administration such financial or other interest in the Council as is likely to affect prejudicially the discharge by him of his functions as a member.

6 Conduct of Business:

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

7 Time & Place for Meetings of the State / Union Territory Council:
The meetings of the UT Council shall ordinarily be held at UT Capital on such dates as may be fixed by the UT Council. The UT Council shall meet every six months.

8 Notice of Meeting:
Notice of every meeting other than a special meeting shall be dispatched by the Member Secretary of District Registering Authority to each member of the Council not less than 15 days before the date of the meeting.

9 Quorum, Call for Meeting, Minutes of Meetings:

(i) One-third of the total number of members of the UT Council shall form a quorum and all actions of the Council shall be decided by a majority of the members present and voting.
(ii) The notice and agenda of every such meeting of the UT Council shall ordinarily be given 15 days before the meeting by the Members Secretary of the Council.

(iii) The proceedings of the meetings of the Council shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson. The decisions taken therein shall be given effect to.

(iv) A copy of the minutes of each meeting of the UT Council shall be submitted to the Chairperson within 5-7 days of the meeting and after having been approved by him/her 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 decision 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 of the meeting.

10 Registration and Filling of Casual Vacancies:

(i) A member desiring to resign his seat on the UT 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 letter by the Chairperson after confirmation from the member concerned about his resignation.

(ii) 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 UT Administration which shall take steps to have the vacancies filled by nomination or election, as the case may be.

11 Finance and Account:

The Accounts of the Council shall be audited annually by a Chartered Accountant, who is to be appointed with the prior approval of the Hon’ble Administrator of UT. Of. Lakshadweep. Any expenditure incurred in connection with such audit shall be payable by the Council.
Establishment of Lakshadweep Clinical Establishment Authority

The UT Administration shall, by notification under Section 10 of the Act and in accordance with the rules framed by Central Government in this behalf set up an authority to be called the Lakshadweep Clinical Establishment Registering Authority for registration of clinical establishments in UT of Lakshadweep.

The Institutional arrangements are under:-

Chairman : District Magistrate
Convenor : DMO(District Medical Officer):
Three Members : To be nominated by District Magistrate
   1) Superintendent of Police
   2) President, District Panchayat
   3) One reputed Medical Practitioner

Functions of the Lakshadweep Clinical Establishment Registering Authority:

(a). to grant, renew, suspend or cancel registration of any clinical establishments.
(b). to enforce compliance of the provisions and rules of the Clinical - Establishments (Registration and Regulation) Act 2010
(c). to investigate complaints of breach of the provisions of this Act or the rules made there under and take immediate action;
(d). to prepare and submit on quarterly basis report containing details related to number and nature of provisional and permanent registration certificates issued; including those cancelled, suspended or rejected to the UT Council;
(e). to report to the UT Council on a quarterly basis on action taken against non-registered clinical establishments running operations in violation of the Act,
(f). perform any other function as may be prescribed by the Central Government and or the UT Administration from time to time;

Powers of the Lakshadweep Clinical Establishment Registering Authority:

The Authority shall, for the purposes of discharging its function 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 objective 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 others

g) Dismissing an application for default or deciding it exparte.

h) Any other matter which may be prescribed.

15 **Time and Place of and Preparation of Business for Meetings of the Lakshadweep Clinical Establishment Registering Authority:**

The meetings of the Authority shall be held monthly at a stipulated date and time.

16 **Conduct of Business:**

Every meeting of the Authority shall be presided over by the Chairperson.

17 **Notice of Meeting:**

Notice of every meeting other than a special meeting shall be dispatched by the convener to each member not less than 15 days before the date of the meeting.

18 **Quorum, Minutes:**

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

(ii) The proceedings of the meetings of the Authority shall be preserved in the form of minutes which shall be authenticated after confirmation by the signature of the Chairperson. The decisions taken therein shall be given effect to subject to their being consistent with the provisions of the Act.

(iii) The proceeding of annual meeting of Authority be submitted to the UT Council.
19 Resignation and filling of casual vacancies:

If a causal-vacancy occurs in the office of any other members, whether by reason of death, resignation or inability to discharge, functions owing to illness or any other incapacity, such vacancy shall be filled by the District Collector by making a fresh appointment and the member so appointed shall hold office for the remaining term of office of the person in whose places/he is so appointed.

20 Registration of Clinical Establishments - Application for Registration:

(i) The applicant shall apply to the Authority for provisional registration, either in person, or by post or through web based online facility with the necessary information as per Annex - 1 Form under Section 14 (1) and 14 (3) of the Act.

(ii) Once the process for permanent registration is started by the State, the clinical establishments shall apply to the Authority for permanent registration, in person, or by post or through web based online facility with the necessary information filled and with evidence of having met the requirements of minimum standards and personnel for different categories of Clinical Establishments in a form and format that may be prescribed by the National Council / UT Administration under Section 24 and 25 of the Act.

(iii) If an establishment is offering services in more than one category as specified under the Clinical Establishments (Registration and Regulation) Rules (Central Government), 2010, 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.

21 Acknowledgement of Application:

The Authority, or any person in his office authorized in this behalf, shall, acknowledge receipt of the application for permanent registration, in the acknowledgment slip provided as per Annex - 2 immediately, if delivered at the office of the authority, or not later than the next working day if received by post and by online acknowledgement to be generated automatically by the system.
22 **Grant of 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 as per Annex - 3 either by post or electronically under Section 15, read with Section 17 of the Act.

23 **Certificate of registration:**

(i) The Authority shall grant the applicant a certificate of permanent registration as per Annexure - 4 either by post or electronically after satisfying itself that the applicant has complied with all the requirements and criteria, including provision of minimum standards and personnel required to run the clinical establishment under Sections 28 and 30 of the Act.

(ii) In case of permanent registration, under Section 29 of the Act, the authority shall pass an order within 112 months -

(a) allowing the application for permanent registration; or

(b) disallowing the application; Provided that the authority shall record its justifications and reasons, if it disallows an application, for permanent registration.

24 **Fees to be charged:**

(i) 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 Annex - 5 under Section 14 (I) read with Section 19 Section 20 (2), Section 22; Section 24, Section 35 of the Act.

(ii) Clinical Establishments owned, controlled and managed by the Government (Central, UT or local authority) or Department of Government, shall be exempt from payment of fees for registration.

(iii) The fees prescribed for various categories of Clinical Establishments may be revised by the UT Council through a notification issued by the UT Administration.

(iv) The fee shall be paid by cash, demand draft drawn / online transaction in favour of the Authority as specified under Section 14 (I) and Section 30 of the Act.

24. The fees collected by the Authority for registration of the Clinical Establishments shall be deposited in a nationalized bank account opened by the UT Council in the name of "UT Council Establishment Regulation, Lakshadweep" and shall be utilized by the UT Council for the activities connected with the implementation of the provisions of the Act:
(i) The Accounts shall be maintained as per the Financial Code rules and shall be audited by engaging a qualified Chartered Accountant. The annual Audit reports shall be submitted to the concerned State Council.

(ii) In the event of any change of ownership or management, the establishment shall intimate to the Authority in writing within one month of such change along with the fee prescribed in Annex - 5 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) and Section 30 of the Act.

(iv) In the event of certificate of registration (Provisional or Permanent) being lost or destroyed, the owner shall apply to the Authority to issue a duplicate certificate upon payment of the fee prescribed under rule (b) Annex - 5 and the provisional certificate shall be marked "Duplicate" as per Annex - 9 under Section 19 and Section 30 of the Act.

25 Renewal of Registration:

(i) The Clinical Establishment shall apply for renewal of provisional registration thirty days before the expiry of the validity of the certificate of provisional registration. In case the application for renewal is not submitted within the stipulated period, the authority shall allow for renewal of registration on payment of the renewal amount as prescribed in Annex - 5 and penalty of Rs.1000/- per month till the date of application for renewal under section 22 of the Act.

(ii) The fee for renewal of registration shall be charged as per the rate notified by the UT Administration from time to time and the period after which a license is to be renewed shall also be prescribed by the UT Administration through an official notification.

(iii) The period after which the Clinical Establishments shall have to apply for renewal will be prescribed by the UT Administration through a notification.

(iv) For renewal of permanent registration, the clinical establishment shall apply three (3) months before expiry of the registration period of two (2) years. The renewal will be granted by the Authority within 3 months of receipt of the application failing which it will be deemed to have been renewed. If the clinical establishment does not apply within one month of expiry of registration period, the registration will be deemed to have been suspended.

(v) Under Section 30 (4) of the Act the clinical establishment shall apply for renewal of permanent
registration six months before the expiry of the validity of the certificate of permanent registration. In case the application for renewal is not submitted within the stipulated period, the authority will allow for renewal of registration on payment of the renewal amount as prescribed in Annex - 5 and penalty of Rs. 100/- per day till the date of application for renewal is accepted.

26 Registers to be maintained, furnishing of returns and display of information Registers to be maintained:

(i) The Authority shall within a period of two years from its establishment, compile, publish and maintain in digital format a register of Clinical Establishments registered by it and it shall enter the particulars of the certificate so issued in a register containing particulars as prescribed under Section 37 (1) (2) and Section 38 (1) (2) of the Act.

(ii) The 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 UT 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 92) of the Act.

27 Display of Information:

(i) The Authority shall, within a period of forty-five days from the grant of provisional registration, mandatorily cause to be published in the public domain through Lakshadweep Times and the Official 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 and details of the Medical Staff (Doctors, Nurses, etc.) as under Section 16 (2) of the Act - Annex -7.

(ii) The UT Council could make changes in the nature of information to be provided in the Public Domain through a notification, except in the case of the mandatory information to be provided under Section 16 (2) of the Act.

(iii) The Authority shall, cause to be published in the public domain through Lakshadweep Times and the Official website, which the Authority will launch, the name of the Clinical establishments which have been granted permanent registration, 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 related to having complied with the minimum standards and personnel prescribed for the particular category of clinical establishment as under Section 26 of the Act.
(iv) The 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.

(v) If any person has any objection to the information published regarding the clinical establishment they shall give in writing the reasons and evidence of objection or non-compliance to the Authority. The Authority shall, within a period of 15 days cause to be published in the public domain the name of the Clinical Establishment whose (Provisional or Permanent) registration has expired as under Section 21 and Section 30 of the Act.

28 Information to be provided by Clinical Establishments:

(i) The Clinical Establishments shall maintain medical records of patients treated by it and health information and statistics in respect of national programmes and furnish the same to the 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 are prescribed as per Section 12(1) (iii) of the Act.

(ii) Copies of all records and statistics shall be kept with the Clinical Establishment concerned for 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.

(iii) 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.

(iv) In addition to the specific provisions of the Clinical Establishments (Registration and Regulation) Act 2010. All establishments shall comply and maintain information and statistics in keeping with other applicable Acts and Rules which are in force in the country.

29 Power to Enter:

(i) Entry and search of the Clinical Establishment can be done by the District Registering Authority or an officer or team duly authorized by it or subject to such general or special orders as may be made by the authority, subject to a unanimous decision by all member of the Authority for conduct of such entry and search.
(ii) Such entry and search of clinical establishments can be conducted if anyone is carrying on a clinical establishment without registration or does not adhere to the prescribed minimum standards or has reasonable cause to believe the Clinical Establishment is being used for purposes other than it is registered or contravenes any of (the provisions or this Act & Rules, shall at all reasonable times enter and inspect any record, register, document, equipment and articles as deemed necessary under the provisions of Section 34 of the Act.

(iii) The inspection team shall normally intimate the establishment in writing about the date of visit. The team shall examine all portions of the premise 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 enquires as they consider necessary to verify the statements made in 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 provided further that surprise inspections may also be conducted by the inspection teams from the UT.

(iv) The Officer and / or inspection team so constituted by the Authority shall submit a report as per Annex - 6 within a week of the inspection to the Authority with a copy to the UT Council.

30 Penalties & Appeals:

Penalties

(i) In keeping with the provisions of Section 41 (1) (2) and (3) Section 42 (1) (2) and (3) of the Act, whoever carries on a clinical Establishment without registration or whoever wilfully 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.

(ii) Whoever carried on a clinical establishment without registration, shall, on first contravention be liable to a monetary penalty up to fifty thousand rupees, for second contravention, to a monetary penalty which may extend to two lakh rupees and for any subsequent contravention to penalty which may extend to five lakh rupees.

(iii) 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.

31 The penalty fees collected by the Authority concerned shall be deposited in a nationalized bank account opened by the UT Council in the name of "UT Clinical
Establishment Regulation, Lakshadweep" and shall be utilized by the UT Council for the activities connected with the Implementation of the provisions of the Act at State level as well as district level:

Appeals

(i) In keeping with Section 36, 41 (4) (5) (6) and (7) and Section 42 (4) (5) (6) and (7), any person or Clinical Establishment, if aggrieved by the decision of the Authority under Sections 29 and 34 of the Act, may file an appeal Annex - 8 to the UT Council within thirty (30) days from the date of receipt of such order along with prescribed fees as indicated in Annex - 5.

(ii) After receipt of the appeal, the UT Council shall fix the time and date for hearing and inform the same to the appellant and others concerned by a registered letter giving at least 15 days time for hearing of the case.

(iii) 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.

(iv) The UT 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 filing the Appeal.

(v) If the UT Council considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal. The decision of UT Council shall be final and binding.

(vi) If no appeal is filed against the decision of the 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.

(vii) The appeal fees collected by the authorities shall be deposited in a nationalized bank account opened by the UT Council in the name of "UT Clinical Establishment Regulation, Lakshadweep" and shall be utilized by the UT Council for the activities connected with the implementation of the provisions of the Act.

32 Miscellaneous:

Any other matter which is required to be or may be prescribed by the U.T. of Lakshadweep Administration from time to time.
This Notification will come into effect in the entire Islands of Lakshadweep from 01.03.2017.

This is issued with the approval of Administrator vide diary No. 53 dated 06.02.2017.

(Dr. TARIQ THOMAS, IAS)
SECRETARY(HEALTH)

To,

(1) The Director Printing and Stationary, Kavaratti for publishing in extra ordinary Gazette
(2) The Chairman and Member of the Lakshadweep U.T. Council Cum District Registering Authority.
(3) The Convenor and members of the Lakshadweep District Registration Authority.