



**PARLIAMENT OF THE DEMOCRATIC
SOCIALIST REPUBLIC OF
SRI LANKA**

**PRIVATE MEDICAL INSTITUTIONS
(REGISTRATION)
ACT, No. 21 OF 2006**

[Certified on 14th July, 2006]

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*Private Medical Institutions (Registration)
Act, No. 21 of 2006*

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L.D. — O. 37/2003.

AN ACT TO PROVIDE FOR THE REGISTRATION, REGULATION, MONITORING AND INSPECTION OF PRIVATE MEDICAL INSTITUTIONS; AND TO FOSTER THE DEVELOPMENT OF, PRIVATE MEDICAL INSTITUTIONS; AND TO PROVIDE FOR MATTERS CONNECTED THEREWITH OR INCIDENTAL THERETO.

WHEREAS it has become necessary for the Government, in the interest of providing a safe and efficient medical service to the public, to set out a National Policy in relation to the provision of medical services through private medical institutions and to identify the manner in which such services are to be so provided in order to achieve its objectives :

Preamble.

NOW THEREFORE BE it enacted by the Parliament of the Democratic Socialist Republic of Sri Lanka as follows :—

1. This Act may be cited as the Private Medical Institutions (Registration) Act, No. 21 of 2006 and shall come into operation on such date as the Minister may appoint by Order published in the *Gazette* (hereinafter referred to as the “appointed date”)

Short title and date of operation.

2. (1) No person shall—

- (a) establish or maintain on any specified premises; or
- (b) operate or permit any other person to operate,

Private Medical Institutions and persons operating them to be registered.

a Private Medical Institution, except under the authority of a Certificate of Registration issued in that behalf in terms of the provisions of section 4 of this Act.

(2) Any person who contravenes the provisions of subsection (1) shall be guilty of an offence.

3. (1) Every application for a Certificate of Registration shall be made to the Private Health Services Regulatory Council through the respective Provincial Director of Health Services in the prescribed form and shall be accompanied by the prescribed fee, and all other relevant documents.

Application for registration.

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(2) On receipt of the applications under subsection (1), the Private Health Services Regulatory Council shall where the Private Medical Institution and premises to which the relevant application relates satisfies the criteria as may be prescribed, inform the Provincial Director of Health Services of the respective Province that the Council has no objection to the registration of such Institution and premises and direct the respective Provincial Director of Health Services to—

- (a) register the Private Medical Institution and its premises with the Private Health Services Regulatory Council and register the applicant as the person registered to maintain such Institution; and
- (b) forward to the applicant the Certificate of Registration in the prescribed form.

(3) A Certificate of Registration granted under this section shall be valid for such period as shall be specified therein.

(4) A Certificate of Registration shall be renewed on application being made in that behalf in the manner specified in subsection (1), prior to one month of the date of expiry of such Registration, and on payment of the prescribed renewal fee.

(5) Fifty *per centum* of the fees collected by each Provincial Director of Health Services under this section shall be remitted to the respective Provincial Council.

(6) The Provincial Director of Health Services of the Province shall in carrying out his duties, act in compliance with such guidelines as are prescribed under this Act, relating to the registration of Private Medical Institutions.

Effect of
registering.

4. (1) Where any Private Medical Institution is being operated or maintained by any person on any premises without being registered as required by section 2, the Provincial Director of Health Services shall inform the Private Health Services Regulatory Council of such fact and the

Regulatory Council shall thereupon issue a directive to such Institution to forthwith register such Institution with the Regulatory Council within such period as shall be specified in such directive.

(2) Non-compliance with a directive issued by the Regulatory Council under subsection (1), shall be an offence under this Act.

(3) Where any person or institution convicted of an offence under subsection (2) continues to commit such offence after a period of one month from the date of such conviction, the Magistrate may upon application for a closure order being made by the Regulatory Council, order the closure of that Private Medical Institution being maintained on such premises, until the institution or person convicted complies with the directive issued by the Council under subsection (1).

5. (1) Any person or body of persons who is on the appointed date, operating or maintaining a private medical institution at any premises shall, within three months from the appointed date, take such steps as are necessary to register himself and the premises concerned with the Private Health Services Regulatory Council.

Registration of
existing Private
Medical
Institutions.

(2) In giving effect the provisions of subsection (1), the provisions of section 2, section 3 and section 4 of this Act shall, *mutatis mutandis* apply, to and in relation thereto.

6. (1) There shall for the purposes of this Act be established a Private Health Services Regulatory Council (in this Act referred to as “the Council”), which shall consist of —

Private Health
Services
Regulatory
Council.

(a) the following members appointed by the Minister (hereinafter referred to as “appointed members”) :—

(i) a representative each to represent each of the associations hereinafter set out, nominated by the respective association;

(a) the Independent Medical Practitioners Association;

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- (b) the Sri Lanka Dental Association;
and
 - (c) the Society of General Medical Practitioners;
- (ii) one person each to represent the fields of Accountancy, Management, Law and Nursing: provided such person is a person who has rendered distinguished service in his respective field;
- (iii) nine representatives from the Association of Private Hospitals and Nursing Homes; and
- (b) the following *ex-officio* members :—
 - (i) the Director General of Health Services;
 - (ii) the Director in-charge of development of the Private Health Sector;
 - (iii) the Registrar of the Sri Lanka Medical Council; and
 - (iv) the Provincial Director of Health Services of each Province.

(2) The Director-General of Health Services shall be the Chairman of the Council, and the Director of Private Health Sector Development shall be its Secretary.

(3) An appointed member of the Council shall, unless such member vacates office earlier by death, resignation or removal or otherwise, hold office for a period of three years.

(4) An appointed member shall be deemed to have vacated office if such member absents himself from three consecutive meetings of the Council without any reason, which the council considers as being an acceptable excuse.

(5) (a) The quorum for any meeting of the Council shall be seven members.

(b) The Chairman shall preside at all meetings of the Council and in the absence of the Chairman, the members present shall elect one from amongst them to preside at the meetings.

(6) The Minister may at any time after assigning reasons therefor, remove an appointed member of the Council from office.

(7) An appointed member of the Council may at anytime resign from his office by letter to that effect addressed to the Minister.

(8) In the event of the vacation of office by an appointed member by death, resignation, removal, the Minister shall, having regard to the provisions of paragraph (a) of subsection (1), appoint another person to succeed such member. The member appointed to fill the vacancy shall hold office during the unexpired period of the term of office of the member whom he succeeds.

7. The Council shall, by name assigned to it under section 6, be a body corporate and shall have perpetual succession and a common seal and may sue and be sued in such name. Council to be a body corporate.

8. (1) The Seal of the Council shall be in the custody of the Secretary of the Council or any other member authorised by the Council. Seal of the Council.

(2) The Seal of the Council may be altered in such manner as may be determined by the Council.

(3) The Seal of the Council shall not be affixed to any instrument or document except in the presence of the Chairman of the Council, and one other member, both of whom shall sign the instrument or document in token of their presence:

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Provided that where the Chairman is unable to be present at the time when the seal of the Council is affixed to any instrument or document, any other member authorized in writing by the Chairman in that behalf, shall be competent to sign such instrument or document in accordance with the preceding provisions of this subsection.

(4) The Council shall maintain a register of the instruments or documents to which the seal of the Council is affixed.

Objects of the Council.

9. The Council shall exercise, perform and discharge its powers, duties and functions under this Act in such manner, as the Council considers best calculated to achieve the following objects :—

- (a) the development and monitoring of standards to be maintained by the registered Private Medical Institutions;
- (b) the method of evaluation of standards maintained by such Private Medical Institutions;
- (c) to ensure that minimum qualifications for recruitment and minimum standards of training of personnel, are adopted by all Private medical Institutions;
- (d) to ensure the quality of patient care services rendered or provided by such Private Medical Institutions.

Duties and functions of the Council.

10. The Council shall exercise, perform and discharge the following powers, duties and functions:—

- (a) the formulation of quality assurance programmes for patient care in Private Medical Institutions and monitoring of the same;
- (b) the maintenance of minimum standards for recruitment of all staff engaged or employed in such Private Medical Institutions;

- (c) the collection and publication of relevant health information and statistics;
- (d) the implementation of a method of grading according to the facilities offered by the respective Private Medical Institutions; and
- (e) such other functions as may be necessary to achieve the objects as referred to in section 9.

11. The Council may where it considers it necessary, delegate the performance and discharge of its duties and functions under this Act to any member or members of the Council or a Committee consisting of members of the Council who shall perform and discharge such duty or function, subject to the general direction and control of the Council.

Council to delegate its duties and functions.

12. (1) The Council shall have its own Fund.

Fund of the Council.

(2) There shall be paid into Fund of the Council—

- (a) all such sums of money as may be voted from time to time by Parliament for the use of the Council;
- (b) all such sums of money as may be received by the Council by way of fees, rates, charges or otherwise in the discharge of its functions;
- (c) all such sums of money as may be made available to it by way of grants or donations.

(3) There shall be paid out of the Fund such sums of money as may be required to defray the expenses incurred by the Council in the exercise, discharge and performance of its powers, duties and functions under this Act.

13. (1) The Minister may on the advice of the Council, by Order published in the *Gazette*, formulate and enforce schemes of accreditation for private medical institutions. Such

Accreditation of Private Medical Institutions.

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Order should carry all the details specifying the facilities, services and any other factors constituting the criteria for accreditation :

Provided however, that period of nine months shall be given to concerned interests, before the implementation of such schemes of accreditation or subsequent changes that may be made thereto.

(2) Notwithstanding the Order published under subsection (1), a Private Medical Institution shall continue to offer its services until such time, the final decision of the Council on accreditation shall be made known to such Institution :

Provided however, in the event of a Private Medical Institution not qualifying for accreditation, sufficient time shall be given in writing to such institution, to achieve the standards specified by the Ministry of the Minister in charge of the subject of Health to qualify for accreditation.

(3) The Council shall where necessary, call upon a panel of persons who in their opinion possess the necessary knowledge, expertise, skill or learning to assist and advise the Council in working out the details in the schemes of accreditation and to help, examine and evaluate the applications made in terms of such schemes.

(4) The Council may implement the schemes of accreditation in stages or in such other manner as the Minister may determine.

(5) An accreditation of a Private Medical Institution under this section shall not restrict such institution from attending to life saving emergencies.

Power to enter
and inspect.

14. (1) It shall be lawful for any authorized officer, without prior notice, at any time by day or night, to enter any Private Medical Institution, or any premises appertaining thereto, and do all such acts as may be reasonably necessary for the purpose of carrying out any inspection, examination, investigation or survey, for the purposes of this Act.

(2) Nothing in the preceding provisions of this section shall be deemed or construed to authorize any person to inspect any medical record relating to any patient in an institution unless there is a special authorization by the Council to inspect any records, other than confidential information which requires the sanction of Court.

(3) Every person who resists or obstructs such authorized officer by the Council in the exercise of the powers conferred by the preceding provisions of this section shall be guilty of an offence under this Act.

(4) For the purpose of this section “authorised officer” means the Provincial Director of Deputy Provincial Director of Health Services of the respective Provincial Council or any other officer, as may on the recommendation of the Council be appointed by the Minister by Order published in the *Gazette*.

15. (1) Any registered person or body of persons who— Offences.

- (a) contravenes or fails to comply with the provisions of this Act or any regulation or rule made there under, or any order or direction lawfully given;
- (b) contravenes or fails to comply with any condition or provision contained in any Certificate of Registration, issued under this Act,

shall be guilty of an offence under this Act.

(2) Any person who—

- (a) attempts to commit an offence under this Act; or
- (b) aids or abets another person to commit an offence under this Act,

shall be guilty of an offence under this Act.

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(3) No prosecution for an offence under subsection (1) or (2) shall be instituted except with the written sanction of the Council.

Penalties.

16. (1) Any person who is convicted after summary trial before a Magistrate, of an offence under this Act, shall be liable on such conviction—

(a) where such offence involves the causing of injury to human life or seriously jeopardizing public health or public safety, to a fine not exceeding fifty thousand rupees;

(b) for any other offence —

(i) in the case of a first offence, to fine not exceeding ten thousand rupees;

(ii) in the case of second or subsequent offence, to a fine not exceeding twenty thousand rupees; and

(iii) in the case of continuing offence, to a further fine not exceeding one thousand rupees for each day on which the commission of the offence is continued after conviction or to imprisonment of either description for a term not exceeding six months or to both such fine and imprisonment.

(2) Where a person convicted of an offence under this Act is convicted for a second offence of like or similar nature, the Magistrate's Court convicting him for the second offence shall cancel any certificate, authorization or permit granted or issued to such person or body of persons under this Act, or any regulation made thereunder and shall cause notice of such cancellation to be notified to the Council.

17. Where an offence under this Act or any regulation or rule made thereunder is committed by a body of persons, then—

Offences committed by a body of persons.

- (a) if that body is a body corporate, every person who at the time of the commission of such offence was the Director, General Manager, Secretary or other similar executive officer of that body;
- (b) if that body is not a body corporate, every person who at the time of the commission of the offence was the Chairman, General Manager, Secretary or other similar executive officer of that body;

shall be deemed to be guilty of that offence, unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of that offence.

18. (1) The Minister may make regulations in respect of all matters required by this Act to be prescribed or in respect of which regulations are authorised to be made.

Regulations.

(2) Without prejudice to the powers conferred by subsection (1), the Minister may on the advice of the Council make regulations in respect of all or any of the following matters:—

- (a) the guidelines to be complied with by Provincial Directors of Health Services in the registration or renewal of registration of Private Medical Institutions;
- (b) the rates, charges and any other expenses, which shall be recovered or received for any services rendered or performed in terms of the Act;
- (c) the layout, construction, illumination, additions and improvements and the maintenance of

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cleanliness of all the buildings and premises of registered Private Medical Institutions;

- (d) the circumstances in which cases of infectious diseases may be admitted for treatment and the precautions to be taken in such event;
- (e) the adoption of universally recognized precautions for the prevention and control of infections;
- (f) the classification of Private Medical Institutions into categories, depending upon services being rendered or functions discharged by such institutions;
- (g) the procedure or practice to be followed in entertaining any complaint against any Private Medical Institution or person attached thereto from any interested or aggrieved person, and the final disposal thereof;
- (h) charges for accommodation, drugs and services rendered by Private Medical Institutions ;
- (i) the appointment of competent officers to prosecute actions instituted under this Act.

(3) Every regulation made by the Minister shall be published in the *Gazette* and shall come into operation on the date of such publication, or on such later date as may be specified in the regulation.

(4) Every regulation made by the Minister shall as soon as convenient after its publication in the *Gazette* be brought before Parliament for approval. Any regulation, which it is not so approved, shall be deemed to be rescinded from the date of its disapproval, but without prejudice to anything previously done thereunder.

(5) Notification of the date on which any regulation made by the Minister is so deemed to be rescinded shall be published in the *Gazette*.

19. (1) The Council may make rules in respect of all or Rules.
any of the following matters :—

- (a) the maintenance of records, books, registers, bills, receipts, returns, statements, forms and other documents by a Private Medical Institution;
- (b) the reports, returns, statements and other information required to be furnished periodically by a Private Medical Institution to the Ministry of the Minister;
- (c) the minimum size of wards or rooms and the minimum floor space, which should be allotted for each patient;
- (d) the provisions of adequate latrine and bathing facilities for in-patients and personnel employed in Private Medical Institutions;
- (e) the machinery, equipment, devices, utensils, apparatus, crockery, fittings, furniture and other requisites of a general or special nature ;
- (f) the immunization of personnel employed in Private Medical Institutions against specified diseases;
- (g) the prohibition or restriction of admission of midwifery cases, except to a maternity home or to such other Private Medical Institution having separate and exclusive facilities for the reception and treatment of such cases;
- (h) the prohibition or restriction of the admission of cases other than midwifery cases to a maternity home or to such other Private Medical Institution having separate and exclusive facilities for the reception and treatment of maternity cases;
- (i) defining staffing patterns including minimum qualification, induction and in-service training and refresher courses that should be followed by such personnel;

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- (j) the definition of the specialized departments and ancillary services that should be maintained in terms of special fields of treatment;
- (k) the disposal of refuse and waste matter;
- (l) the provision of sinks, taps and outlets in wards, kitchens, bathrooms and latrines in proportion to the ratio of patients and personnel employed therein;
- (m) the provision of housing, residential quarters or transport facilities required for maintaining the health of patients; and
- (n) the provision of adequate expertise for the maintenance of all institutional assets, machinery and equipment.

(2) No rule made by the Council shall have effect unless it has been approved by the Minister and published in the *Gazette*.

Interpretation.

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

“accreditation” means a process that is adopted for the purpose of certification of the technical competence and quality of service and facilities of a Private Medical Institutions; and

“Private Medical Institution” means any Institution or establishment used or intended to be used for the reception of, and the providing of medical and nursing care and treatment for persons suffering from any sickness, injury or infirmity, a Hospital, Nursing Home, Maternity Home, Medical Laboratory, Blood Bank, Dental Surgery, Dispensary and Surgery, Consultation Room, and any establishment providing health screening or health promotion service, but does not include a

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house of observation, Mental hospital, Hospital, Nursing Home, dispensary, Medical Centre or any other premises maintained or controlled by the State, any private dispensary or Pharmacy or drug stores exclusively used or intended to be used for dispensing and selling any drug, medical preparation or pharmaceutical product, or any Institution or premises registered for any purpose under the provisions of Ayurveda Act, No. 31 of 1961 and the Homeopathy Act, No. 7 of 1970.

21. (1) The Nursing Homes (Regulation) Act (Chapter 220) is hereby repealed. Repeals.

(2) Notwithstanding the repeal of the Nursing Homes (Regulation) Act, the registration of any Private Medical Institution registered thereunder shall be deemed to be valid and effectual and shall continue to be so valid and effectual for a period of three months from the appointed date, within which period such medical institution is required to apply for registration in terms of the provisions of this Act.

(3) Where any Private Medical Institution referred to in subsection (2), fails to obtain a registration under this Act as required by that subsection within the period specified therein, the registration obtained under the repealed Act shall cease to be valid and effectual from and after the expiry of such specified period.

22. In the event of any inconsistency between the Sinhala and Tamil texts of this Act, the Sinhala text shall prevail. Sinhala text to prevail in case of inconsistency.

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