

Report of the
Workshop held to reach consensus to formulate
amendments and to critically analyze PMIR Act in
relation to Health Sector Regulations

Under the directions
His Excellency the President
of
Democratic Socialist Republic of Sri Lanka.



Compiled by
**Government Medical Officers Association
(GMOA)**

Forward

Health is a basic human need and health sector needs regulations. Health sector regulations have three major components.

1. Regulations on human resource which includes professional standards
2. Regulations on Health Institutions
3. Regulations on Drugs, Devices and Consumables

Regulations on human resource which includes professional standards

At the moment regulations on human resource including professional standards of Health sector employees are maintained by following Acts of parliament.

1. Medical Ordinance (No. 26 of 1927)
2. Ayurvedic Act (No.31 of 1961)
3. Homeopathy Act (No. 7 of 1970)

Regulations on Health Institutions

Up to July 2006 regulations on Medical Institutions were done by Nursing Homes (Regulation) Act, which only regulate private sector health institutions. On 14th July 2006 Nursing Homes (Regulation) Act was repealed and Private Medical Institution (Registration) Act was introduced in place of Private Nursing Homes (PNH) Act under the pretext of “Improving Private Health Sector”. However the contents of the Private Medical Institution (Registration) Act (PMIR) are in violation of several fundamental principles of health sector regulations. This also has several important omissions. This situation has arisen probably because the framers of the Private Medical Institutions (Registration) Act have drafted the PMIR Act without consulting relevant experts in the respective fields and without reaching consensus among stakeholders.

Under the directions made by His Excellency, on 11.01.2008, I as the Secretary GMOA convened a workshop, on 20.01.2008 to reach consensus with all parties concerned. We could reach a unanimous consensus with the entire Medical profession to prove that this act has several major fundamental deficiencies. There are many commissions and as well as omissions to serve the expected purpose of “Health Sector Regulations”. Perhaps PMIR would bring irrecoverable damage to the health sector due to deficiencies in its contents.

As such, I would report back to your Excellency on behalf of the entire medical profession that we are in unanimous agreement on amending the Act in favour of safeguarding and improving the health sector in general.

Dr. Anuruddha Padeniya
Secretary/ GMOA

Sequence of Events

1949	The Nursing Homes (Regulation) act was enacted to regulate the Private Health Sector
1952/1953	Nursing Homes (Regulation) Act was amended in 1952 and 1953.
1992	Presidential Task Force on Health Policy was appointed in 1992 and as a policy measure recommended a new Private Medical Institutions (Registration) Act and an advisory body under this act will have representation of users as well'
27 th October 1998	Prelude to the enactment of the Private Medical Institutions (Registration) Act a circular was issued in 1998 by then Secretary/ Health to regularize the Private Practice by Government Doctors but it was not implemented (Annexure 1)
14 th July 2006	PMIR Act No.21 of 2006 was certified
1 st December 2006	GMOA pointed out the deficiencies in the PMIR Act and request to suspend its implementations (Annexure 2)
25 th June2007	Minister appointed the Private Health Sector Regulatory Council to implement the provisions of the act. (Annexure III)
6 th July 2007	Minister was convinced on the deficiencies and act as follows. <ol style="list-style-type: none">1. Agreed to suspend the implementation of the provisions of the act in relation to the Government Medical Officers.2. Appointed DGHS to prepare the amendments with relevant stakeholders and with legal professionals. (Annexure IV)

Guiding Principles of Health Sector Regulation

Following concepts were established at the two workshops held to discuss and formulate principles on Health Sector Regulations.

- Regulation of Health institutions should cover all institutions including Private as well as Government.
- Maintaining the standards of Allopathic Medical Professionals and other health care workers should be done through the **Medical Ordinance** and it should be only through the Medical Ordinance. If there is any deficiency with regard to the standards of the medical profession and its related activities should be addressed through the Medical Ordinance. Necessary amendments and regulations should be done without a delay after adequate consultation and consensus among the relevant stake holders.
- Minimum standards of the medical professional consultation practice including its physical arrangement should only be regulated under medical ordinance. However all the medical practitioners registered under the medical ordinance are bound to maintain professional standards and the quality of service provided.
- Ayurvedic and Homeopathy acts may also need amendments to improve the current situation.
- Private Health sector needs a mechanism to provide subsidy, but government should not tax the sick citizens of the country.
- Any implementation arm should have a mechanism to appeal and to report back.
- PMIR Act need to be amended in the areas of its contents analyze under “Analysis of the important sections of the private medical institution act” of this report.

Analysis of the important sections of the private medical institution act.

Title of the act. (Section 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”)

The title of the act is not specific but it is vague. It does not serve the purpose for which it is intended for.

Conflicts with the Medical Ordinance (section 2)

(1) No person shall

- (a) establish or maintain on any specified premises; or
- (b) operate or permit any other person to operate 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 subscription (1) shall be guilty of an offence.

The above section clearly contradicts with the sections 29, 41 and 43 of the Medical ordinance, which make the persons registered under the said acts entitled to practice medicine and surgery or Dentistry in Sri Lanka. Accordingly, medical professionals registered under the medical ordinance should be excluded from registration and regulation under this act.

Composition and Appointment of Regulation Council (Section 6(1))

6. (1) There shall for the purpose of this act be established a private Health Service Regulatory Council (in this Act referred to as “the Council” which shall consist of

- (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
 - (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 of the Private Health Sector
 - (iv) the Provincial Director of Health Service of **each Province**

The total numbers of council members are twenty eight. Out of them four members are independent namely Independent Medical Practitioners Association, Sri Lanka Dental Association, Society of General Medical Practitioners and the Registrar of the Sri Lanka Medical Council.

Eleven members are bureaucrats of the Ministry of Health and four members are appointees of the Minister of Health. All these members are under the influence of Minister of Health. There fore this regulatory council will be politicized and will not be independent.

Further, there is no adequate stakeholder representation in the regulatory council. The Sri Lanka Medical Council is not represented adequately. The Sri Lanka Medical Association and other Professional Colleges have been ignored.

On the other hand appointment of representatives of various organizations by the Minister is a hindrance to their independence in the council. Therefore council members should be categorized in to three groups namely, Ex – officio members, nominated members of stake holders and members appointed by the minister.

Presidential Task Force appointed in 1992 to prepare a National Health Policy recommended to establish a Registration Act and an advisory body under this act to have representation of users as well. This fact had been totally ignored.

Hence the composition of the council needs to be discussed in depth before reaching consensus in the presence of all the relevant stake holders.

Quorum of the Regulatory Council (Refer Section 6 (5))

6 (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 effect one from amongst them to preside at the meetings.*

Eleven members are bureaucrats of the Ministry of Health and four members are appointees of the Minister of Health. Hence, these fifteen members are under the direct influence of the Minister. Further, nine members are appointed by the Association of the Private Hospitals and Nursing Homes. Since the quorum is seven, an organized group of members can complete the quorum and take biased decisions which are legitimate and final.

Appointing and acting chairman from among the members of the council to preside the meetings in the absence of the Chairman is not justifiable.

Hence the quorum of the council needs to be discussed in depth before reaching consensus in the presence of all the relevant stake holders.

Minister has the power to remove any appointed member at any time. The reasons are not specified (Refer Section 6 (6))

6 (6) *The Minister may at any time after assigning reason therefore, remove an appointed member of the council from office*

Removal of nominated members of various organizations by the Minister of Health is not acceptable. As a result, members of the regulatory council would not be able to maintain their independence and impartiality.

Further more, when a stake holder association which nominate its members to the regulatory council, finds that their nominees is not serving the interest of the respective association there is no mechanism to remove such a members.

In the event of a nominated member resigns or is expelled from the respective association, he/she still continues as a council member representing the said association.

When formulating the new act the power of the minister should be restricted to remove his nominees after assigning reasons.

Conflicts with Medical Ordinance (Section 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 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.*

The minimum qualifications for recruitment and the minimum standard of training of medical professionals and other paramedical categories are already regulated by the Sri Lanka Medical Council. Therefore this section should only apply to the categories that are not eligible for registration by Sri Lanka Medical Council.

Conflicts with Medical Ordinance (Section 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*
- (b) and monitoring of the same;*
- (c) the maintenance of minimum standards for recruitment of all staff engaged or employed in such Private Medical Institutions;*
- (d) the collection and publication of relevant health information and statistics;*
- (e) the implementation of a method of grading according to the facilities offered by the respective Private Medical Institutions; and*
- (f) Such other functions as may be necessary to achieve the objects as referred to in section 9.*

The minimum qualifications for recruitment and the minimum standard of training of medical professionals and other paramedical categories are already regulated by the Sri Lanka Medical Council. Therefore this section should only apply to the categories that are not eligible for registration by Sri Lanka Medical Council.

Delegation of duties and functions of the council (Section 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.

Delegation of duties and functions of the council to a single member may lead to a biased and partial situation.

Fund of the council (Section 12)

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

(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.

This makes the individuals and institutions registered under to make a mandatory financial contribution to the fund of the council while the regulatory council discharges its functions. This sort of taxation will definitely be reflected on the sick who receive the services of private medical institutions. Instead of appreciating their move to seek medication from private medical institutions with out being a burden to the state health sector this act has gone to the extent of taxing them indirectly. This sort of taxation of the sick is highly unacceptable. Hence, we propose to introduce a mechanism to subsidise the cost in the private sector.

Management of the fund of the council should be transparent and accountable.

Accreditation (Section 13(1))

(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 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 concern interests, before the implementation of such schemes of accreditation or subsequent changes that may be made thereto.

Smaller institutions will be affected by the decisions taken upon a simple majority. Smaller institutions need adequate protection. The new act should be spelled in such a way that that smaller institutions are encouraged to achieve higher standards while not compromising the required criteria.

Power to enter and inspect (Section 14)

Clause 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.***

(4) *For the purpose of this section "authorized 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.*

Appointing any officer with out technical capacity or expertise, as an authorized officer will be detrimental to the maintenance of the credibility of the council.

The authorized officer should be a person with necessary expertise such as a medical practitioner with a valid registration under section 29 of the Medical Ordinance or under section 43 of the Medical Ordinance.

Offences (Section 15)

- 1) Any registered person or body of persons who-
 - (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.
- 3) No prosecution for an offence under subsection (1) or (2) shall be instituted except with the written sanction of the Council.

There is no provision for the medical institutions to appeal regarding the decisions of the council. The nature and the composition of the appealing body needs consensus of the stake holders.

Regulations made by the Minister (Refer clause 18(1))

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 authorized to be made.
- (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:
- (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;**
- (h) **charges for accommodation, drugs and services rendered by Private Medical Institutions ;**

Constituting the regulatory council becomes meaningless if the minister could make regulations on his own. Making the regulations without the sanction of the regulatory council with regard to the health care delivery of the private sector may lead to disastrous situations.

Professional charges can not be decided by the regulatory council as they come in to the territory of the ethical practice of the medical professionals who are governed by the medical ordinance.

Rules made by the council (Section (19))

- (1) The Council may make rules in respect of all or any of the following matters :-
- (i) *Defining staffing patterns including minimum qualification, induction and in-service training and refresher courses that should be followed by such personnel;*
- (2) *No rule made by the Council shall have effect unless it has been approved by the Minister and published in the Gazette.*

The minimum qualifications for recruitment and the minimum standard of training of medical professionals and other paramedical categories are already regulated by the Sri Lanka Medical Council. Therefore this section should only apply to the categories that are not eligible for registration by Sri Lanka Medical Council.

The need of Approving of the rules by the minister which have been formulated by the council is a threat to its independence.

Interpretation (Section 20)

“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 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**

This definition needs extensive revision and the definition should not be in conflict with the medical ordinance.

