



## Opinion

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## Critique on the Private Health Sector Regulatory Framework in Sri Lanka

Himali Wijegunasekara<sup>1</sup>

<sup>1</sup> Senior Registrar (Medical Administration) Ministry of Health, Sri Lanka, MBBS, Diploma in Family Medicine, MSc (Medical Administration), MD (Medical Administration)

### Abstract

**Introduction:** Many governments have permitted private providers to invest in health care, as a cost sharing effort. However, it is essential to assure the reliability, quality and safety of their service provision. Therefore, Regulations have been set out and supervised by regulatory bodies to improve quality, safety and effectiveness of care. In this regard, Sri Lanka has enforced the “Private Medical Institutions (Regulation) Act- No 21 of 2006” which is the foundation for the private health sector regulatory framework. **Description:** Private Health Services Regulatory Council was formulated for the regulation, registration, monitoring and inspection of private medical institutions and facilitate their development. Many functions are in operation to accomplish its objectives. **Feeling:** I feel contented about the well formulated and enacted regulatory framework; and rapid expansion of private health sector in infrastructure and in high technology; however, I feel unhappy about not having a proper mechanism for performance evaluation and disciplinary actions for any malpractices; and about weaknesses in coverage of registration. **Evaluation:** Presence of a Private Medical Institutions (Regulation) Act, regulatory framework and a Regulatory Council; clear objectives, multidisciplinary stakeholders; involvement of the Provincial Director and Regional Directors, formulating guidelines, Quality Assurance programs, and Health Information Management System were identified as good. **Monitoring** for registration of GP centres; dealing with malpractices; attending public complaints; performance evaluations; fulltime medical staff and Health Information System seemed to be not satisfactory. **Analysis:** Some factors such as legislative power; participatory decision making; improved accountability and responsibility; availability of network of field officers; and aiming at a standardized system have positively impacted on the performance of private sector. At the same time, inadequate fulltime medical personal, resistance of labor unions; taxation issues; inadequacy of resources and coordination have negatively impacted. **Conclusions:** Private health sector regulatory framework has shown both strengths and weaknesses in implementation. **Recommendations:** Recommendations were suggested to strengthen development of permanent medical staff, monitoring over registration and operations, performance displaying, implementation of penalties for malpractices, maintenance of Health Information System, and price stability.

**Keywords:** Private health sector, Regulatory framework, Strengths, Weaknesses

### INTRODUCTION

**Private health care system** in many of the middle-income countries have grown up tremendously over the past few decades. This growth is mainly due to the lack of adequate quality of public health care services due to low budgetary allocation [1].

In response to this issue, health care has been reformed in many countries to relax the licensing of private health care providers, granting permission for public sector personal to engage in private practice. Many governments have created an enabling environment for private providers for investing in health care, as a cost sharing effort. This trend encouraged the private health care sector to expand rapidly and to play a major role in health care provision in many countries [1].

At the same time, it is the governments’ responsibility to intervene when and where necessary to assure the reliability, quality and safety of service provision in private sector to protect care receivers from the abuse with malpractice and negligence. Therefore, regulation is a vital aspect in privatization [2].

**Regulations** is “the control with rules and principles” which are set out the desired behavior. **Regulatory agencies** supervise the conformity to the regulations to protect consumers and investors. Expected results are to increase the efficiency, to reduce the information asymmetry and to develop commitment [1,2].

Care Quality Commission (2009) and National Health Service - Improvement (NHSI) (2016) are some examples for regulatory bodies established in United Kingdom to improve quality, safety and effectiveness of care and continuous quality improvement of hospitals, GP practices, dental services, mental health services, social care services and radiology services by regularly inspecting for required standards, issuing registrations and licensing, rating and taking disciplinary actions [3].

#### \*Corresponding author:

**Dr. Himali Wijegunasekara**  
Senior Registrar (Medical Administration) Ministry of Health, Sri Lanka, MBBS, Diploma in Family Medicine, MSc (Medical Administration), MD (Medical Administration)  
Email: himaliadm@gmail.com

Sri Lanka has several regulatory mechanisms such as Sri Lanka Medical Council for the medical officers, and other councils for nursing officers and para medical staff for registration and to ensure qualified workforce engaged in both public and private health care practice.

In addition, National Medicinal Regulatory Authority regulates the production, importation, registration, distribution, sale and use of pharmaceuticals and medical devices used both in public sector and private sector through National Medicinal Regulatory Authority Act, No 5 of 2015, Sri Lanka [4].

Ayurveda Act, No 31 of 1961 [5], Homeopathy Act, No 7 of 1970 [6] and Nursing Homes (Regulation) (Amendment) Act, No 63 of 1988 [7] are some of the legislations existing in Sri Lanka for a considerable period of time.

“Private Medical Institutions (Regulation) Act - No 21 of 2006” [8] was enforced in Sri Lanka to directly oversee the operations of the private health sector. Further, National health policy (2016-2025) [9] too emphasizes the regulation of the private health sector to ensure quality service and financial risk protection of patients and to strengthen the mechanisms to regulate the prices of medical drugs and devices.

### **Description**

Private Medical Institutions (Regulation) Act - No 21 of 2006 [8] is the foundation for the Private health sector regulatory framework. It was formulated for the regulation, registration, monitoring and inspection of private medical institutions in the country and facilitate their development.

The Act has facilitated to establish the “Private Health Services Regulatory Council (PHSRC)” which is chaired by the Director General of Health Services and supported by the secretary - the Director of Private Health Sector Development (PHSD) of the Ministry of Health. Members of the PHSRC include representatives from medical and dental practitioners’ associations and societies, private hospitals associations, other non - health fields, and ex – officio namely the Registrar - SLMC and Provincial Directors [8].

Objectives of the council are; to develop and evaluate standards of quality of patient care, deciding of minimum qualifications in recruitment and standards of training. In addition, Council is expected to conduct Quality Improvement programs, to maintain the Health Information Management System and to implement a method of “Grading” of institutions according to facilities available. It may enforce Schemes of Accreditation in stages to improve quality and safety. Further, Council provides information on registration process, does price control activities, gives temporary registration for consultants, approves new hospitals, new procedures, handle public complains, and collaborate with insurance companies. Council is expected to develop circulars and guidelines for the implementation of the activities to achieve its objectives. Rules and regulations are to be developed to improve documentation, physical environment, equipment, facilities, midwifery services, staff recruitment, training, employee safety, infection control, refuse & waste disposal, transport facilities, sending annual Returns to the Ministry of Health etc. [8].

At the point of registration; (1). General information such as name, address, name of the person operating, district and province, type of institution, ownership, Business/company registration number, Board of Investment registration number (2). Details of human resources such as names, place of permanent employment, qualifications, fulltime/part time, SLMC registration (3). Method of record keeping (4). Units and facilities (beds, rooms, facilities) (5). License from the Atomic Energy Authority (6). Clinical waste disposal, sterilization, (7). Availability of emergency kit, equipment and facilities are gathered and applications are sent through the relevant Provincial Director to the secretary, PHSDC.

Authorized officers such as the Provincial Director, Regional Director have the legal power to inspect and investigate any institution other than the medical records which are confidential. If found guilty it can proceed with relevant procedures which leads to penalties such as cancellation of registration, fining and imprisonment.

### **Feeling**

I feel very contented to find that Sri Lanka is having a well formulated and enacted private health sector regulatory framework to improve quality, safety and efficacy of services provided by the wide spread private sector health institutions of a huge range covering the entire country.

In the same way, I am very glad to see that the private health sector is expanding very rapidly in infrastructure and in high technology in investigations and treatment, to share the burden of health care cost with the government, to meet the increasing demand of people with increasing income, aging and prevalence of Non-Communicable Diseases.

However, I feel surprised to see how such an expanded private health sector is operating mainly with part time practitioners.

I feel worried to see that there is no proper mechanism established to evaluate the performance and to “Rate” the institutions, for the care receivers to choose better care providers with rational investigations and treatment.

I wonder what type of disciplinary actions the PHSRC are taking against the low morale, poor knowledge and skills, malpractices, negligence of practitioners, who have registered only once with the professional bodies, with no requirement for renewal.

Also, I feel unhappy that the regulatory mechanism has failed to improve coverage of registration of many small-scale private institutions such as dispensaries and surgeries.

### **Evaluation**

Following were recognized as positive;

- There is an Act, enacted by the Parliament of the Democratic Socialist Republic of Sri Lanka on the regulation of private medical institutions in the country.
- All the private medical institutions and persons need to be registered in the private health service regulatory council.
- Members of the PHSRC include multidisciplinary stakeholders to make decision making.
- Provincial Director has been made responsible to collect, assess and forward the applications with the required fee in his province.
- In the amended act regulatory powers have been given even to Regional Directors and to the Fly Squad Unit.
- PHSRC has objectives to ensure standards of the institutions, expertise in health care team, standards of training and to ensure quality of patient care.
- It has the authority to develop guidelines on registration, employee safety, patient complaints and charges.
- It has duties to develop Quality Assurance programs, to maintain a Health Information Management System, to “Grade” institutions and to enforce schemes of accreditation.
- It has given authority for authorized officers to do inspection, examination, and investigation of private medical institutions and if found guilty, to go for penalties.

However, there are aspects with deficiencies;

- Laws to deal with malpractices and negligence in provision of private health care is inadequate.
- Even though the professional bodies such as Sri Lanka Medical Council are empowered to take disciplinary action against misconduct, cases of punishments are seen only rarely.
- There is no adequate system to “Rate” the performance.
- There is no system to publish quality standards of private medical institutions in the website of the PHSRC or for private medical institutions to display their PHSRC rating publically.
- There is no mechanism to publicize cases of negligence and malpractice.
- There is no provision for the private sector to expand its capacity with fulltime medical staff.
- Government’ contribution to support the private institutions to absorb and train sufficient number of skilled man power is not satisfactory.
- Monitoring capacity within the regulatory bodies to improve the registration and operations of private health care providers is not sufficient.
- There is no adequate actions taken to maintain the Health Information System of private providers.
- There is no system to regulate and supervise health insurance organizations in their transactions.
- The coordination between the private and public health institutions is weak in responses to major health problems in the country.
- The measure taken by the regulatory author on market failure leading to high cost is not adequate.

### **Analysis**

- PHSRC has obtained the legislative power through the Act, to regulate private medical institutions in the country and to take legal action, if the requirements are violated.
- Multidisciplinary team of members in the PHSRC gives participatory decision making taking into account the perspectives of the government, personal regulatory bodies, private sector providers and implementers at field level so that adherence to decisions is more powerful.
- The compulsory requirement of registration of both the institutions and personnel have created an environment, where patients are managed only by qualified personnel and ensured their accountability and responsibility in service provision.
- However, Medical Officers engaged in part time private practice in dispensaries & surgeries show a resistance for registration due to taxation issues. This has resulted in poor coverage and poor regulation by the PHSRC on them. Even though the regulatory frame work is well designed it is not well operationalized. Causes could be low capacity of the council due to inadequate man power, inadequate assistance received from the provincial, regional and divisional level

health authorities, and over protection of medical officers by the powerful labor unions.

- Provincial Director is the responsible authority to facilitate the registration process. As the public health services are based on the provincial setting, a mechanism to identify new entrants can be easily done using the widespread network of field officers such as Public Health Inspectors, Public Health Midwives and Food and Drug Inspectors under the leadership of Medical Officers of Health. In addition, regulatory powers given even to Regional Directors and to the Fly Squad Unit have improved the system of registration and inspections.
- PHSRC’s objectives of ensuring standards of the institutions, personnel, training and patient care would have a big impact on the quality, safety and effectiveness of services provided by private health institutions. Further, the rules, regulations, circulars and guidelines issued by the PHSRC would provide a standardized system for the private providers to follow which will protect the patients who suffer from information asymmetry.
- PHSRC’s mechanisms in handling patient complaints and in ensuring employee safety will compel private providers for better adherence to regulations which results in patient satisfaction and employee satisfaction.
- Maintenance of a Health Information Management System is crucial in making evidence-based decisions with regard to morbidity and mortality data and availability and distribution of health facilities, expertise and services.
- The Act has lawfully given the authority for inspection and investigation of private medical institutions so that corrective measures can be taken to improve the services.

On the other hand;

- Laws to deal with malpractices and negligence in provision of private health care is inadequate. If the existing laws are applied efficiently most of these issues can be addressed. This situation can badly affect both the quality and the cost.
- Enforcement of powers such as suspension/cancellation of registration and implementation of other types of penalties needs strengthening. Penalties may have a positive consequence on performance.
- There is no adequate system to monitor the performance which has resulted in poor accountability, responsibility and commitment. A comprehensive monitoring system may require a considerable number of resources and coordination for effective results.
- As in some other countries like UK, reporting the performance of private medical institutions in government websites and making the private institutions to display their rating can influence them for positive performance.
- In Sri Lanka, the system to publicize cases of negligence and malpractice is not well implemented probably to protect the dignity of the profession.
- There is no provision for the private sector to expand its capacity with fulltime sufficient number of qualified medical staff.
- There are no adequate actions taken to maintain the health Information System of private providers.

- The coordination between the private and public health institutions is weak in responses to major health problems in the country.
- The measure taken by the regulatory authority on market failure leading to high costs and inefficiencies of private sector are not adequate.

## CONCLUSION

Private health sector regulatory framework has shown both strengths and weaknesses in implementation.

Some factors such as legislative power for registration, inspection and investigation; participatory decision making; resulted improved accountability and responsibility of private sector; availability of network of field officers to tracking; handling patient complaints and aiming at a standardized system have positively impacted on the performance of private sector.

At the same time, inadequate fulltime medical personal, resistance of powerful labor unions on training of medical personnel; resistance for registration due to taxation issues; inadequacy of resources for effective outcomes; inadequacy of reliable information flow; and market failure leading to high costs were seen as weaknesses.

## Recommendations

- Government should support private institutions to absorb and train sufficient number of skilled man power.
- Monitoring capacity of regulatory bodies to improve the registration and operations of private health care providers should be strengthened.
- Performance of private medical institutions should be displayed in websites and making them to display their rating for more positive performance.
- Implementation of penalties such as suspension/cancellation of registration should be strengthened to control malpractices and negligence.
- Maintenance of the Health Information System and information sharing should be established among both private and public providers.
- Measures should be taken to standardize and stabilize pricing in private sector.

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