

2024 ජූලි 10
2024 யூலை 10
10 July 2024



NAOSL

වාර්තාවේ අංකය : MED/B/PR/2022/09
அறிக்கை இல. : MED/B/PR/2022/09
Report No : MED/B/PR/2022/09

ශ්‍රී ලංකාවේ පෞද්ගලික සෞඛ්‍ය සේවාව නියාමනය කිරීමේ ක්‍රියාවලියේ
කාර්යසාධනය ඇගයීම

இலங்கையின் தனியார் சுகாதார சேவைகளை ஒழுங்குபடுத்தும்
நடவடிக்கைகளின் செயலாற்றுகையை மதிப்பீடு செய்தல்

Evaluation of the Performance of the Private Health Service
Regulatory Process in Sri Lanka

ජාතික විගණන කාර්යාලය
தேசிய கணக்காய்வு அலுவலகம்
NATIONAL AUDIT OFFICE



Evaluation of the Performance of the Private Health Service Regulatory Process in Sri Lanka



Report Number: MED/B/PR/2022/09



ජාතික විගණන කාර්යාලය
தேசிய கணக்காய்வு அலுவலகம்
NATIONAL AUDIT OFFICE



Contents

1.	Executive Summary	4
2.1	Background	8
2.1.1.	The beginning and expansion of private health service.....	8
2.1.2	Health Insurance	9
2.2	Strengths and Weaknesses of the Private Health Sector	10
2.3	Regulation	11
2.4	Authority for Audit	13
2.5	Audit Approach.....	13
2.6	Audit Objectives and Criteria	15
2.7	Audit Methodology.....	17
2.8	Scope of Audit	17
2.9	Limiting the Scope of Audit.....	18
3	Detailed Audit Findings.....	19
3.1	Health Policies and Plans.....	19
3.1.1	National Health Policy	19
3.1.2	Health Master Plan (2016-2025)	19
3.1.3	National Health Strategic Master Plan (2016-2025)	20
3.2	Private Medical Institutions (Registration) Act No. 21of 2006	21
3.2.1	The objectives of adopting the Act	21
3.2.2	Composition of the Private Health Services Regulatory Council	21
3.2.3	Decision given by the Supreme Court regarding the composition of the Governing Body.....	22
3.3	Representation of the Provincial Councils	23
3.4	Not defining "authorized officers" properly.	23
3.5	Participation of the members for the Governing Council meetings and meetings conducted by the Private Health Services Regulatory Council.....	26
3.6	Assigning to perform the functions and duties of the Regulatory Council.....	27
3.7	Making Regulations to carry out the Functions of the Act.....	30
3.7.1	Accreditation of Private Medical Institutions	30
	The following facts were observed in this regard.	30
3.7.2	Making Regulations under Section 18 of the Act.....	31
3.8	Making Rules to carry out the Functions of the Act	32
3.9	Areas not covered by the Act	33
3.10	Failure to Fulfill the Objectives Mentioned in the Act.....	34
3.11	Registration of Private Medical Institutions	34
3.11.1	That registration is essential for operating the private medical institutions	34

3.11.2	Validity of Registration Certificate	35
3.11.3	Sub-Committee on Evaluation of Registered Applications.....	35
3.11.4	Registration of Laboratories	37
3.11.5	Discrepancy of data on Registered Laboratories	38
3.12	Human Resource Development in Private Medical Institutions.....	38
3.12.1	Training of Human Resources in Private Health Institutions	39
	The audit observations in this regard are given below.	39
3.12.2	Training Sub-Committee.....	41
3.12.3	Complaints Regarding the Human Resource	42
3.13	Regulation of fees of the Private Medical Institutions	42
3.13.1	Formulation of Directives on Pricing	43
3.13.2	The programme of preparation and implementation of definite cost method for specialist consultations, medical services and surgeries in hospitals and institutions of the private sector.....	44
3.13.3	Regulation of charges recovered in respect of laboratory tests.	44
3.13.4	Imposition of Fines on Recovering Monies in Violation of Maximum Limit of Charges.	48
3.13.5	The Sub-Committee of Pricing of private Health Services Regulatory Council	49
3.13.6	Non-payment of Attention towards Prices Charged on Medicines	49
3.14	Private Medical Institutions Complying with Environmental Laws	50
3.15	Grading of Private Medical Institutions	52
3.16	Complaints Received Against Private Medical Institutions.....	52
3.16.1	Resolution of Complaints against Private Medical Institutions	52
3.16.2	Internal control over complaints	54
3.16.3	Sub-Committee for Complaints.....	54
3.16.4	Complaints being investigated by Other Parties.....	56
3.16.5	Regulation of Physical Resources/space of Private Health Institutions	57
3.17	Database of the Private Health Institutions.....	57
3.18	Evaluation of the Contribution to the Government Sector by the Private Medical Institutions	59
3.19	Private Health Sector Development (PHSD) Division and Institutional Structure of Private Health Services Regulatory Council (PHSRC).....	62
3.19.1	Staff	62
3.19.2	Fund Composition.....	62
3.19.3	Financial Performance of the Council.....	65
4.	Audit Recommendations	67

1. **Executive Summary**

life and a positive concept that analyses the social and individual resources. Due to this, all the countries of the world give more priority to the health of their people. Since the past, all Sri Lankans have been entitled to free health service, and due to the significant contribution made by all the governments to improve the health of the people, Sri Lanka had surpassed all the countries in South Asia in the year 2022 in achieving a higher Human Capital Index of 0.782.

Even though a free health service was established in Sri Lanka, private medical institutions have been established all over the island at present, and they provide a high contribution to the health sector. Therefore, the Parliament had passed the Private Medical Institutions (Registration) Act, No. 21 of 2006 as 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. The Private Health Services Regulatory Council had been established for its purposes in the year 2007 and the Ministry of Health has established a separate division called the Private Health Sector Development Division for the development of the private health sector.

There has been an increase in the number of patients, who seek the services of the private sector, as overcrowding in the public hospital system, have to be on the waiting lists for a long time for surgeries and tests, the inability of the government to make a high contribution to the health sector due to the economic crisis, and the media advertises that low-quality medicines are being used in the Government hospitals. At the same time, there has been an increase in receiving complaints against private medical institutions, and therefore, this performance audit was conducted to evaluate the legal background of private medical institutions and the performance of the relevant government institutions in relation to their operation and regulation.

It was observed among the major audit observations identified here that although the problems regarding the regulation of the private health sector and the proposed strategies to mitigate them had been identified in the National Strategic Framework for Development of Health Services 2016 – 2025, the Ministry of Health has not achieved positive progress by following those strategies, viz, the constitution of this council has been challenged due to the increase in the number of members appointed by the minister than the number of members who are appointed ex officio and as a result, even though the Ministry of Health has stated that the process of revising the Private Medical Institutions Registration Act No. 21 of 2006 has been initiated, the parties responsible for amending the Act have not done so even by the year 2023, 16 members out of the total of 28 members of the Regulatory Council or 57 per cent of the total number of members have been appointed by the minister in charge and the quorum of a meeting of the Regulatory Council is 07 and therefore, 07 members, out of the 16 members have the ability to hold a council meeting and take decisions, and the

existence of a conflict of interest due to the fact that the owners of the private health institutions that are subject to the regulation of the regulatory council are members of the regulatory council. Moreover, 08 sub-committees were appointed by the Private Health Services Regulatory Council to discharge duties and functions of the council according to Section 11 of the Act and the above situation was also observed in these sub-committees.

Moreover, even though the number of private hospitals registered in the Private Health Services Regulatory Council was 171 in the year 2023, it was also observed that members only to represent a few hospitals were continuously appointed in the appointment of members to the Governing Council, although all the private Medical institutions should be registered according to the Private Medical Institutions (Registration) Act No. 21 of 2006, the Regulatory Council has not prepared and implemented a formal system to execute provisions of Section 4 of the Act in relation to the identification, registration of private medical institutions and in taking action pertaining to private medical institutions that are not getting the registration, not revising the registration fees introduced by the Regulatory Council in the year 2007 up to the year 2023, these orders have not been made and enforced up to the date of the report although the criteria, facilities, services and certain other factors included therein for accreditation of private medical institutions in terms of Section 13 of the Act should be implemented by means of an order published in the Gazette on the advice of the Council.

Further, it was observed that the regulations made and published in the Government Gazette up to the date of the report have not been submitted to the Parliament and enforced and regulations have not been made regarding many matters that had been authorized to make regulations under the Act, rules had not been made and enforced on any matter that should be published in the government gazette after making rules by the Regulatory Council and approving the rules by the Minister until the date of the report. Accordingly, it was observed that these regulations and rules have not been made and formally enforced although 17 years have passed since the Act was effective and due to this, the Ministry of Health has not successfully fulfilled its responsibility to regulate the private health service in such a manner that it is confirmed that efficient services are provided to the public through the private health services.

At the time of deciding the charges for the services of the private sector hospitals and institutions, the private hospitals had filed lawsuits against the determination of the maximum charges on a common basis without ranking the medical institutions and had not given their consent for controlling prices, the matter has not been resolved till the date of the report, and various complaints have been received to the Private Health Services Regulatory Council, the Ministry of Health and its Flying Squad Division, as well as to the Consumer Affairs Authority and the Central Environmental Authority, and uncertainty as to whether a fair solution has been provided to the complaints owing

to the existence of problems related to the complaints received and the decisions taken by the Private Health Services Regulatory Council.

Among these complaints, there were 51 complaints, viz. 52 per cent out of the total No. of complaints, were received in relation to 09 leading private hospitals of the island representing the governing body of the Private Health Services Regulatory Council, out of the complaints submitted in 99 occasions to the Sub-Committee on Complaints, held from 2017 to 30 June 2023. Complaints on unfair charging, problems related to medical and the other staffs, allegations related to treatments, allegations related to professional ethics, allegations related to the death of patients as well as allegations related to kidney trade, and the Flying Squad Division of the Ministry of Health had received 72 complaints in the period of 04 years from the year 2019 to the year 2022 regarding the professionals working in private medical centres instead of working in government hospitals during the duty hours as the private hospitals rely on the professionals of government health services due to the lack of human resources.

Although it has been stated in the Act that one of the tasks of the Private Health Services Regulatory Council is to collect and publish relevant health information and statistics, the data related to private health services had not been included in the National Data System. It was also observed that the Department of the Registrar of Companies had no methodology of obtaining registered data according to institutional categories and non-availability of an accurate data system related to private health institutions in any government institution.

The matters such as the sub-committee on technical evaluation and waste management aimed at making recommendations regarding the supply of orderly disposal/destruction of waste in private medical institutions/centres and making recommendations regarding the provision of incinerator machine required for waste disposal equipment to the respective provincial councils on a temporary basis had not met from 2017 to 31 December 2023 and 10 complaints out of the 19 complaints, i.e. 52.6 percent received by the Central Environmental Authority, received on functioning of private health service institutions in the past 3 years without complying with the environmental laws and regulations, i.e. not disposing of clinical waste properly were private hospitals that represent the members of the governing board of the Private Health Services Regulatory Council were majorly observed.

In order to minimise these deficiencies related to private medical institutions established in Sri Lanka, the Parliament should pass a new regulatory act solely for the regulation of private health services, or one of the objectives of the existing Act, which was to improve the growth of private medical institutions, should be removed from the objectives of the Act and amending the existing act with a suitable governing body for regulation of the private health services, reorganizing the regulatory agency by amending the authorized officers mentioned in the act, submitting and approving in the Parliament the regulations published in the gazette according to the act and, preparing

rules and publishing them in the gazette by the minister and enforcing them, to ensure that private medical institutions have the required trained staff and to ensure compliance with the national recruitment criteria while recruiting professionals, to prepare standards for hospital charges for various services, to develop a code of ethics for professionals and organizations and ensure that professionals and organizations adhere to it, to ensure that the national information system receives information from private health institutions, to place private health medical institutions under the coordination of an officer working in the offices of the Medical Officer of Health to regulate private health medical institutions at the local level, to establish a transparency in relation to the information on the methods of charging fees and update of these information systems in the relevant websites for achieving the goal of ensuring healthy lives and promoting well-being for all at all ages under Sustainable Development Goal 3 through the contribution of both the public and private sectors are recommended.

2. Introduction

2.1 Background

2.1.1. The beginning and expansion of private health service

The beginning of private healthcare goes back to the distant past even before Sri Lanka gained independence. According to information reported, the British government recognized the need for private medical services for the people of Sri Lanka with the end of the Second World War, and took over the military hospital where the wounded soldiers were staying and established a hospital named as Ceylon Hospital in 1945 and it is now known as Durdans Hospital. Moreover, the Nursing Homes (Regulation) Act No. 16 of 1949 was introduced to regulate the centres established under the name of Nursing Homes. These medical institutions, which were established for the treatment of the middle-class elites who had a high level of purchasing power, later began to be established in the main cities of the island with the open economic system in 1977. The people who can dedicate a part of their income for medical purposes were attracted to these private hospitals due to the high quality medical equipment, attractive care and services, efficient service.

According to a survey report published in 2014 under the title Health Care in Sri Lanka- What Can the private Health Sector Offer under Human Development Network project of the World Bank, when medical officers of the government were allowed to engage in dual practice after 1977, the people who were in long queues for treatment in public hospitals due to the severe congestion of the government hospitals, gradually started to draw towards these hospitals. Moreover, according to the National Health Information Publication - 2020, the minimal conditions such as the number of government hospitals in the island was 646, the number of doctors per 100,000 population was 98, the number of dental surgeons was 7, the number of nurses was 212, and the number of hospital beds per 1,000 population was 04 were prevailed and the extension of these centres grew as the public got used to obtain even general treatment from specialist doctors. Furthermore, people who do not have economic viability also seek the services of the private sector due to the problems in the health service offered by the public sector or due to high quality health care offered by private health centres. According to the information given to the audit by the Private Health Services Regulatory Council, a brief note about the private medical institutions that were registered with the institution is given below.

Type of Private Medical Institution -----	2020 -----	2021 -----	2022 -----	2023 -----
Private Hospitals	107	131	162	171
Medical Centres	154	154	183	261
Other private medical centres	51	65	66	149
Private Ambulance Services	8	8	10	12
Full Time Specialist Medical Services	2	3	02	03
Part time Specialist Medical Services	4	3	03	06

Full Time Dental Services	35	26	36	42
Part time Dental Services	24	14	19	45
Full Time General Dispensaries	157	133	111	152
Part time General Dispensaries	276	219	204	430
Private laboratories	381	438	469	648
Grand total	1199	1194	1265	1919

2.1.2 Health Insurance

(a) Life Insurance Schemes/Health Insurance Schemes

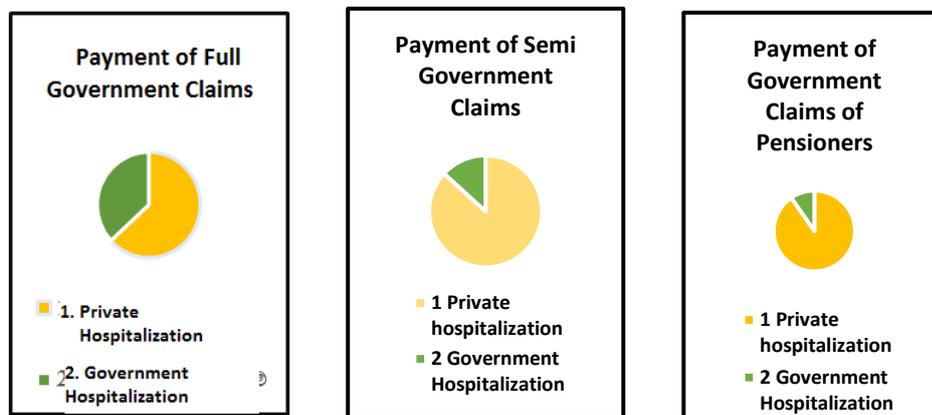
The speed of people being drawn to private medical institutions has increased with the introduction of life insurance systems/health insurance systems as a new frontier in insurance, and with the aim of increasing the welfare of employees in the private sector, and providing the facility of reimbursement of medical assistance on the basis of insuring employees under various insurance covers. This is confirmed by the growth of the number of health insurance policies from 11,893 in 2017 to 31,380 in 2021. According to the 2021 annual report of the Insurance Regulatory Commission of Sri Lanka, this is further confirmed by the fact that the health insurance sector has occupied the second place in the general insurance business.

(b) Agrahara Insurance

Agrahara Insurance Scheme is the largest medical insurance scheme in Sri Lanka and its membership has exceeded 845,000 since the introduction of Agrahara Insurance Scheme for Government Employees in 2006. This covers nearly 2.3 million Sri Lankans and their families. This is a contributory system and a monthly contribution is levied from all pensionable government employees. This Agrahara insurance scheme is also available for semi-government employees. There is also a strong demand for the Agrahara Retirement Insurance Scheme, which was introduced from May 2016, and thus the speed of the government employees and retired government employees flocking to private medical institutions for treatment has increased. Agrahara claim payment details for 2022 are given below.

Type of Claims -----		No. of claims paid -----	Value of Claims (Rs. Million)
Payment of full government claims			
1	Private hospitalization	15,479	1,286.68
2	Government Hospitalization	58,775	750.46
Payment of semi government claims			
1	Private hospitalization	1,764	158.21

2	Government Hospitalization	1,968	24.43
Payment of government claims of Pensioners			
1	Private hospitalization	1,450	66.46
2	Government Hospitalization	1,158	7.02



(Source-Official website of Agrahara Insurance Trust Fund as at 23 August 2023)

2.2 Strengths and Weaknesses of the Private Health Sector

As outlined under the National Health Strategic Master Development Plan, the infrastructure of the private health sector is huge and millions of rupees have been invested in it. However, there are many facilities and hi-tech equipment and technological facilities but equally lack of human resources. It has been mentioned that due to the heavy dependence on the health care professionals of the public sector health services for the functioning of those hospitals, they are facing severe obstacles. It is also stated that human resources should be developed to meet the demands of the private health sector and the matters such as the mission of this sector to streamline the registration of private medical institutions, prepare standards and guidelines, and enhance the performance of the private health sector by providing technical guidance and support for human resource development were also indicated under this development plan. However, the quality of health services provided by the private health sector is seriously threatened by the inadequacy of qualified and trained staff for the continuous 24 hours a day, and the quality of the health services provided by the public sector has been hindered by paying more attention to health institutions in the private sector due to financial benefits. It has been stated that basic education courses and new courses / courses to fill the gaps in the field of nursing and nursing assistants will be implemented to meet the demand of the private health sector, and the basic course and a new / gap filling course for dental assistants are being carried out.

As outlined under the National Health Strategic Master Development Plan, there has been a conversation since recently about the excessive fees charged by the private health sector. Individual patients and relatives, community groups of patient rights organizations, journalists, professional groups and politicians began to raise their voice

on the excessive charging by private hospitals, health professionals and even private medical laboratories. Public interest had been created, and the Private Healthcare Regulatory Council responded immediately by carefully analyzing the situation with many consultations from relevant stakeholders. Setting of maximum fees for specialist consultations and the development of administrative fees for specialist consultations was initiated, and secondly, the Private Healthcare Regulatory Council was interested in setting maximum fees for 33 commonly performed medical laboratory tests for large-scale laboratories as well as for medium and small-scale laboratories. Private hospitals, channeling centers and private medical laboratories were requested to refrain from charging fees exceeding the maximum charges and informed to charge less if required to do so and charges for various other procedures are being developed. The Consumer Affairs Authority (CAA) has also issued a gazette notification and it has also been stated that the private medical sector has been informed to issue a detailed bill for customers, who pay more attention to consumer rights.

2.3 Regulation

Health services in the public sector are regulated by the Ministry of Health, offices of Provincial Director of Health Services, offices of Regional Director of Health Services and offices of Medical Officers of Health. Moreover, the Ministry of Health has established a separate division under the leadership of a director called the Private Health Development Division for the development of the private health sector. Moreover, a separate semi-government body called the Private Health Services Regulatory Council has been established under the Private Medical Institutions (Registration) Act No. 21 of 2006 for the regulation of private medical institutions.

Accordingly, the Private Health Service Regulatory Council is a regulatory council established under the Private Medical Institutions (Registration) Act, No. 21 of 2006, certified on 14 July 2006 to execute and carry out the said duties and functions.

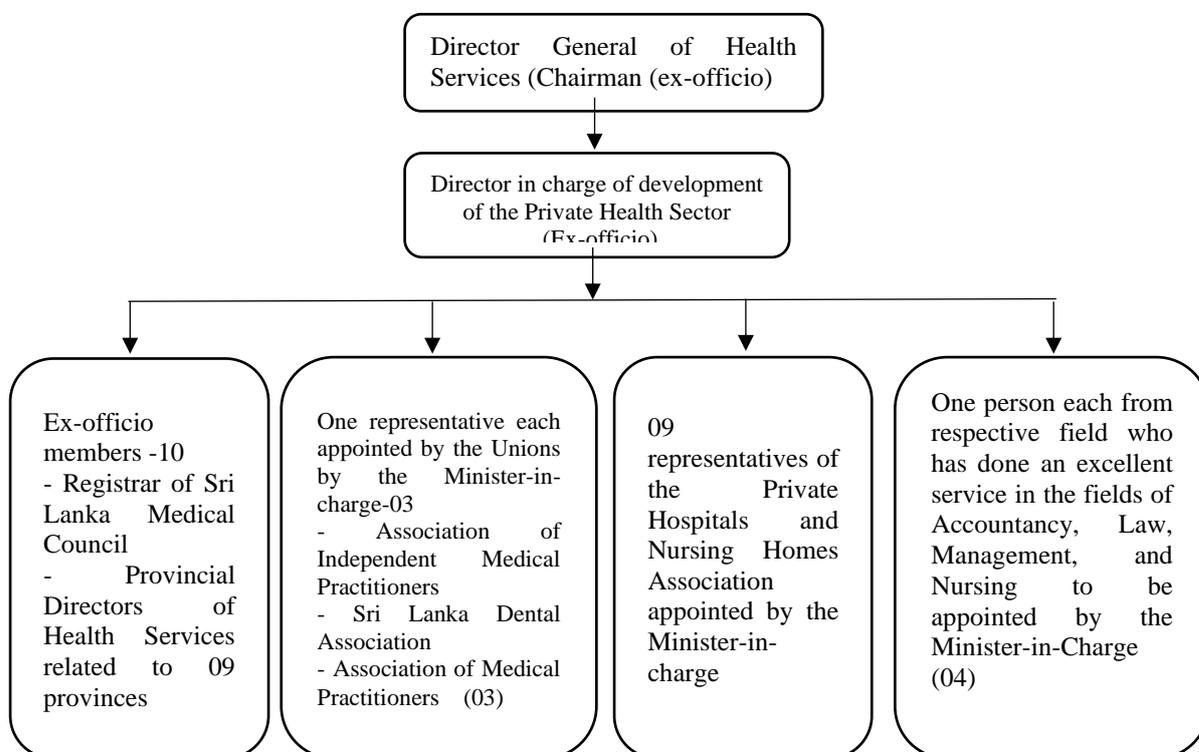
According to section 20 of this Act, it has been indicated that Private Medical Institution” means any Institution or establishment used or intended to be used for the reception of, and the providing of medical and nursing care and treatment for persons suffering from any sickness, injury or infirmity, 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.

Accordingly, it has become a requirement of the government to prepare a national policy related to the provision of medical services through private medical institutions and to identify how those services should be provided in order to achieve those objectives for the provision of a safe and efficient medical service to the public. Therefore, the Private Medical Institutions (Registration) Act No. 21 of 2006 provides 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.

The Private Health Services Regulatory Council aims at developing and monitoring the standards to be maintained by registered private medical institutions, and acts as a method of evaluating the standards maintained by such private medical institutions. It is further the objective of the Council to ensure that minimum qualifications for recruitment in the recruitment of employees and to ensure that minimum standards of staff training are followed by all the private medical institutions and to ensure the quality of care services for patient provided by those private medical institutions.

Moreover, formulation and supervision of quality assurance programmes for the care of patients in private medical institutions and to exercise the powers, duties and functions of the Council in maintaining minimum standards for the recruitment of all staff engaged or employed in such services, and it shall be the responsibility of the Private Health Services Regulatory Council to collect related health information and statistics and publish them and to implement a system of grading according to the facilities provided by the relevant private medical institutions and to perform such other functions as may be necessary to achieve the objectives. The composition of the governing body of this Council is as follows.



2.4 Authority for Audit

The audit was conducted under my direction in accordance with Article 154(1) of the Constitution of the Democratic Socialist Republic of Sri Lanka and the provisions of the National Audit Act No. 19 of 2018.

2.5 Audit Approach

(a) The health of the people is very important when considering the factors such as uplifting the human capital and the improvement of the living standards of the people, out of the fundamental factors that should be included in the strategic plans that are necessary for the development of a country. The social cost of not having a healthy nation may be an obstacle for the development of the country. Accordingly, the details of the expenditure incurred for the health sector as a percentage of national expenditure of Sri Lanka in the last 15 years were as follows.

Year -----	Gross National Expenditure Rs. Million	Health Expenditure ----- Rs. Million	Health Expenditure as a Percentage of National Expenditure -----
2006	713,145	54,363	7.60
2007	885,952	63,464	7.20
2008	996,126	68,604	6.90
2009	1,747,064	67,448	3.90
2010	1,751,113	80,027	4.60
2011	1,961,053	82,179	4.20
2012	2,192,234	89,291	4.10
2013	2,411,606	120,346	4.90
2014	2,601,723	155,008	5.96
2015	3,203,280	181,122	5.65
2016	3,106,443	192,535	6.20
2017	3,470,589	206,182	5.94
2018	3,970,636	234,899	5.92
2019	4,075,827	262,436	6.44
2020	4,457,390	250,813	5.63

Source - Annual Health Statistics

When considering the health expenditure of Sri Lanka during the period from 2006 to 2020, although the amount incurred out of the national expenditure for health in Sri Lanka had increased from Rs. 54,363 million to 250,813 million, the amount incurred out of the national expenditure for health in a percentage basis had ranged between 3.9 percent to 7.6 percent. Although the highest percentage of the initial year used for these comparisons was quoted, it had largely fluctuated afterwards and then taken a lower percentage. Therefore, the trend of patients in turning towards private hospitals rather

than turning to Government hospitals had developed due to the insufficiency of physical facilities and medicines in hospitals.

Due to the existence of a trend of encountering various issues/difficulties in comparison to the trend in obtaining the services of the service institutions including private sector hospitals by both the affluent and poor persons in this manner, the requirement of inquiring analytically how effective the regulatory measures taken by the Government sector to minimize these issues has emerged.

- (b) The number of private health institutions registered by the Private Health Services Regulatory Council from 2017 to 2023 stood at 1114, 1395, 1502, 1199, 1194 and 1919 respectively. Accordingly, the number of private health institutions registered in 2017 had gradually increased in 2018 and 2019 and it had reduced in 2020 and 2021 and had again increased in 2023. Although the number of private institutions providing health services across the island had increased to more than 6000, the institutions had not conformed to a proper regulatory framework. As a result, not only the patients but also the whole society at large had to face problems and thereby this had been converted in to a complex social and economic issue beyond the realm of the health sector.
- (c) Due to the increase in the quality of living standards / literacy of the people, the increase in the risk of getting non-communicable diseases and the increase in the aging population, the number of people seeking preventive services has grown rapidly and they have turned to private health services. Therefore, problems have arisen in the provision of higher quality services to the people in the private health sector.
- (d) It had been revealed at the audit of annual financial statements that it has been failed to prepare and implement a formal methodology to discharge the functions of the development and monitoring of standards to be maintained by the registered Private Medical Institutions; the method of evaluation of standards maintained by such Private Medical Institutions; to ensure that minimum qualifications for recruitment and minimum standards of training of personnel, are adopted by all Private medical Institutions; to ensure the quality of patient care services rendered or provided by such Private Medical Institutions As per Section 09 of the Private Medical Institutions (Registration) Act, No 21 of 2006,.

The above mentioned issues have provided the access to carrying out this performance audit.

2.6 Audit Objectives and Criteria

Main Objective of the Audit

Evaluating the legal background related to the Private Medical Institutions established in Sri Lanka, their operation and the performance of the relevant government agencies related to the regulatory process.

Sub-objectives of Audit -----		Criteria -----	Sources -----
2.6.1	Evaluation of the legal background and registration process related to Private Medical Institutions	i. Private Medical Institutes should be regulated as per the National Health Policy of Sri Lanka	National Health Policy of Sri Lanka (2016-2025)
		ii. The laboratories of private medical institutes need to be regulated as per the National Health Laboratory Policy.	National Health Laboratory Policy (2006)
		iii. Private Medical Institutes should be registered under the Private Medical Institutions (Registration) Act No. 21 of 2006.	Private Medical Institutions (Registration) Act No. 21 of 2006.
		iv. The fees prescribed by the Extra-ordinary Gazette No. 1489/18 dated 22 March 2007 should be charged.	Extra-ordinary Gazette No. 1489/18 dated 22 March 2007
		v. Private Medical Institutes should be regulated as per the decisions of the Governing Board Meetings.	Decisions of the Governing Board Meetings of the Private Health Services Regulatory Council.
2.6.2	Evaluation of whether the Private Medical Institutes provide a qualitative, reasonable and satisfactory service to the patients and the contribution being extended by the	i. Having accomplished the tasks under Sections 10 (a) to (e) of the Private Medical Institutions (Registration) Act No. 21 of 2006.	Private Medical Institutions (Registration) Act No. 21 of 2006
		ii. Having made and implemented the regulations under the Section 18 of the Private Medical Institutions (Registration) Act No. 21 of 2006.	Private Medical Institutions (Registration) Act No. 21 of 2006

	relevant government agencies for such provision.	iii. Having made and implemented the regulations under the Section 19 of the Act.	Private Medical Institutions (Registration) Act No. 21 of 2006
		iv. The Private Medical Services should be constantly supervised by the government as per the National Health Policy of Sri Lanka (2016-2025), and whether services with higher standard are provided to the parents at an affordable cost should be certified.	National Health Policy of Sri Lanka (2016-2025)
		v. The proceedings should be made in accordance with the guidelines issued by the Regulatory Council.	Guidelines issued by the Private Health Services Regulatory Council.
2.6.3	Evaluation of the coordination and participation among the institutions for the regulation of health activities, and the process of maintaining data and information and communicating to the related sectors by the Private Health Service institutions	i. As per the National Health Policy of Sri Lanka (2016-2025), more attention should be given for patients' rights and an appropriate methodology should have been established to obtain systematically updated information about the health facilities being provided in all public and private sectors as well.	National Health Policy of Sri Lanka (2016-2025)
		ii. Policy declaration No. 2.2 of the National Policy on Health Information 2017.	National Policy on Health Information 2017
		iii. Methodology of reporting information to e-IMMR Information System and Regional Health Information System.	e-IMMR Information System
		iv. Methodology of reporting data / information to the Private Health Services Regulatory Council.	Private Medical Institutions (Registration) Act No. 21 of 2006

2.6.4	Evaluation of the contribution given by the Private Health Service Institutions in parallel with the Public Sector to maintain the health service of the country.	Providing sufficient contribution to maintain the health services of the country by the private medical institutions	<ul style="list-style-type: none"> • Research reports • Annual Reports of the respective institutes.
-------	---	--	--

2.7 Audit Methodology

Below-mentioned audit methodologies were followed.

- (a) Study on legal background related to Private Medical Institutes (National Health Policy and National Multi-Sectoral Action Plan, Respective Acts, Orders, Guidelines, Circulars)
- (b) Having discussions with relevant officers.
- (c) Studying about the data regarding the private medical institutes.
- (d) Analysis of complaints received from varied parties regarding the Private Medical Institutes.
- (e) Information about the registration and supervision of Private Health Services Institutes was obtained from the Provincial Directors of Health Services.
- (f) Information of public petitions about the Private Health Services Institutes was also obtained from Consumer Affairs Authority, Central Environmental Authority and Flying Squad Unit of the Ministry of Health.
- (g) Studying the reports of the researches conducted regarding the Private Medical Institutes.
- (h) Studying the reports issued by the World Health Organization regarding the Private Medical Institutes.

2.8 Scope of Audit

- (a) Since the accurate data about the number of Private Health Services Institutes functioning in Sri Lanka are not available in any public institute, this audit was carried out based on the data being maintained by the Private Health Services Regulatory Council.
- (b) This audit does not include the Pharmacies being maintained by the private sector and only the public petitions that have been received about the medicines given to the residential patients by the private hospitals were considered.
- (c) A physical inspection was not done by the audit on whether the private health service institutes are started and maintained in line with the relevant criteria, and the audit observations were made based on the public complaints received from various parties in that connection.

- (d) The attention was paid only about the basic training related to the human resource of the private health service institutes and the professional rights / privileges of those employees are not discussed in this audit.

2.9 Limiting the Scope of Audit

As an accurate data system about the contribution of private health service institutes to the public sector to maintain the health service of the country is not available and as the census conducted at MOH Office level since 2017 has not been completed even by the time of the audit, full trust could not be kept on the data related to the private health service institutes that are already maintaining the health services.

Also, even if the arrangements were made by the audit selecting a random sample of the existing private health service institutes in the country and accompanying a representative nominated by the relevant Provincial Director of Health Services to physically check by the audit officers about whether the relevant private health service institutes have been duly registered; whether the data submitted by the registered private health service institutes at the time of registration is correct, whether the confirmations given by the government officials after checking the relevant private health service institutes according to the registration application forms are correct, whether the orders published in the gazette by the Private Health Services Regulatory Council are implemented by the relevant private health service institutes and to identify the other deficiencies in the respective private health service institutes, the related physical audit activities were stopped due to the objection raised by a private hospital owner who is also a member of the Private Health Services Regulatory Council and the President of the Private Hospitals and Nursing Homes Association. Although the Director General of Health Services was requested on 08 December 2022 to provide an opportunity for that, it was not possible to obtain the actual information planned to be obtained through the relevant physical audit as the said opportunity was not given till the date of this report.

In this audit, more accurate analysis was hindered as the information requested from the Secretary to the Ministry of Health and the Chairman of the Private Health Services Regulatory Council from time to time was not provided within the specified timeframe and the required information was not presented completely and in the manner requested.

3 Detailed Audit Findings

3.1 Health Policies and Plans

3.1.1 National Health Policy

The National Health Policy of Sri Lanka; which had been introduced as per the Cabinet Memorandum No. 17/1366/718/084 dated 25 June 2017 presented by the Minister of Health, Nutrition and Indigenous Medicine for a ten-year period (2016-2025) identifying the main policy directives called strengthening service delivery to achieve preventive objectives, providing an appropriate and accessible patient care services with a high quality for all Sri Lankan citizens, promoting the equitable access to quality rehabilitation care services, establishing a planning method based on the data of service delivery to strengthen the continuous health service delivery systems, minimizing the circumstances where patients have to spend money personally, securing a comprehensive system through better restructuring including human resource management and building strategic partnerships with all healthcare providers, had been approved at the Cabinet Meeting held on 18 July 2017 with the recommendations of the President.

The facts that the patients have to spend their own money to receive treatment, i.e. developing new strategies and ensuring qualitative services to reduce the financial risk of the patients, and regulating the private health sector to protect the patients from financial risk had been identified within this policy in relation to the scope of our audit.

3.1.2 Health Master Plan (2016-2025)

The above-mentioned National Health Policy of Sri Lanka 2016-2025 and the related Health Master Plan (2016-2025) had been approved in the Cabinet meeting held on 18 July 2017 with the recommendations of the President. In the Curative Service section of this Health Master Plan, the problems related to the unregulated private health sector and the proposed strategies had been identified in the Thematic Area No. 2.8 as follows.

Ref. No. -----	Problems identified -----	Proposed Strategies -----
2.8.1	Shortage of Human Resource, Full-time doctors, Trained Nurses and other categories.	Confirming that the services of full-time doctors, trained nurses and other categories can be obtained.
2.8.2	Inadequate and unsuitable regulatory mechanism.	➤ Strengthening the regulatory mechanism. ➤ Making standards on hospital charges for varied services.
2.8.3	Availability of regulations being partial in taking the regulatory decisions of the institutes.	Restructuring the regulatory institute.

2.8.4	Non-maintenance of professional and institutional ethics.	<ul style="list-style-type: none"> ➤ It is required to ensure that the professionals and institutes follow an ethical system. ➤ National Recruitment Criteria should be certified as being followed when the professionals are recruited.
2.8.5	Unavailability of private sector information.	That the information is received to the National Information System should be ensured.
2.8.6	Non-implementation of national guidelines by the private sector	Making sure that National Guidelines and Clinical Management are followed.
2.8.7	Wasting time of experts for general practices	<ul style="list-style-type: none"> ➤ Increasing the awareness of the general public. ➤ Promoting the referral system. ➤ Linking the General Practices to identified population.

In the proposed strategies to reduce the problems of regulating the private health sector as above have been identified by the year 2016, the audit observations about the non-achievement of a positive progress by the Ministry of Health subsequent to following those strategies will be discussed in next paragraphs.

3.1.3 National Health Strategic Master Plan (2016-2025)

An expectation of the government and especially the Ministry of Health as the central point under the Director Board of Private Health Sector Development under the program related to regulation, development and strengthening of the private health sector in the Curative Service section of the National Health Strategic Master Plan - 2016-2025 related to the National Health Policy 2016-2025 is that even the private health sector provides quality, efficient and safe health service to its clients. Consequently, it has been informed that the Ministry of Health has recognized its responsibility towards the people of the country and established a mechanism for the development and regulation of the private health sector. Also, in order to fulfill this responsibility, it has been stated that the Director Board of Private Health Sector Development was established for the first time in 1998, the Private Medical Institutions (Registration) Act No. 21 of 2006 was introduced and implemented with effect from 15 December 2006, and the Private Health Services Regulatory Council is the body established to exercise and perform its powers, duties and functions from the year 2006 and its acts as a system of evaluating the standards maintained by registered private medical institutes, and that it further expects to achieve the objective of certifying the minimum qualifications for recruitments and adopting the minimum standard by the private medical institutes for training of personnel as well as ensuring the quality of patient care services.

Further, strengthening the regulatory mechanism of the private health sector, human resource development to meet the demands of the private health sector, adherence to

national guidelines and treatment protocols by the private health sector, getting health information from the private health sector into national data system, connecting to a population prescribed for general practice and developing a proper referral and re-referral system and other particulars had been mentioned as the target areas related to this section of this Strategic Master Development Plan and the audit observations about the circumstances where the attention was not given to these points /adequate attention was not given to these points have also been presented in paragraphs 3.2 to 3.19 of this report.

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

3.2.1 The objectives of adopting the Act

This Act had been passed to make provisions to register, regulate, supervise and inspect the private medical institutes; to improve the growth of those institutes; and to make provisions for all matters related or incidental thereto. According to the preamble of the Act, it is stated “As it has become necessary for the Government 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”. Consequently, it was observed that the objective of this Act is not restricted to the regulation of private medical institutes, but also aims to improve the growth of private medical institutes. Within the efforts being made to achieve these two objectives through a single Act, the private medical service which is currently very widespread in the country has been adversely affected on its turning into a service that provides a quality and responsible safe service to the public. It has currently been identified that the private investments in the country should be expanded and that the private sector should give more contribution to the economy, and relief has been provided by various Acts for that purpose. In this circumstance, the private medical service is also being expanded day by day, and as the health service is a very sensitive service that should be subject to formal regulation in a manner that ensures the safety of the lives of the public, and as it is the prime responsibility and duty of the government to act on behalf of it, the requirement to establish and implement a strong regulatory mechanism rather than the existing regulatory mechanism for the regulation of the private health service was observed.

3.2.2 Composition of the Private Health Services Regulatory Council

Private Health Services Regulatory Council was established to perform the functions as per the Section 6 (1) of the Act, and this council had been overall consisted with following twenty eight (28) members.

Category -----	Member Details -----	Number -----	Total -----	Percentage -----
Ex-officio Members	Director General of Health Service (Chairperson)	01		
	The Director of the Ministry of Health in-charge of development of the Private Health Sector (Secretary);	01		

	The Registrar of the Sri Lanka Medical Council; and	01	12	43
	The Provincial Director of Health Services of each Province	09		
Members appointed by the Minister	Member of the Independent Medical Practitioners Association	01	16	57
	Member of the Sri Lanka Dental Association; and	01		
	Member of the Society of General Medical Practitioners	01		
	One person each to represent the fields of Accountancy, Management, Law and Nursing: who has rendered distinguished service in the respective field	04		
	Representatives from the Association of Private Hospitals and Nursing Homes	09		
	Total Members		----- 28 =====	----- 100 =====

It was not confirmed that the Governing Body of 28 members that has been appointed under Section 6 of the Private Medical Institutions (Registration) Act No. 21 of 2006 to carry out the works of this Act has proceeded as an appropriate and independent Governing Body to regulate the private health institutions in the country as institutions that provide safe and efficient services to the public. Although it has been 17 years since the Act was passed, it had not been able at least to make regulations regarding the tasks authorized under the Act and publish in the Government Gazette and approve by presenting to the Parliament, prepare rules regarding the matters authorized by the Act and the obtain the approval of the Minister in charge of the subject and publish in the Government Gazette or at least to register all the private health institutions in the country which is an essential requirement of the Act. Also, the registration fees introduced in 2007 had not revised for 16 years until the amendments were made according to the 174th Governing Council meeting held on 15 September 2023. When these facts were considered, it was observed that there is a need to pass a new parliamentary act included with appropriate provisions and a composition of the governing body to regulate the private health institutions in the country or to amend the existing act appropriately for the regulation of private health institutions.

3.2.3 Decision given by the Supreme Court regarding the composition of the Governing Body.

The Private Medical Institutions (Registration) Bill for the regulation, monitoring, supervision and inspection of private medical institutions and all matters connected or incidental thereto had been presented to the Parliament on 23 June 2000 by the Minister of Health. According to a petition submitted to the Court by the Association of Private Hospitals and Nursing Homes which was not an incorporated body at that time and its Secretary, it was decided that $\frac{1}{3}$ of the governing body should be represented by the representatives of the Association of Private Hospitals and Nursing Homes in order to pass this Act by a simple majority in the Parliament. As the inclusion of improving the growth of private medical institutions within the objectives of this act has influenced

this decision, and as it is a prime and indispensable responsibility of the government to make the private medical institutions operating in the country into institutions that provide safe and efficient services to the public as specified above and to regulate these institutions so as to confirm the said fact, the need of passing and implementing a suitable regulatory act for that purpose was observed. Herein, the need of creating a new regulatory agency or structure with legal provisions in order to regulate private health service so that the public can get a more safe, quality and efficient service at affordable and fair rates was observed.

3.3 Representation of the Provincial Councils

According to the 13th amendment of the Constitution of the Democratic Socialist Republic of Sri Lanka, the subject of health has been decentralized to be implemented at Provincial Council level and the Provincial Directors of Health of the nine provinces of the island are included among the twenty-eight (28) members of the Governing Body of the Regulatory Council of the Private Health Services established to implement the functions of the Private Health Institutions (Registration) Act No. 21 of 2006 in respect of regulating the private health sector, and they also contribute at the provincial level on checking whether the relevant criteria have been met in the registration of private health institutions and carrying out on-site inspections when necessary. The attendance of the Provincial Directors of Health Services for the meetings of governing council during the last 5 years was at a poor level, and an adequate contribution was not given by the Provincial Directors of Health Services to maintain specific information about the Private Medical Institutions operating in the province or to take legal actions against the unregistered Private Medical Institutions. Also, even if 50 percent of the income received from the registration of private medical institutions located in the respective provinces should be credited to the respective provincial council fund under the specific provisions stipulated in the Act, the Private Health Services Regulatory Council had continuously delayed giving this amount to the provincial councils. Although this situation has been pointed out by the audit for many years, it was observed that the provision of 50 percent of the revenue to be given to these provincial councils continues to be delayed.

3.4 Not defining "authorized officers" properly.

As stated under the title “Development and Strengthening of the Regulation of the Private Health Sector” in the Section of Curative Service in Volume II of the National Health Strategic Master Development Plan approved by the Cabinet of Ministers on 18 July 2017, it had been stated that "the Director General of Health Services shall be the Chairman of the Council, the Director of Private Medical Sector Development shall act as the Secretary of the Private Health Services Regulatory Council and the Registrar of the Sri Lanka Medical Council and the Directors of Health Services in 09 Provinces shall be appointed on ex officio basis, 09 representatives from the Association of Private Hospitals and Nursing Homes and 16 members shall be appointed by the Minister and consequently the constitution of this council has been subjected to challenges as the number of members appointed by the minister is larger than the

number of members appointed on ex-officio basis. Also, "the inclusion of private care providers into the private health service regulatory mechanism and regulatory council is a situation against the good practices and this is a unique/identical situation for Sri Lanka as well as the South East Asian region, and whether the current regulatory mechanism is working effectively or not has been challenged, and; in fact, on the other hand, this has affected the voice of private health service in terms of the composition of the council as well as the decision-making process, and therefore, the Ministry has recognized the necessity of more power and autonomy in the regulations and started the process of amending the Private Medical Institutions Registration Act No. 21 of 2006 to include the members with more positions as well as to define "authorized officers" more accurately. However, the audit observations on not proceeding in line with this perspective are as follows.

- (a) The actions had not been taken by the responsible parties to minimize the above problems stated in the National Health Strategic Master Development Plan or to amend the Act with relevant changes even by the year 2023.

- (b) 16 of the total 28 members of the Regulatory Council or 57 percent of the total number of members, including 03 persons representing 03 societies consisting of medical professionals who run a large number of private medical institutions in the island and 09 from the representatives of the Association of Private Hospitals and Nursing Homes have been appointed by the Minister in charge of the subject, and it is observed that there is a conflict of interest as the decisions can be taken even by the majority of the said 16 members in a certain council meeting since the quorum of a meeting of the regulatory council is 07 and due to the owners of the private health institutions regulated by the regulatory council being members of the regulatory council.

Accordingly, as 09 representatives of the Association of Private Hospitals and Nursing Homes who represent this council have involvement in the ownership of the hospitals where the largest number of patients are treated in the island, a risk of adverse effect of this interest was observed in terms of getting approval from the governing council they represent at a circumstance where a prosecution is required in connection with the offenses related to those hospitals.

- (c) The number of ex-officio members is 43 percent of the total members and as the tendency of those members to participate in the governing board meetings is decreased, the percentage of the participation of the members; who are the owners of the private health institutions, appointed by the minister for the regulation of private medical institutions has increased. Consequently, it was observed that those members can give more influences on the decision-making regarding the affairs of the council. Accordingly, it was observed during the audit that the percentage of the participation of the members; who are the owners of private health institutions, appointed by the minister to regulate the

private medical institutions for 39 times out of 54 meeting times; that is 72 percent, held from the year 2018 to 2023 was at a level between 50 percent and 93 percent.

- (d) As per Section 5 (b) of the Private Medical Institutions (Registration) Act No. 21 of 2006, the Director General of Health Services, who is appointed ex officio as the Chairman, shall preside over all the meetings of the Council and appoint a member from among the members present to preside the meetings in the absence of the Chairman. Also, in 08 meetings out of the total number of 54 meetings held by the regulatory council from the year 2018 to 2023 (31 December), the chairmanship had been held by the representatives of the Association of Private Hospitals and Nursing Homes.
- (e) The complaints submitted in 99 cases regarding the private medical institutions had been discussed from time to time in 14 meetings of the sub-committee on complaints from 2017 to 30 June 2023. Among these 99 complaints, the number of complaints received in relation to 09 leading private hospitals in the island represented by the governing body of the Private Health Services Regulatory Council was 51; that is 52 percent of the total number of complaints, and it was observed that the issues regarding charging unreasonable fees, problems connected with doctors and other staff, problems related to treatments, issues regarding professional ethics, problems related to the deaths of patients and problems related to kidney business are among these complaints. Also, the total number of complaints that had been received regarding the other private health institutions in the island was 48 and it was 48 percent of the total number of complaints.
- (f) In the past 3 years, the Consumer Affairs Authority had received 39 complaints regarding private health service institutions. It was a significant factor that 22 complaints out of these 39 complaints; that is 56 percent, had been received in relation to private hospitals represented by the governing board members of the Private Health Services Regulatory Council.
- (g) Also, during the past 3 years, 108 complaints had been received by the Flying Squad Division of the Ministry of Health regarding private health service institutions. Among these complaints, there were 20 complaints related to private hospitals represented by the governing board members of the Private Health Services Regulatory Council. It was a significant factor that these complaints included the complaints related to charges, human resources, laboratories, deaths and other reasons.
- (h) Even if the number of private hospitals registered in the Private Health Services Regulatory Council in the year 2023 was 171, the members had been appointed to Governing Council so as to represent only a few hospitals continuously and

two members out of these 09 members had been appointed representing the same hospital.

3.5 Participation of the members for the Governing Council meetings and meetings conducted by the Private Health Services Regulatory Council.

According to Section 06 of the Private Medical Institutions (Registration) Act No. 21 of 2006, the provisions have been made regarding the persons who should represent the Private Health Service Regulatory Council, the quorum of a meeting and the removal of members. However, the terms about the period that the Governing Council meetings should be held and the frequency of conducting the meetings had not been made. The facts observed during the audit conducted regarding the participation of the members of the council for the meetings are as follows.

- (a) As per the Section 6(2) of the above Act, it is stated that the Director General of Health Services shall be the Chairman of the Council. Accordingly, the chairman of this council had attended only 03 meetings out of 10 meetings held in the year 2018 and 03 out of 9 meetings held in 2019 and did not participate in all 05 meetings held in 2020. He had participated in 05 out of 08 meetings held in 2021, 06 out of 11 meetings held in 2022, and 04 out of 11 meetings held in 2023.
- (b) According to Section 6(1)(b)(iii) of the above Act, the Registrar of the Sri Lanka Medical Council is also an ex-officio member and he had participated in 04 meetings out of 10 meetings held in 2018 and in all the 09 meetings held in 2019 and he had participated in 03 out of 05 meetings held in 2020 and 04 out of 8 meetings held in 2021. Also, he had participated in very few meetings such as 03 out of 11 meetings held in the year 2022 and only 09 out of 11 meetings held in 2023.
- (c) According to Section 6 (1)(b)(iv) of the said Act, the Provincial Director of Health Service of each province is also an ex-officio member and accordingly the participation of nine Provincial Directors of Health Service of 09 provinces in the regulatory council meetings held from 2018 to 2023 was not an a positive level.
- (d) During the examination of the percentage of participation of the representatives of the three associations namely the Independent Medical Practitioners Association, Sri Lanka Dental Association and Medical Practitioners Association appointed by the Minister according to section 6(1)(a)(i) of the said Act in the meetings of the last 06 years, the Independent Medical Practitioners Association and the Sri Lanka Dental Association represented more than 60 percent and however the Medical Practitioners Association represented only from 25 percent to 63 percent.

- (e) According to section 6(1)(a)(ii) of the said Act, it has been stated that one person from each field of accountancy, management, law and nursing who has done an excellent service from the said fields will be appointed by the minister. It was observed that the percentage of participation of the representative from the field of accountancy in council meetings held during the previous 06 years was at a level of 18 percent to 73 percent, and the representative from the management field had a level of participation from zero to 63 percent, and the representative of the field of law had not participated in any meeting during 2019 and 2021 and shown a participation from 18 percent to 40 percent in the remaining 03 years. Also, even if the representative of the nursing field showed participation from 20 to 63 percent from 2018 to 2021, he had continuously participated in all meetings in the years 2022 and 2023.
- (f) According to section 6(1)(a)(iii) of the said Act, it has been stated that 09 representatives from the Association of Private Hospitals and Nursing Homes are appointed by the Minister. Accordingly, the average of the participation of 7 members out of those 09 was at a level from 38 percent to 72 percent for the 54 meetings held from 2018 to 2023. Only the Chairman of the Association of Private Hospitals and Nursing Homes had attended all the meetings held during these 6 years.
- (g) If a member; appointed as per the section 6(4) of the said Act, does not attend three consecutive meetings of the council without any reason deemed acceptable by the council, it is stated that the said member shall be deemed to have been resigned. However, in case of the members who did not attend the meetings for more than three consecutive terms, the proceedings had not been made as per the relevant section.

Accordingly, it was observed that the above mentioned factors had directly caused the inability of the Private Health Services Regulatory Council to achieve the basic objectives of the Private Medical Institutions (Registration) Act No. 21 of 2006.

3.6 Assigning to perform the functions and duties of the Regulatory Council

According to Section 11 of the Private Medical Institutions (Registration) Act No. 21 of 2006, “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”. It is stated that the member, members or committee so assigned shall perform those functions and duties subject to the general direction and control of the council. Consequently, 08 sub-committees had been appointed by the Private Health Services Regulatory Council; as the Registration Application Evaluation Committee, Office Management Committee, Training Committee, Pricing Committee, Complaint

Committee, Grading Committee, Guidelines Committee, Technical Evaluation and Waste Management Committee. During the sample audit conducted regarding the appointment of these sub-committees and their functions, the following points were observed.

- (a) As per the examination conducted regarding the number of representatives of the Association of Private Hospitals and Nursing Homes; appointed by the Minister in charge of the subject, that had been appointed to the for the 08 sub-committees of the Private Health Services Regulatory Council and the total number of committee members, the percentage of the representatives of the association of private hospitals and nursing homes was from 22 percent to 60 percent from the members appointed for the 8 sub-committees of the council that were in operation by 2022, and the percentage of the representatives of the association of private hospitals and nursing homes from the members appointed for 6 sub-committees of the council that operated in 2023 was from 12 percent to 44 percent. The particulars in this regard are as follows.

	Name of the Committee	Time Period	Total Number of Members	Number of Representatives of the Association of Private Hospitals and Nursing Homes	Number of Representatives of the Association of Private Hospitals and Nursing Homes as a percentage of total number of Members
	-----	-----	-----	-----	-----
1	Registration Application Evaluation Committee	(Up to 2022)	9	2	22
		2023	8	1	12
2	Office Management Committee	(Up to 2022)	10	5	50
		2023	12	5	42
3	Training Committee	(Up to 2022)	8	3	38
		2023	9	2	22
4	Pricing Committee	(Up to 2022)	9	5	55
		2023	10	4	40
5	Complaint Committee	(Up to 2022)	8	4	50
		2023	9	3	33
6	Grading Committee	(Up to 2022)	8	2	25
7	Guidelines Committee	(Up to 2022)	6	2	33
8	Technical Evaluation and Waste Management Committee (Up to 2022)		5	3	60

- (b) In the appointment of representatives for the sub-committees, it was observed that the Chairman of the Association of Private Hospitals and Nursing Homes who is one of the 9 representatives of the Association of Private Hospitals and Nursing Homes had been appointed for all the 8 sub-committees. In addition, it was observed that he represents the Audit and Management Committee and also holds the position of Chairman of the Office Management Committee.
- (c) Representation of 08 sub-committees established from the members appointed by the Minister for the Governing Board of the Private Health Service Regulatory Council; including the 09 representatives of the Association of Private Hospitals and Nursing Homes appointed by the Minister for the Governing Board of the Private Health Service Regulatory Council was from 50 percent to 88 percent by the year 2022, and the representation in 2023 was at a range from 56 percent to 78 percent. The details are given below.

Name of the sub-committee	Number of Total Members	Number of members appointed by the Minister for the Governing Body of the Regulatory Council	Representation of the members appointed by the Minister as a percentage of total number of members
-----	-----	-----	-----
Training Committee -2022 -2023	8	7	88
	9	5	78
Office Management Committee -2022 -2023	10	8	80
	12	9	75
Pricing Committee -2022 -2023	9	7	78
	10	7	70
Complaint Committee -2022 -2023	8	5	63
	9	5	56
Technical Evaluation and Waste Management Committee	5	3	60
Registration Application Evaluation Committee -2022 -2023	9	5	56
	8	5	62

Grading Committee -2023	8	4	50
	9	5	56
Guidelines Committee	6	3	50

- (d) The meetings of the 8 sub-committees appointed by the Regulatory Council had been held in diverse ways in each year and some sub-committees had met in a very limited number of times during a year. The details are given below.

Sub-committee -----	2017 -----	2018 -----	2019 -----	2020 -----	2021 -----	2022 -----	2023 -----
Registration Application Evaluation Committee	Information has not been presented	12	11	8	10	10	10
Office Management Committee	5	8	5	4	6	8	10
Training Committee	5	3	5	3	4	2	6
Pricing Committee	7	2	1	1	3	No	5
Complaint Committee	1	2	1	2	2	2	5
Grading Committee	Information has not been presented						2
Guidelines Committee	Information has not been presented			1	1	1	No
Technical Evaluation and Waste Management Committee	Information has not been presented						

- (e) The quorum for the meetings of any sub-committee had not been decided and it was observed according to the information submitted to the audit that the number of members who participated in the sub-committee meetings was less than 50 percent of the total number of members of the sub-committee.

3.7 Making Regulations to carry out the Functions of the Act

3.7.1 Accreditation of Private Medical Institutions

The following facts were observed in this regard.

- (a) In accordance with section 13(1) of the Private Medical Institutions (Registration) Act No. 21 of 2006, 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 Council to delegate its duties and functions Fund of the Council. Such order should carry all the details specifying the facilities, services and any other factors constituting the criteria for accreditation: However, by June 30, 2023, the orders related to these accreditation activities had not been prepared and made into a law.

- (b) In the guidelines related to private medical laboratory services that were not formally approved by the Private Health Services Regulatory Council on March 19, 2021, there was no emphasis on the need for the relevant institutions to obtain an accreditation certificate.
- (c) Persuasion to be obtained the International standard certificates (ISO Certificates) issued in relation to health services, especially quality certificates such as ISO 17025 / ISO 15189 issued for laboratory services, were not made.

Due to this, it was observed during the sample audit that 08 complaints were received related to informal activities by the laboratories during the period from 2019 to 2022.

3.7.2 Making Regulations under Section 18 of the Act

According to section 18(1) of the Private Medical Institutions (Registration) Act No. 21 of 2006, the Minister may make regulations in respect of all matters authorized by this Act. According to section (2) without prejudice to the powers conferred by sub-section 18(1) it is stated that the Minister may make orders on the advice of the Council in relation to the following 09 matters or any of them. Also, according to Section 18(3) of the Act, it is also indicated that every regulation made by the Minister shall be published in the Gazette and according to Section 18(4) of the Act; every regulation made by the Minister shall be submitted for Parliament's approval as soon as possible after being published in the Gazette.

Information about 09 sections to be prepared and the 02 regulations published in the gazette is given below.

Section of the Act -----	Matter -----
18(2)(a)	The guidelines to be compiled with the provincial Directors of Health Services in the registration or renewal of registration of Private Medical Institutions (Regulations had not been prepared)
18(2)(b)	The rates, charges or other expenses, which shall be recovered or received for any services rendered or performed in terms of the Act,(Regulations had not been prepared)
18(2)(c)	The layout, construction, illumination, additions and improvements and the maintenance of the cleanliness of all the buildings and premises of registered Private Medical Institutions (Regulations had not been prepared)
18(2)(d)	The Circumstances in which cases of infectious diseases may be admitted for treatment and the precautions to be taken in such event (Regulations have not been prepared stating that national guidelines apply to the private sector as well)

18(2)(e)	The adoption of universally recognized precautions for the prevention and control of infections (Regulations have not been prepared stating that national guidelines apply to the private sector as well)
18(2)(f)	The classification of Private Medical Institutions into categories, depending upon services being rendered or functions discharged by such institutions
18(2)(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 (Regulations have not been framed)
18(2)(h)	Charges for accommodations, drugs and services rendered by Private Medical Institutions (Private Medical Institutions (Fees) Orders No. 2 of 2007 have been prepared and published in Gazette No. 1526/7 dated 04 December 2007 but these regulations have not been passed by Parliament. It is stated that these regulations are made under section 18(2)(b).
18(2)(i)	Appointment of competent officers to prosecute actions instituted under this Act (Regulations have not been framed)

3.8 Making Rules to carry out the Functions of the Act

Section 19(1) of this Act provides that the Council may make rules in respect of all or any of the following matters and in terms of Section 19(2) any rule made by the Council shall be in force until approved by the Minister and published in the Gazette. It is stated that it is not. Accordingly, out of the 14 matters that can be regulated in the Act, no rules have been prepared and only 11 guidelines have been prepared. It was not confirmed that the approval of the minister in charge of the subject was received for this guideline and the guidelines were not published in the gazette by the minister.

Matters for which rules can be prepared are as follows.

Section of the Act -----	Matter -----
19(1)(a)	The maintenance of records, books, registers, bills, receipts, returns, statements, forms and other documents by a Private Medical Institution
19(1)(b)	The reports, returns, statements and other information required to be furnished periodically by a Private Medical Institution to the Ministry of the Minister .
19(1)(c)	The minimum size of wards or rooms and the minimum floor space, which should be allotted for each patient.

19(1)(d)	The provisions of adequate latrine and bathing facilities for in-patients and personnel employed in Private Medical Institutions.
19(1)(e)	The machinery, equipment, devices, utensils, apparatus, crockery, fittings, furniture and other requisites of a general or special nature.
19(1)(f)	The immunization of personnel employed in Private Medical Institutions against specified diseases.
19(1)(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.
19(1)(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;
19(1)(i)	Defining staffing patterns including minimum qualification, induction and in-service training and refresher courses that should be followed by such personnel
19(1)(j)	The definition of the specialized departments and ancillary services that should be maintained in terms of special fields of treatment
19(1)(k)	The disposal of refuse and waste matter
19(1)(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.
19(1)(m)	The provision of housing, residential quarters or transport facilities required for maintaining the health of patients; and.
19(1)(n)	The provision of adequate expertise for the maintenance of all institutional assets, machinery and equipment

3.9 Areas not covered by the Act

As stated in the survey report titled HNP-Discussion Paper-2014 (what can the Private Health Sector Offer) published under the World Bank after conducting a survey on the private medical sector in Sri Lanka, the following issues were not covered by this Act.

- (a) It is not specified what are the mandatory duties of private medical centers.
i.e. Submission of morbidity and mortality statistics to Offices of Medical Officers (MOH), notification of notifiable diseases.
- (b) What regulatory action can be taken by the Private Healthcare Regulatory Council if a private medical center has acted in violation of a rule or regulation.
For example:- There is no provision in the Act for the Council to conduct a preliminary or formal inquiry and impose regulatory sanctions such as issuing a warning.

Due to this, there were no provisions in the Act regarding matters such as publishing the name of the erring company, suspension or cancellation of the license.

- (c) The Act did not address the ethical issues surrounding technology assessment and regulation.

For example:- Embryo transfer, storage of human tissue and genetic analysis of human tissue sent abroad are not addressed.

3.10 Failure to Fulfill the Objectives Mentioned in the Act

By December 31, 2023, although 17 years have passed since the passing of the Act, in terms of Section 9 of the said Act, it had failed to develop and monitor the standards to be maintained by registered private medical institutions, to implement a system of evaluation of the standards currently being maintained, ensure that minimum qualifications were followed in recruitment and to ensure that minimum standards were followed in training staff and to prepare and implement a formal system to ensure the quality of patient care services provided and performance of duties.

3.11 Registration of Private Medical Institutions

3.11.1 That registration is essential for operating the private medical institutions

The following facts were observed in this regard.

- (a) Although some programs had been implemented pursuant to the provisions of Section 2(1) of the Private Medical Institutions Registration Act No. 21 of 2006 that all private medical institutions shall be registered and the Regulatory Council to identify, register and enforce the provisions of Section 4 of the Act in respect of unregistered private medical institutions, no successful progress had been made.
- (b) In the year 2017, the Director General of Health Services through the Provincial Health Services Directors had informed them to conduct a census on the private health institutions located in the province and submit information. Thus, up to 31 December 2023, 324 out of 361 Medical Officer of Health offices had received relevant information and 37 Medical Officer of Health offices had not submitted relevant information.
Details of Medical Officer Offices (MOH) for which information is not submitted are shown in Annex No. 01.
- (b) According to the information submitted to the audit by the Private Health Services Regulatory Council on 31 December 2023, the number of private health institutions in Sri Lanka up to that date is 6002, but The Regulatory Council had informed the audit that the data also includes institutions such as Ayurvedic medical institutions and massage centers. However, as on 31 December 2023, the number of registered private health institutions was 1919.

Among these, out of 275 private hospitals reported to be operating all over the island, only 171 institutions were registered on that day. This number was only 62 percent of the existing number of private hospitals. Details are shown in Annex No. 02.

- (c) According to the official website of the Association of Private Hospitals and Nursing Homes, as of November 16, 2023, the number of its member hospitals was 67, but it was observed that the number of active hospitals on that day was 62 and 03 member hospitals were not registered with the Private Health Services Regulatory Council.
- (e) It was reported to the audit that the following problems were faced by the Provincial Health Services Directorates in the process of registering private health service institutions and it was not observed that timely solutions were given to reduce these problems when consulting the relevant committee reports.
 - i. Difficulty in identifying all the private medical institutions in the Western Province as they are large in amount.
 - ii. Cost of transportation and time consuming for all private health institutions.
 - iii. Cost of transportation and time consuming for all private health institutions
 - iv. Absence of checklist for nursing training institutes
 - v. It is difficult to disclose information related to all institutions because information about private medical institutions is only available at the provincial level.

3.11.2 Validity of Registration Certificate

Section 3(3) of the Private Medical Institutions (Registration) Act No. 21 of 2006 provides that a certificate of registration granted under section 3(3) shall be valid for such period as may be specified therein and section 3(4) provides that a certificate of registration is notified to be renewed one month prior to the expiry date and upon payment of the prescribed renewal fees. But the Private Health Services Regulatory Council had not maintained such a system for the last 17 years and in the Governing Body meeting held on August 11, 2023, attention had been focused on the imposition of fines for delays.

3.11.3 Sub-Committee on Evaluation of Registered Applications

The audit observations in this regard are given below.

- (a) For this sub-committee, 08 members of the Governing Body of the Regulatory Council were appointed in 2023, and although there is a representative of the legal field in the governing body who can indicate whether the applications received for registration have met the relevant legal criteria and make decisions

related to the legal environment in which registration cannot be granted, he was not included in the sub-committee.

- (b) The average participation of the members appointed by the minister for 10 sub-committee meetings held up to 2023 was 67 percent.

- (d) In terms of Section 3(1) of the Private Medical Institutions (Registration) Act No. 21 of 2006, each request for a certificate of registration shall be submitted to the Private Health Services Regulatory Council through the Provincial Director of Health Services of the province concerned in the prescribed form, with the prescribed fees and a certificate of registration in accordance with Section 3(4) of the Act, it is indicated that the certificate for registration shall be accompanied by all other relevant documents and a request for renewal as specified in Section 3(1) of the Act shall be made one month prior to the date of expiry of such registration and shall be renewed after payment of the prescribed renewal fees.

However, the Evaluation Committee of Registered Application which met on March 17, 2023 had decided that it is unnecessary to submit applications for renewal of registration through the Director of Health Services of the province excluding the said articles, and that applications for initial registration should only be sent through the Director of Health Services of the respective province and the application already submitted should be brought directly to the Private Healthcare Regulatory Council for updating the registration under online registration through the Director of Health Services of the province This decision was approved in the 170th Governing Council held on 21 April, 2023.

Although five private medical institutions had been given the registration certificate under a coverage approval without obtaining the list of tests submitted by the Provincial Health Services Director during the registration, it was observed during the sample audit of the relevant files that the report had not been obtained by the audit date of July 26, 2023. Thus, arrangement had been made to give registration to these institutions without confirming whether the relevant places were subjected to a physical inspection and all the criteria were met according to the existence of common public life and the regulation of very sensitive institutions through the director of health services of the province.

- (d) The committee had also decided to issue registration to all the private medical institutes that had applied for registration under the online registration system due to technical glitches in the online registration system. Thus, although it was recommended to be registered 29 private hospitals and 10 large-scale laboratories that were approved by the sub-committee for indicating registration applications that met on 09 June 2023 and 32 private hospitals and 05 large-scale laboratories that were approved by the sub-committee for indicating

registration applications that met on 07 July 2023 with immediate effect. The following deficiencies remained in the private hospital registration applications submitted to the Committee of Registered Applications Evaluation which met on 07 July 2023.

Deficit -----	No of hospitals -----
Non-availability of inspection list of Provincial Director of Health Services	05
Lack of relevant details to have a full-time doctor	04
Lack of relevant details to have a full-time nursing officer	02
Absence of Medical Laboratory Technicians (SLMC Registered MLT)	01
Absence of Atomic Energy Authority certification	01
Absence of Central Environment Authority license	12
Non-existence of fire safety certificates	11
Absence of Radiographer -SLMC Registered	04
Failure to meet all relevant criteria	20

3.11.4 Registration of Laboratories

To be read with Section 3 of the Private Medical Institutions (Registration) Act No. 21 of 2006 and under Section 18 of this Act, the Minister of Health under Annex II of the Order published in the Special Gazette No. 1521/26 dated November 02, 2007, the application form had been published for the registration of private medical laboratories. It was observed that the registration done according to this form has the following defects

- (a) Under No. 10 of the said Gazette Notice, it had been asked only about the waste disposal method and the inquiry was not heeded whether the Environmental Protection License (EPL) and Schedule Waste License SWL for the disposal of clinical waste mentioned in the Central Environment Authority Act, had been obtained.
- (b) The National Health Laboratory Policy was approved by the Council of Ministers on 1 December, 2006 and it has been mentioned that this policy covers all laboratories in the government and private sector and after annual inspection that all these laboratories are in accordance with the prescribed standards; licenses should be obtained from the Sri Lanka Accreditation Board. But in the form mentioned in the gazette notification, no attention was paid to asking whether this license has been obtained.

3.11.5 Discrepancy of data on Registered Laboratories

The audit observations in this regard are given below

- (a) By the end of 2016, Sri Lanka Accreditation Board Act No. 32 of 2005 had awarded accreditation to 17 medical/therapeutic laboratories based on ISO-15189:2012. As of 2016, it was observed that the number of private laboratories registered with the Private Health Services Regulatory Council was 374, and it was observed that more laboratories than those licensed by the Accreditation Board were registered with the Private Health Services Regulatory Council.

- (b) It was observed that as of 31 December, 2023, the number of private laboratories registered with the Private Health Services Regulatory Council was 648 and as of December 31, 2022, the number of private laboratories that had obtained an Environmental Protection License (EPL) for the disposal of clinical waste mentioned in the Central Environmental Authority Act was 35. It was observed that the number of private laboratories that have obtained a Schedule Waste License (SWL) is 36. It was observed that a large number of private laboratories that are run without meeting the requirements of the Central Environment Authority Act have been registered with the Private Health Services Regulatory Council.

3.12 Human Resource Development in Private Medical Institutions

The audit observations in this regard are given below

- (a) It is mentioned that the infrastructure of the private health sector is huge as indicated under the program related to the regulation, development and strengthening of the private health sector in the Curative Service section of the National Health Strategic Master Plan 2016-2025, Millions of Rupees have been invested in it, however, there are many facilities and hi-tech equipment and technology facilities but equally facing many hindrance due to the lack of human resources i.e. the works of those hospitals are highly dependent on health care professionals from various government health services. It is also stated that human resources should be developed to meet the demands of the private health sector and the mission of this sector is to streamline the registration of private medical institutions, prepare standards and guidelines, provide technical guidance and support for the development of human resources and develop the performance of the private health sector. The facts of doing are also given.

- (b) Also, it is stated in this plan that the services of medical professionals have been given to the private sector mainly due to the dual practice privilege they enjoy and in addition, the challenge faced by the private sector is different when dealing with nursing and paramedic professionals. The facilities for producing their own health professionals are also severely limited due to many reasons. It

has been stated that the quality of health services provided by the private health sector is seriously threatened by the lack of 24-hour qualified and trained staff and the increased focus on the private sector due to financial benefits may even hamper the quality of health services provided by the public sector, basic education courses and new courses/gap filling courses in nursing and nursing assistant field will be implemented to meet the demand of private health sector and basic course and new/gap filling courses for dental assistants are being planned.

3.12.1 Training of Human Resources in Private Health Institutions

The audit observations in this regard are given below.

- (a) As stated in Section 9 of the Private Medical Institutions (Registration) Act No. 21 of 2006, among the objectives of the Regulatory Council is to ensure that all private medical institutions follow the minimum qualifications in the recruitment of staff and ensure that the minimum standards are followed in the training of the staff. Although the Act did not authorize the Regulatory Council to train the staff of private medical institutions, the Regulatory Council had spent Rs.2, 424,698 in 2019, Rs.540,484 in 2020 and Rs.2,742,700 in 2023 for the implementation of a training program called Refresher Gap Filling Course for nurses working in private hospitals.

- (b) Although orders of the Private Medical Institutions (Registration) No. 1 of 2007 made by the Minister of Health under Section 18 read with Section 3 of the Private Medical Institutions (Registration) Act No. 21 of 2006 should be published in the Extraordinary Gazette No. 1489/18 dated 22 March 2007, these orders were not submitted to Parliament as per Section 18(4) of the Act. It is stated that the registration certificate issued in accordance with the order No. 4 of the Private Medical Institutions (Registration) Orders No. 1 of 2007 should be in the format shown in Schedule "C", but the relevant Schedule was named as Schedule "A". However, this Schedule "C" was amended by an amendment published in the Extraordinary Gazette No. 1510/8 dated 13 August 2007, in which, the person registered to operate a private medical institution "scientifically and medically in the most appropriate condition and of good quality It was stated that certain quality goods, services and facilities should be provided and a staff of trained medical workers should be maintained and the institution should be maintained in good condition by providing unexpired medicines. Also, in the guidelines published by the Private Health Services Regulatory Council, the following criteria were made regarding the staff to be maintained in each private institution.

Guideline number and date -----	Relevant field -----	Minimum staffing standards -----
02 (19 March 2021)	Private Hospitals (Nursing Homes) Maternity Homes	<ul style="list-style-type: none"> ▪ A full time Medical Director ▪ Registered Medical Officers of Sri Lanka Medical Council (full time or part time) ▪ Sri Lanka Medical Council Registered/Private Healthcare Regulatory Council Listed Chief Nurse/Chief Nursing Officer ▪ Registered Nurses of Sri Lanka Medical Council / Registered Nurses of Private Healthcare Regulatory Council ▪ Pharmacists registered with the Sri Lanka Medical Council ▪ Sri Lanka Medical Council Registered X-ray Technologists ▪ Trained supporting staff
03 (19 March 2021)	Medical Centers/ Screening centers/Day Care Centers/Channeli ng Service Centers	<ul style="list-style-type: none"> ▪ Registered Headquarters Medical Officer of Sri Lanka Medical Council ▪ Registered Medical Officers of Sri Lanka Medical Council (full time or part time) ▪ Sri Lanka Medical Council Registered Head Nurses / Trained Nurses ▪ A female nurse or attendant (must always be present at reception) ▪ Sri Lanka Medical Council Registered Medical Laboratory Technologists (MLT) ▪ Dental Surgeon Registered with Sri Lanka Medical Council (Full Time / Part Time) ▪ Registered pharmacists of Sri Lanka Medical Council / Trained dispenser ▪ Sri Lanka Medical Council registered X-ray technologists and trained supporting staff as appropriate

However, it was basically observed during the audit based on the facts mentioned in the allegations included in a sample of complaints received in the past years that a staff with a highly suitable and well-trained staff has not been maintained scientifically and medically according to these guidelines.

Below is a summary of the contents of 33 complaints received by the Ministry of Health/Private Health Services Regulatory Council and 21 complaints received by the Consumer Affairs Authority.

- i. Death of patients due to medication and treatment errors
- ii. That pharmacists pretend to be doctors and treat
- iii. Doctors acting excluding of professional ethics
- iv. There should be a full-time medical director but there is not
- iv. Treating patients by pretending to be doctors
- v. Employment of unregistered doctors
- vi. Providing incorrect laboratory reports
- vii. On the inadequacies of hospital staff
- viii. That medical institutions are maintained without pharmacists

3.12.2 Training Sub-Committee

The audit observations in this regard are given below.

- (a) Eight members were appointed for this sub-committee until March 10, 2023, and in the 169th Administrative Council meeting held in 2023, it was stated that 10 members were appointed, including a nurse training consultant who is not a governing member. Accordingly, out of these 10 members, 7 members (along with two members of the Private Hospitals and Nursing Homes Association) were members appointed by the Minister to the Governing Council. According to a decision taken in the 176th Governing Board meeting held on 10 November 2023, 07 members were appointed for this sub-committee, and there were four members appointed by the minister, a nursing training consultant who is not a governing member. The participation of the members appointed by the Minister to the Governing Body of the Regulatory Council for these sub-committee meetings held until 30 June 2023 was 40 and 75 percent of the number present.
- (b) Only 03 members out of 08 members participated in the training sub-committee meeting held on 10 June 2022 and it was decided to establish. 04 common training centers of 04 hospitals including the hospital represented by one member are present in the meeting held on that day. Also, in the meetings held on 21 October 2022 and 03 February 2023, discussions were held in this regard and in these meetings, among the 03 hospitals that were proposed to be selected as Individual Training Centers, a female doctor who worked there a complaint was submitted on 22 June 2022, regarding the hospital staff and it was mentioned that there has not been a full-time medical director since 2014 (although there should be a full-time medical director according to the Private Health Services Regulatory Council's Guideline No. 02).
- (c) On February 09, 2021, a memorandum of understanding was signed among the three parties, the National Apprenticeship Technical Training Authority, the Private Hospitals and Nursing Homes Association and the Private Health

Services Regulatory Council for the purpose of training the nursing and paramedic teams required by private medical institutions. According to this MoU, the first party was the National Apprenticeship Board, the second party was the Private Hospitals and Nursing Homes Association, and the third party was the Private Healthcare Regulatory Council. According to this MoU, the following courses were planned to be held.

- ❖ Nursing training courses
- ❖ Nursing Assistant (Medical/Dental) Training Courses
- ❖ Interim Medical Staff/Data Technician Training Courses
- ❖ Nursing Tutor training courses
- ❖ Dental Surgical Assistant Training Courses
- ❖ Other courses as per demand
- ❖ Nursing and Paramedic Gap filling courses

This agreement is valid only for 05 years i.e. until February 2026 and it was observed that only 3,232 students have been trained in 05 phases of the above 07 courses which had been held by 30th June 2023.

3.12.3 Complaints Regarding the Human Resource

Audit observations in this connection are as follows.

The following are the particulars with regard to the complaints received to the Flying Squad Division of the Ministry of Health from 2019 to 2022 and out of those complaints, 07 per cent to 83 per cent of compliant are in connection with the human resource. That is, most of the complaints received were related to being employed in private medical centers during duty hours without serving at Government hospitals.

Total number of complaints received	2019	2020	2021	2022
	63	12	18	15
Complaints regarding the human resource	52	07	12	01
percentage	83	58	67	07

3.13 Regulation of fees of the Private Medical Institutions

As has been mentioned under the programmes related to regulation, development and strengthening of private sector in the Curative Service part of the National Health Strategic Master Plan- 2016-2025, there was much public interest regarding the high charges charged by the private sector. Various parties including individual patients and relatives had clamored against the high charges being recovered by private hospitals, Medical Professionals and private laboratories. Accordingly, a requirement has arisen with regard to regulating the charges, and the Private Health Services Regulatory Council had responded by paying attention towards the instructions of related parties and carefully analyzing the situation. Accordingly, it was expressed that revision of maximum charges for specialist consultation and administrative

charges for instructions for a specialist consultation was begun, and secondly, the Private Health Services Regulatory Council had shown interest in prescribing the maximum charges for 33 mostly done laboratory tests carried out by the large scale, medium scale and small scale laboratories. Further, it was requested not to exceed the maximum charges of private hospitals, channeling centers and private medical laborites and in case such a requirement is necessary, a lower charge can be recovered, and it had been stated that a gazette notification has been issued by the Consumers Affairs Authority, and that the private medical sector had been informed that a detailed bill be issued to consumers who are interested in consumer rights. The following facts were observed at the audit carried out in this regard.

3.13.1 Formulation of Directives on Pricing

Evidence had not been provided to the audit to the effect that the private medical institution (charges) directives No 2 of 2007 formulated under section 18(2)(b) of the Private Medical Institutions (Registration) Act No 21 of 2006, published in the Extra Ordinary Gazette No 1526/7 dated 04 December 2007, had not been presented to parliament, and obtained approval as per the provision of section 18(4) of the Act. Further, although it had been mentioned that these directives were formulated under section 18(2)(b), it was observed that the powers for formulation of these directives had been vested with the Minister concerned by section 18(2)(h) of the Act.. As per directive No (2) and (3) of the Private Medical (Charges) Directives Act No 2 of 2007, any professional engaged in medical profession as the case may be or any medical practitioner, Dental Surgeon, Specialist Medical Professional engaged in medical, surgical or dental professions or a General practitioner or any institution providing healthcare services shall.

- “Inform the patient or person accompanying the patient about the charges the medical professional may charge in respect of various services supplied by that each medical practitioner, dental surgeon, specialist medical practitioner or the general medical practitioner.
- Conspicuously display a table of charges to be recovered in respect of the types of services supplied by him or her, at the place he or she runs the clinic or the premises in which the consultation is provided. And or else should see to it that such a table is so displayed.
- “A see to it that, as per the directive No 04 of those directives, when it comes to a private medical institution, a handbook on the charges to be paid by the patient to that institution in respect of the services provided by that institution and a complete table of charges recovered by the specialist medical practitioners at that institution should be given by that institution for the information of the patient”

- According to the directive 05, provided a revision is carried out of the charges or recoveries definitely mentioned in the said handbook or table, it is the duty of such specialist medical practitioners or private medical institutions to update the table of charges or handbook as case may be and make arrangements to mention since when the new charges take effect.
- As per the directive No 06, it is mentioned that any person flouting the provisions of these directives is liable for commission of a crime.

No formal measures had been taken at the relevant institutional level regarding the institutions which did not act as mentioned above and it had been informed that a letter of awareness building in this regard was sent on 09 November 2023 to all medical institutions. The summarized details on the complaints received are mentioned bellow.

- (a) Prior to the conduct of the operation, although a much less cost being mentioned as the likely cost of the operation, there have been instances of earlier estimated cost being inflated on the final bill in a large scale .
- (b) Charging higher hospital charges.
- (c) Charging unfair costs during Covid-19 period.
- (d) Non-producing of detailed bills.

3.13.2 The programme of preparation and implementation of definite cost method for specialist consultations, medical services and surgeries in hospitals and institutions of the private sector.

Arrangements had been made to get a definite Costs Method prepared by a private firm by paying Rs. 2,070,000 thereto for specialist consultations, medical services and operations of the medical institutions and the hospitals of the private sector in the year 2018. However, a case had been filed by 03 private hospitals in October 2018 against the Minister of Health, including 08 more parties, regarding the preparation of maximum charges to be recovered commonly from all private hospitals disregarding the different quality levels of such hospitals. These legal affairs had not been completed by 31 December 2023 and owing to that, the regulation of charges of private medical institutions could not be carried out.

3.13.3 Regulation of charges recovered in respect of laboratory tests.

The following observations were made in this regard.

- (a) According to the letter No CAA/P&M/07/LABT / 2023-01/05 dated 07 June 2023, addressed to the Secretary of the Ministry of Health by the Consumer Affairs Authority, it had been revealed at the survey on the essential laboratory charges across Sri Lanka concluded by the Consumer Affairs Authority as at 10 April 2023, that the laboratory test charges are recovered in the following manner from all districts except for Colombo District.

District	Sample Hospitals		UFR	ESR	FBS	PPBS	ECG
				-----	-----	-----	-----
Kandy	05	Minimum price	390.00	300.00	300.00	300.00	420.00
		Maximum price	620.00	590.00	630.00	630.00	910.00
Matale	05	Minimum price	390.00	340.00	320.00	320.00	500.00
		Maximum price	620.00	590.00	630.00	630.00	910.00
Nuwaraeliya	05	Minimum price	250.00	250.00	200.00	200.00	250.00
		Maximum price	620.00	590.00	630.00	630.00	910.00
Anuradhapura	14	Minimum price	240.00	200.00	150.00	150.00	350.00
		Maximum price	620.00	590.00	630.00	630.00	910.00
Polonnaruwa	05	Minimum price	250.00	275.00	200.00	200.00	250.00
		Maximum price	500.00	500.00	500.00	500.00	400.00
Batticaloa	05	Minimum price	300.00	300.00	150.00	200.00	300.00
		Maximum price	400.00	400.00	400.00	400.00	400.00
Ampara	07	Minimum price	200.00	200.00	150.00	150.00	500.00
		Maximum price	620.00	590.00	630.00	630.00	910.00
Trincomalee	05	Minimum price	300.00	200.00	310.00	300.00	350.00
		Maximum price	560.00	500.00	560.00	560.00	400.00
Mannar	04	Minimum price	300.00	300.00	150.00	150.00	400.00
		Maximum price	500.00	480.00	250.00	150.00	500.00
Vavuniya	05	Minimum price	300.00	250.00	200.00	200.00	400.00
		Maximum price	500.00	500.00	500.00	500.00	500.00
kilinochchi	05	Minimum price	400.00	500.00	400.00	400.00	350.00
		Maximum price	680.00	640.00	690.00	720.00	800.00
Jaffna	06	Minimum price	380.00	320.00	360.00	300.00	400.00
		Maximum price	620.00	590.00	630.00	630.00	800.00
Hambantota	07	Minimum price	200.00	200.00	150.00	200.00	350.00
		Maximum price	440.00	500.00	500.00	400.00	500.00
Galle	09	Minimum price	320.00	275.00	250.00	250.00	350.00
		Maximum price	620.00	590.00	630.00	640.00	1250.00
Matara	05	Minimum price	350.00	350.00	250.00	250.00	400.00
		Maximum price	550.00	450.00	510.00	510.00	600.00
Monaragala	05	Minimum price	200.00	150.00	100.00	100.00	200.00
		Maximum price	330.00	200.00	200.00	200.00	600.00
Badulla	04	Minimum price	288.00	288.00	150.00	160.00	400.00
		Maximum price	620.00	590.00	630.00	630.00	640.00
Puttalam	05	Minimum price	200.00	150.00	130.00	130.00	300.00
		Maximum price	300.00	350.00	150.00	200.00	350.00
Kalutara	05	Minimum price	100.00	200.00	100.00	100.00	350.00
		Maximum price	400.00	350.00	400.00	400.00	750.00
Gampaha	05	Minimum price	250.00	250.00	100.00	100.00	350.00
		Maximum price	580.00	510.00	400.00	400.00	750.00
Ratnapura	09	Minimum price	250.00	250.00	150.00	150.00	500.00
		Maximum price	500.00	500.00	400.00	300.00	750.00
Kegalle	07	Minimum price	230.00	200.00	120.00	120.00	400.00
		Maximum price	400.00	380.00	400.00	400.00	650.00

- (b) At the survey conducted by the Consumer Affairs Authority on the inconsistencies of prices of laboratory tests, and according to the survey conducted using 13 medical institutions in Colombo district, it had been revealed that a sum of Rs. 300 to Rs. 630 for FBS (Fasting Blood Sugar)

laboratory test, a sum of Rs. 400 to Rs. 620 for UFR (Urine Full Report), a sum of Rs.1450 to Rs. 2490 for TSH (Thyroid Stimulating Hormone) laboratory test, a sum of Rs.340 to Rs.590 for ESR (Erythrocyte Sedimentation Rate) laboratory test , a sum of Rs.1500 to Rs.2900 for Lipid Profile laboratory test, a sum of Rs.1800 to Rs.3,010 for the HBAIC (Hemoglobin A 1C) laboratory test and Rs.500 to Rs.1200 ECG were charged(Electrocardiogram). (Particulars are mentioned in annexure No 03).

- (c) At the Sub-Committee of Recovering charges of Private Health Services Regulatory Council that had met on 13 June 2024, it had been decided to prepare an interim formula until the grading of hospitals is implemented. Accordingly, the proposed cost plan prepared by the representatives of the Private Hospitals and Nursing Homes Union is as follows.

Type of test	Cost till laboratory report is prepared (Rs.)	Profit margin received by the hospital (35 per cent) (Rs.)	Maximum amount for laboratory report (Rs.)
UFR	473.25	165.63	638.88
ESR	475.93	166.57	642.50
FBS	522.52	182.88	705.40
PPBS	522.52	182.88	705.40
ECG	871.73	305.10	1176.83
Grouping Blood	602.77	210.96	813.73
HB	732.77	256.46	989.23
HBAIC	1592.77	557.46	2150.23
Lipid Profile	2013.06	704.57	2717.63
Liver Profile	3092.77	1082.46	4175.23
ALT/SGPT	642.77	225.00	867.77
AST/SGOT	642.77	225.00	867.77
Bilirubin Total	652.77	228.00	880.77
Bleeding time/cloting time	426.12	149.00	575.12
Cholestrol Total	662.77	232.00	894.77
CRP	952.77	333.46	1286.23
Creatinine Serum	687.77	240.71	928.48
Electrolytes	1062.77	371.96	1434.73
Free Thyroxine	1532.77	536.46	2069.23
Free Trilodothyonine	1532.77	536.46	2069.23
FBC	732.77	256.46	989.23
VDRL/SYPHIL IS	769.77	269.42	1039.18
Pregnancy Test-Urine	380.00	133.00	513.00

PT INR	1112.77	389.46	1502.23
Renal Profile	4620.77	1617.26	6238.03
Speciman for AFB	750.00	262.50	1012.50
Stool Culture & ABST	1399.00	489.65	1888.65
Stool Full Report	400.00	140.00	540.00
Thyroid Profile	4748.31	1661.90	6410.21
Urea-Blood	672.77	235.46	908.23
Uric Acid-Serum	752.77	263.46	1016.23
Urine Culture & ABST	1399.00	489.65	1888.65

The following facts were observed.

- (i) Due to the currently recovered maximum charge is much lower than the charges mentioned in the proposed Cost Plan, the patients in those districts having to pay a higher fee than the currently existing costs in the implementation of this price formula.

For an example, the following is the currently existing and proposed cost plan in respect of UFR Laboratory reports.

Description	Price (Rs.)
Proposed price	638
Colombo district price	400-620
Price of 6 districts	between 100-450
Price of 4 districts	200-500
Price of 4 districts	200- 620
Price of 5 districts	300-560
Price of 4 districts	300-620
Price of one district	400-680

- (ii) Accordingly, following the declaration of maximum price limits through a gazette notification of the charges recovered by the private medical institutions, although the attention of the Council should have been drawn towards the justice being meted out to the general public when taking legal action against those institutions that do not comply with the above maximum price limits, the Secretary of the Council had taken steps to submit the list of costs to the Consumer Affairs Authority, preparation of which had been made with profits margins being determined solely on the requirement of representatives of the Private

Hospitals and Nursing Homes Union. The relevant committee information upon which the relevant decisions were made is as follows.

Date	Subject	Decision	responsibility	Time frame
2023.05.19	Laboratory test charges	All members have agreed to revised charges of 33 common laboratory tests.	Private Hospitals and Nursing Homes Union	On or before 13 June 2023
Do	Specialist and hospital consultation charges	All members have agreed to revised specialist and hospital consultation charges. it has been decided to obtain observations from the relevant institutions and the Private Hospitals and Nursing Homes Union have agreed to send observation regarding the hospital charges.	Manager - Private Hospital and Nursing Homes Union	Do
2023.06.13	Specialist and hospital consultation charges	It was decided to obtain observations for consultation fees from the relevant institutions, and Association of Private Hospitals and Nursing Homes have agreed to send observation regarding the hospital charges	Secretary Manager-operations	Do
Do	Charges for 33 selected laboratory tests	It was decided to prepare an interim formula till a method of grading is implemented.	Secretary	On or before 21 July 2023
Do	Charges for 05 selected laboratory tests	All have agreed to submit the cost structure for 5 relevant laboratory tests.	Secretary	On or before 16 July 2023

3.13.4 Imposition of Fines on Recovering Monies in Violation of Maximum Limit of Charges

When the instances were reported of recovering monies from the general public in violation of the maximum charges mentioned in extraordinary gazette notifications published regarding charges recovered by private health services institutions of Sri Lanka, fine money amounting to Rs. 10,905,000 had been recovered having carried out raids on 18 occasions and taken legal actions in 10 Magistrate Courts during the period from 13 August 2021 to 23 March 2023.

3.13.5 The Sub-Committee of Pricing of private Health Services Regulatory Council

The following observations were made in this regard.

- (a) Out of 9 members in total appointed to the Sub Committee during the period from 2017 to 2022 , established for making decisions related to justifiably regulating the charges recovered from patients by the private medical institutions, 7 members including 4 members of the Private Hospital and Nursing Homes Union had been appointed to the Governing Board by the Minister with more than 77 percent representation by him. Out of 10 members in total, 7 members including 4 members of the Private Hospital and Nursing Homes Union had been appointed to the Board of Control by the Minister with more than 70 percent representation by him during the year 2023.
- (b) It was observed at the audit test check that the Private Health Services Regulatory Council, the Ministry of Health and the Consumer Affairs Authority had received 15 complaints on recovering charges by the private hospitals and the officer representing the legal division had not been selected for the Sub-Committee established in this regard.
- (c) Since this Sub-Committee had not met sufficient number of rounds, a delay had been caused with regard to taking decisions related to justifiably regulate the charges recovered from patients. Related information is as follows.

Year	2017	2018	2019	2020	2021	2022	2023
Number of rounds met	7	2	1	1	3	Nil	5

3.13.6 Non-payment of Attention towards Prices Charged on Medicines

Audit observations in this regard **are** mentioned bellow.

- (a) The regulations made by the Minister under section 18 of the Private Medical Institutions (registration) Act No 21 of 2006 to be read with section 3 of that Act, had been published in the gazette extra ordinary No1510/8 dated 13 August 2007. The procedure to be followed by the person who registered to operate a private medical institution is mentioned in this gazette notification and as per chapter (a) thereof, it is indicated that the unexpired medicines should be given as per chapter (b) thereof, it is mentioned that essential medicines named by the Ministry of Health should retained. When the Health Services Institutions are issuing medicines to patients, action had not been taken to revise the relevant orders, by including the conditions/guidelines to the effect that the terms regarding maximum prices published from time to time in gazette extra ordinary notifications, be adhered to as per National Medicines Regulatory Authority – NMRA Act No 05 of 2015. (For example – the gazette No 2077/55 of prescribing the maximum price for medicines issued in 2022)

It was observed at the audit test check that due to this reason, information related to 08 complaints received by the Ministry of Health/Private Health Services Regulatory Council and 3 complaints received by the Consumer Affairs Authority on medicines supplied to inpatients by the pharmacies of certain private medical institutions are unfairly priced.

- (b) Since the following information requested by the National Medicines Regulatory Authority on 31 July 2023 had not been submitted even by 31 December 2023, it was not possible to further investigate them.
- Information related to pharmacies registered as at 30 June 2023, maintained at private hospitals.(Name, address and registered number of the hospital) 2023
 - Information on the regulation role of the National Medicines Regulatory Authority regarding the amounts charged on medicines by these pharmacies.
 - Information on the fines charged / legal action taken in the instances where unfair amounts of money have been charged in contravention of maximum charges limits in the years 2021,2022, up to 30 June 2023.

3.14 Private Medical Institutions Complying with Environmental Laws

- (a) The Sub-Committee on Technical Evaluation and Waste Management, with a view to taking decisions on the proper disposal/destruction of waste materials of private medical institutions/centers and the provision of Incinerator Machines required for disposing waste materials on temporary basis to each Provincial Council had not met since 2017 to 30 June 2023. Out of the 5 members appointed to this Sub- Committee, three members represented the Private Hospitals and Nursing Homes Union. The representative of the Legal Division had not been involved with this Sub-Committee.
- (b) 19 complaints had been received by the Central Environment Authority regarding violations of environmental rules and regulations or non-disposal of clinical waste properly by the private health services institutions during the past 3 years. One striking fact here was that 09 out of the 19 complaints or 52.6 per cent represented the private hospitals, members of whom belonging to the board of control of Private Health Services Regulatory Council.
- (c) As per the powers vested by section 23(a) of the National Environment Act No 47 of 1980 as amended by Act No 56 of 1988 and Act No 53 of 2000, and in accordance with the sub-part of 68 of part B of the gazette notification published in the extra ordinary gazette No1533/16 dated 25 January 2008, the requirement of obtaining an Environmental Protection License – EPL should be fulfilled. The following facts were observed at the analysis of the information

submitted in this regard to the audit by Central Environment Authority's letter No CEA/EPC/07/G12/AUD/01/2022 dated 24 April 2023.

- (i) Accordingly, the private hospitals, private medical institutions and private medical laboratories registered at the Private Health Services Regulatory Council in 2022 stood at 162, 183 and 469 respectively and this Environmental Protection License – EPL had been obtained for 2022 by 77 private hospitals, 19 private medical institutions and 34 private medical laboratories only. Accordingly, although the fact that obtaining this certificate is essential at the registration, disregarding that requirement, registration had been granted for all institutions that had made requests therefor.
 - (ii) The total number of institutions registered with the Private Health Services Regulatory Council in the year 2022 stood at 375 amongst which included part time general medical centers, dental clinics, and specialist medical services and full time medical centers, dental clinics, and specialist medical services and none of those private medical institution had obtained the Environmental Protection License – EPL issued by the Central Environmental Authority.
- (d) The legal requirement of obtaining a Schedule Waste Management License – SWML should be fulfilled in respect of the disposal of clinical wastes which are mentioned in schedule VIII as of hazardous nature, as per directive No 15 in part II of the National Environment (Protection and Quality Regulations) No 01 of 2008 which was published by the Minister of Environment and Natural Resources in the Gazette Extra Ordinary No.1534/18 dated 1 February 2008 under Section 32 to be read with 23(a) and 23 (b) of the National Environment Act No 47 of 1980. Accordingly, this license should be obtained for the disposal of clinical wastes by all health services institutions including medical laboratories and research institutions. The following facts were observed at the analysis of the information contained in the letter No 07/WM/113/2017 dated 02 March 2023 submitted to the audit.
- i. The number of all private medical institutions registered in 2022 with the Private Health Services Regulatory Council stood at 1265 and 115 private medical institutions had taken action to obtain this license during the period from 2018 to 2023 and out of them only 71 institutions had taken action to obtain the registration of the Private Health Services Regulatory Council.
 - ii. It was observed at the audit that out of these registered institutions the validity period of the licenses of five institutions had expired.

- iii. No any full time or part time dental medical Institution, general medical center and specialist services medical institution had taken action to obtain this license and it had not been indicated in the Check List prepared as per the guidelines drawn up by Private Health Services Regulatory Council, and given to the Directors of Provincial Health Services that it is essential to have obtained this license.
- iv. Central Environmental Authority through its letter No CEA/07/HW/&CW dated 12 October 2022 had informed a private hospital that since there is a legal requirement for it to obtain a Schedule Waste Management License – SWML and therefore to submit an application within 14 days from this letter and caring on with the relevant business activity without obtaining the said license is a punishable offence under National Environmental Act No 47 of 1980. When checking the file related to this hospital, that although around one year had elapsed even by the day of audit which is 26 July 2023, no written evidence had been submitted to the effect that the said license was obtained.

3.15 Grading of Private Medical Institutio

Audit observation in this regard is mentioned bellow.

- (a) Functions and duties of this Council are mentioned in section 10 of the Private Medical Institutions (Registration) Act No 21 of 2006 and under section 10 (d) of the Act, a mention is made of implementation of a grading system in accordance with facilities provided by each private medical institution. Activities related to grading private medical institutions had not completed even by 31 December 2023 and due to this reason, activities related to regulating charges too had halted.
- (b) The Sub-Committee on grading had not met from 2017 to 30 June 2023 and the Committee had met twice during the period from July to December 2023. It was observed that the structure of that sub committee did not evince any likelyhood of being able to take decisions to regulate independent and private medical institutions. The legal representative had not been appointed to this Committee.

3.16 Complaints Received Against Private Medical Institutions

3.16.1 Resolution of Complaints against Private Medical Institutions

It was mentioned that activities such as, formulation of standards and guidelines for private hospitals, medical centers, full-time and part-part time medical centers, full-time and part-part time dental centers, medical laboratories, private ambulance services, nursing homes,, care giving and long term care giving mentioned with respect to the programme for regulation, development and strengthening of private health sector under Curative Services in the National Health Strategic Master Plan 2016-2025;

preparation of procedures for managing human resource development institutions and complaints had been completed; and, the Ministry of Health was taking action to publish them in the Gazette after being amended.

As for the inspection of institutions with the Private Health Services Regulatory Council, the Mission of this Plan mentioned that errors caused by institutions should be minimized when responding to the complainants against the institutions, and the regulatory mechanism should be strengthened when executing the punishments.

According to Section 18 (2) (g) of the Private Medical Institutions (Registration) Act, No. 21 of 2006, the Minister shall make Regulations as per Section 18 (2)(1) of this Act relating to “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”. Nevertheless, no evidence was made available to the Audit that the Minister had made Regulations in such a manner; instead, the Private Health Services Regulatory Council had only prepared a Guideline comprising 02 pages (including 12 matters) on 19 March 2021 titled “PHSRC Guideline 05 Complain Handling Process”

The following matters were observed on this Guideline.

- a) The Guideline so prepared, had not mentioned about the maximum duration to be spent by each party for resolving complaints. (It was only mentioned in Paragraph 10 that the report of investigation should be sent to the Regulatory Council by the Provincial Director of Health Services within a period of one month)
- b) This Guideline had not mentioned a methodology to acknowledge the party lodging the complaint and inform them on follow up actions / outcome relating to the complaint. Furthermore, no attention was brought on a methodology to facilitate online submission of complaints.
- c) Furthermore, those complaints had not been classified as simple, medium, and complex by the Council, and action had not been taken to include a copy of the complaints relating to having a detrimental impact on the patients, into the file pertaining to the relevant health institution. Moreover, no rules had been made to blacklist or downgrade a relevant institution in the event of such an institution found guilty on a complaint.
- d) As such, it was observed that the methodology specified in Section 18 (2) (g) of the Private Medical Institutions (Registration) Act, No. 21 of 2006 and the matters mentioned above, had not been taken into consideration in preparing the Guideline.
- e) Complaints received in relation to the Private Medical Institutions

As per the letter No.PHSRC/Acc/In/01/2024 dated 29 January 2024 of the Private Health Institutions Regulatory Council, it was observed that the progress of the resolution of complaints during past several years was not in a satisfactory level in accordance with the following data.

Year	No. of complaints	No. of complaints resolved
2018	30	10
2019	17	Nil
2020	18	13
2021	13	09
2022	27	23
2023	56	13

3.16.2 Internal control over complaints

The audit observations in this regard are as follows.

- a) A database had not been formally maintained on the complaints received during the preceding years by the Private Health Services Regulatory Council until being pointed out by the Audit on 03 March 2023.
- b) The Council had not maintained a register on complaints even up to 27 February 2023, and hence, there existed no methodology to clearly identify the information such as, number of complaints received yearly, source of complaint, further action taken with respect to a complaint, and number of complaints resolved.
- c) Once a complaint is received, a file should be opened thereon with a Minute Sheet and further action should be taken. However, no information on the files thus opened with respect to the complaints received during 2020-2023 had not been maintained, and 33 files had not been maintained by indicating complaint number and relevant matter out of 49 files on complaints taken for audit from the institution. Furthermore, 42 files did not contain Minute Sheets.

3.16.3 Sub-Committee for Complaints

The following audit observations were made in this regard.

- a) Eight members had been appointed until 2022 for the sub-committee established to investigate and take decisions after taking into consideration the please / complaints of the generalpublic against the private medical centers. Five members had been appointed by the Minister to the governing body of the Council including 04 members of the Association of Private Hospitals and Nursing Homes. Of the 08 members appointed after 10 March 2023, three members appointed by the Ministry to the governing body of the Council

including the Chairman of the Association of Private Hospitals and Nursing Homes, had been appointed to this sub-committee.

- b) Although complaints of miscellaneous nature had been received throughout the year from various parties, an adequate number of meetings of the sub-committee had not been held to discuss and solve such complaints. Only 16 meetings of the sub-committee had been held during 2017- 30 June 2023; and, less than 37 per cent of the members had taken part only in 05 of those meetings held in 2023. It was also observed that 50 per cent or more of the members of the Association of Private Hospitals and Nursing Homes appointed by the Minister had participated in 10 of the 16 meetings of the sub-committee whilst the legal representative had participated only in 03 of the 16 meetings.
- c) Based on the following matters, it was observed in examining the Minutes of the meetings of sub-committee presented to the Audit relating to complaints that some of the complaints had been brought for discussion at several sessions of the meetings and an extensive period had been taken in that connection.
 - i. The issue of a Cardiologist registered temporarily with a private hospital had been taken for discussion at the meeting held on 24 July 2020 with respect to the Complaint No. PHSRC/CSC/640/2020. It was revealed that the said Cardiologist had practiced without a valid registration, and it was decided to wait until the receipt of the Minister's report before taking further action. It was mentioned in the Minute of the meeting held on 27 September 2021 that the same Complaint No. had been taken for discussion again, but the issue was related to a Covid-19 vaccine. As such, it was observed in audit that two different matters had been brought for discussion under the same Complaint No., there existed no evidence that the issue had been solved, and a period of over one year had been spent in that connection.
 - ii. The Complaint No. PHSRC/CSC/649/2020 had been brought for discussion on 24 July 2020 relating to a death occurred at a private hospital due to medical negligence, and this complaint had been forwarded to the Western Provincial Office of the Director of Health Services for further investigation. It was mentioned in the Minute of the meeting held on 21 July 2022 that officers of the Western Provincial Office of the Director of Health Services had met the Director and Chief Executive Officer of the relevant hospital, and as such, it was recommended that appeal of the patient should be taken into consideration thereby reducing the hospital charges whilst adhering to good practices. Thus, a period of 02 years had been spent for resolving this complaint.

- iii. The Complaint No. PHSRC/CSC/651/2020 was about a private hospital charging fees unfairly. This matter was brought for discussion at the meeting held on 24 July 2021, and that complaint had been forwarded to the Western Provincial Office of the Director of Health Services for further investigation. It was mentioned in the Minute of the meeting held on 21 July 2022 that hospital charges of the patient would be reduced, and a period of one year had been spent on that complaint as well.
- iv. As for the Complaint No. PHSRC/CSC/655 /2020 received against a private hospital by stating that the hospital had not responded satisfactorily to a complaint lodged against that hospital, it was mentioned in the Minute of the meeting held on 27 September 2021 that the response of the hospital in that connection was not sufficient. It was stated in the Minute of the meeting held on 08 March 2022 that the hospital be requested calling for explanations on the failure to give treatments on time and the Council had no legal provisions to grant compensation. Accordingly, although 06 months had been lapsed this complaint had not been resolved.
- v. The Complaint No. PHSRC/CSC/822/2021 relating to medical negligence on an ophthalmic treatment provided by a private hospital had been brought for discussion on 27 September 2021, and it was decided at the discussion that an internal investigation be conducted by the hospital in that connection. It had been decided at the meeting held on 08 March 2022 that the complainant be informed to bring this matter before the Medical Council of Sri Lanka. As such, it was observed that the complaint had been presented to the complainant himself after a lapse of 06 months.
- vi. The Complaint No. PHSRC/CSC/842/2022 blaming the hospital staff that the failure of the first surgery performed in a private hospital led to the deterioration of the complainant's mental condition, had been brought for discussion at the meeting held on 08 March 2022. The measures such as, informing the hospital to provide training for the hospital staff relating to pleas of the patients and detailed bills should be presented, had been discussed therein. It had been discussed at the meeting held on 27 January 2023 that the hospital should be requested for a detailed bill. However, it was observed in audit that this complaint had not been resolved even after 10 months.

3.16.4 Complaints being investigated by Other Parties

The Audit observed instances in which complaints received against private health institutions had been investigated by the Western Provincial Office of the Director of

Health Services as well as Flying Squad of the Ministry of Health. The following observations are made in that regard.

- a) Although it was observed in examining the relevant reports that a group of officers of the as Flying Squad of the Ministry of Health was involved in investigations, the reports presented to the Audit indicated that only the relevant Medical Officer had participated when complaints had been investigated by the Western Provincial Office of the Director of Health Services.
- b) It was observed in examining some of the reports of complaints furnished to the Audit that a period ranging from 04 months to one year had been spent to investigate a complaint since the date of receipt.
- c) Twenty four of the 39 complaints received by the Consumer Affairs Authority against private health services institutions during the 03 preceding years, had been forwarded to the Private Health Services Regulatory Council. The Council had not taken speedy action in relation to that matter.

3.16.5 Regulation of Physical Resources/space of Private Health Institutions

The Directives of Private Medical Institutions (Registration) No. 01 of 2007 published in the Gazette Extraordinary No. 1521/26 dated 02 November 2007 in terms of Section 18 of the Private Medical Institutions (Registration) Act, No. 21 of 2006, had mentioned about the physical resources to be maintained by the private health institutions. Nevertheless, it was observed in audit that complaints had been received against institutions which had not maintained physical resources in accordance therewith.

3.17 Database of the Private Health Institutions

This had been discussed under the following policies and plans.

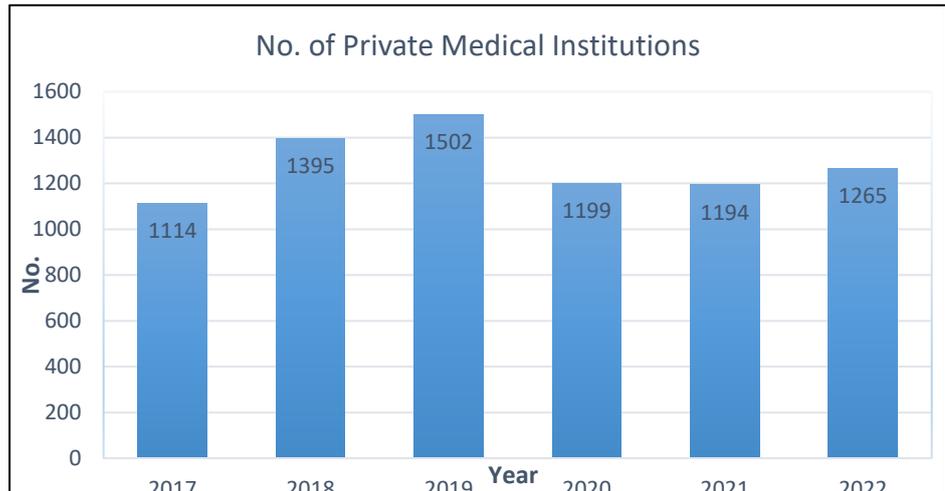
- a) Collecting health-related information from the private health sector for the national database had been mentioned in the programme for regulation, development and strengthening of private health sector shown under Curative Services of the National Health Strategic Master Plan 2016-2025.
- b) Section (d) of the Strategic Guidance in National Health Policy of Sri Lanka mentioned that all the patients would be provided with a continuous service through a strengthened health service based on data relating to services whilst Paragraph (d) (1) described about ascertaining the patients' rights, confidence of the general public, and satisfaction of patients/clients.
- c) According to Policy No. 2.2 of the National Policy on Health Information – 2017, health related data/information collected from the Government or non-Government sector should be linked to the national health information system. The Key Activity 2.2.1.1 thereof required that all the Government and non-

Government institutions (including the private health care service) should recognize the data to be provided for the national health information system within a period of 06 months; and, Key Activity 2.2.1.2 necessitated the establishment of a mechanism within a period of 18 months to report on health related data collected from Government (except for health) and non-Government institutions (including the private health care service).

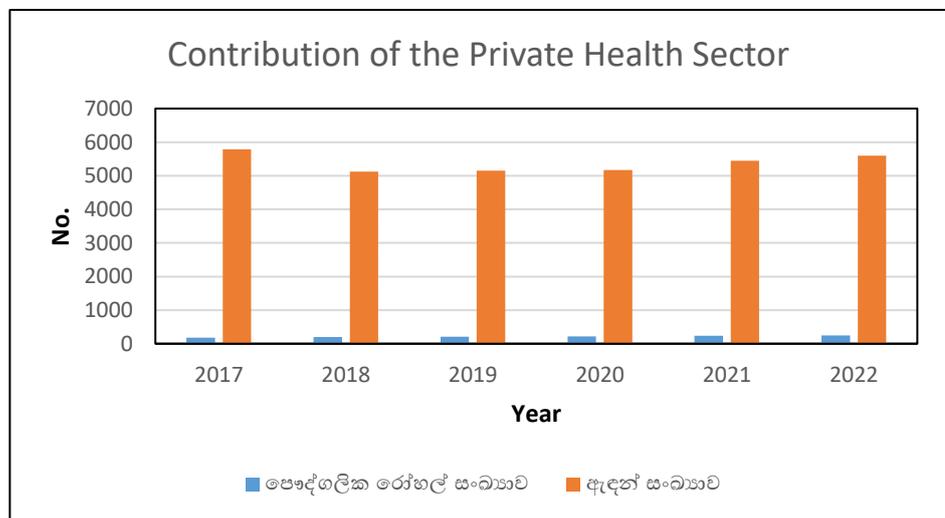
- d) According to Section 10 (c) of the Private Medical Institutions (Registration) Act, No. 21 of 2006, collection and publication of relevant health information and statistics, is a duty of the Private Health Services Regulatory Council.
- e) The Cabinet had approved the National Health Laboratory Policy on 01 December 2006. It was also expected through this policy to collect the health-related data from all the laboratories of public and private sector and provide such data for the relevant Government institutions.

The objectives mentioned in the said policies and plans, had not been achieved as expected even by 30 June 2023. Particulars are given below.

- i. The Ministry of Health had conducted awareness programs on the collection of data for several private hospitals in the year 2020. However, out of 09 private hospitals liaised with parties functioning as members of the governing body of the Private Health Services Regulatory Council, it was observed that 03 hospitals (02 hospitals during the period 2021-2023 and another one only in the year 2021) had provided the Ministry of Health with data on live admissions, live discharges and deaths after being categorized in terms of disease, gender and age whereas another private hospital had provided such data during the period 2021-2023. Accordingly, it was observed in audit that non-inclusion of activities of the private health sector in the National Health Bulletin published by the Ministry of Health annually in order to facilitate the decision making process of miscellaneous parties in the country, would cause an unfavorable impact on the decisions taken nationally and internationally.
- ii. A source through which accurate data would be collected on the number of private medical institutions of all categories in Sri Lanka could not be identified. Information on the number of private hospitals and beds relating to the period 2017-2022 is given in the following Table in accordance with the report of the Central Bank of Sri Lanka.



Source – Reports of the Central Bank



Source – Reports of the Central Bank

3.18 Evaluation of the Contribution to the Government Sector by the Private Medical Institutions

Audit observations in that connection are as follows.

- a) As compared to the other countries in the region, 83 per cent of the deaths occurred in Sri Lanka are due to non-communicable diseases. In terms of early detection and management of diseases, the lack of human and physical facilities available at *Suvadivi Centers* that contribute at the primary level, as well as the lack of hospital facilities for heart surgery compared to the total population in a background where coronary heart disease is the main cause of death in Sri Lanka and congestion of the Colombo National Hospital, the effort to make the Sri Lankan community a healthy nation in accordance with the Universal Health Coverage has become a burden that cannot be borne by the public sector alone. Accordingly, the private health sector has provided a unique contribution to the higher demand for health facilities which cannot be provided by the

Government alone. Furthermore, the role played by the private health sector specially in situations like the Covid-19 pandemic, should be appreciated by the Government.

- b) According to the information given in annual reports of the year 2022 published in the websites of some of the well-known hospitals in Sri Lanka and the said report of the research, the following matters were observed.
- i. Contribution of the private hospitals to preventive services and tests as well as surgeries during the year 2022 is given below.

Name of the Private Hospital	No. of Beds/Rooms available	Patients Admitted	Consultant Appointments	No. of Laboratory Tests	No. of Surgeries Done	No. of Laboratories
Nawaloka Hospital	400	22,406	385,282	Not given	11,501	Not given
Asiri Group of Hospitals (06 Hospitals)	700	3.5 million	Not given	450,000 (Monthly)	Not given	Not given
Durdens Hospital	Rooms 60 Wards 12	436,251	Not given	2,468,515	36,590	1,617
Lanka Hospital	350	25,019	Not given	Not given	Not given	Not given
Hemas Hospital	192	Not given				32
Source – Annual reports of the private hospitals.						

- ii. Compliance with National/International Standards

Although it is not made mandatory by the Private Health Services Regulatory Council, the private hospitals have obtained accreditation certificates thus providing services of higher quality as mentioned below – an aspect that should be further encouraged by the Government. Particulars on accreditation certificates obtained by some of the well-known hospitals are given below.

Name of the Accreditation -----	Hospitals Represented by the Governing Body -----			
	Asiri Group of Hospitals	Nawaloka Hospital	Durdens Hospital	Hemas Hospital
ISO-9001:2015 Quality Management Systems Certificates	Only Asiri Central Hospital	Yes	Not Given	Not Given

OH-SAS 18001:2007 Occupational Health & Safety Management Systems Certification	Asiri Group of companies (6 hospitals	Not Given	Not Given	Not Given
ISO 14001:2015 Environmental Management System	Asiri Group of companies (6 hospitals	Not Given	Not Given	Not Given
ISO 22000:2018 Food Safety Management Certification	Asiri Group of companies (6 hospitals	Not Given	Not Given	Not Given
Australian Council ON Health care Standards International(ACH-SI)	Exclude Asiri Central Hospital(5)	Not Given	Not Given	Not Given
Joint Commission International (JCT) Accreditation the gold standard in global health care. JCT is widely accepted to be the author & evaluator of the most rigorous international standards in patient safety & quality	Only Asiri Central Hospital		Yes	Yes
ISO-15,189:2012	Not Given	Not Given	Yes	Yes
ISO-27,001	Not Given	Not Given	Yes	
MTQUA-Certification	Not Given	Not Given	Not Given	Yes
CAP Certification	Not Given	Not Given	Not Given	Yes

Source – Annual reports of private hospitals.

c) Utilization of Labor Force

Data on full-time employees of the private health institutions, except for the professionals of the Government sector employed in such institutions on part time basis, is not collected. It is observed in examining the annual reports of these institutions that the contribution made by these institutions to employ a significant part of the labor force that can provide effective service to the national economy, is also significant. Data on human resources of several well-known hospitals relating to the year 2022 is given below.

Name of the Hospital	No. of Consultants	No. of Total Employees
Nawaloka Hospital	800	2,095
Asiri Group of Hospitals	1,700	
Durdens Hospital	Not given	2,032
Hemas Hospital	Not given	2,974
Lanka Hospital	1,016	2,008
Source – Annual reports of private hospitals		

3.19 Private Health Sector Development (PHSD) Division and Institutional Structure of Private Health Services Regulatory Council (PHSRC)

3.19.1 Staff

- (a) A Private Health Development Division headed by a Director had been established by the Ministry of Health for the development of private health division and Director in charge of the development of private medical divisions and 03 supporting service staff serve in this Division. A staff consisting with 11 officers is maintained by the Private Health Services Regulatory Council and even though the approval of the General Treasury should be obtained for such staff in terms of the paragraph 3.1 of Operation Manual issued by the Department of Public Enterprises on 16 November 2021, no action was taken accordingly. In addition, though the appointments had not been specifically made for the regulation of private medical institutions in all Provincial Health Services Director Offices, some staff contributes for this task.
- (b) Office Management Sub Committee
10 members had been appointed for this committee from 2017 to 2022 and it was 07 members after 10 March 2023. 05 members out of 07 selected in 2023 for this subcommittee established for the fulfillment of the responsibilities such as purchases of Regulatory Council, human resources management issues and taking administrative decisions were the members appointed to the governing body of the Regulatory Council by the minister. 02 members out of them were the representatives from the private hospitals and nursing homes association. The Chairman of the private hospitals and nursing homes association had been appointed as the Chairman of this committee also.

The participation of the members appointed to the governing body of the Regulatory Council by the minister for this subcommittee in 2023 was from 67 percent to 75 percent.

3.19.2 Fund Composition

Even though the Private Health Services Regulatory Council should have its own fund as per Section 12 of Private Medical Institutions (Registration) Act No.21 of 2006 , it had been indicated that 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.

The following observations are made related to this.

- (a) An income as registration fee is received to the council by registration of the private medical institutions. But no amendment was made until it had been decided to increase the registration fee by 50 percent at the meeting of governing body held on 15 September 2023 since the commencement of the regulatory council. (2007)The information on charge of the registration fee is as follows.

Private Medical Institution -----	Category -----	Annual Registration Fee ----- (Rs.)
Private Hospitals and Nursing Homes	Beds 01 to 25	20,000
	Beds 25 to 50	30,000
	Beds 50 to 100	50,000
	Beds more than 100	Rs.1,000 for each bed
Medical Laboratories	Small Laboratories/Collection Centers	5,000
	Medium Scale Laboratories	15,000
	Large laboratories	50,000
Medical Centers	Medical Centers/Patients Examination Centers/Day Time Medical Treatment Centers/Channel Services	15,000
	Full-time general medical practice/Dispensaries/Medical Clinics/Full-time dental surgeries	10,000
	Part-time general medical practice/Dispensaries/Medical Clinics/Fulltime dental surgeries	5,000
	Fulltime engagement in specialist profession	15,000
	Part-time engagement in specialist profession	10,000
	Private ambulances	10,000
	Home care nursing services	5,000
	Blood banks	25,000

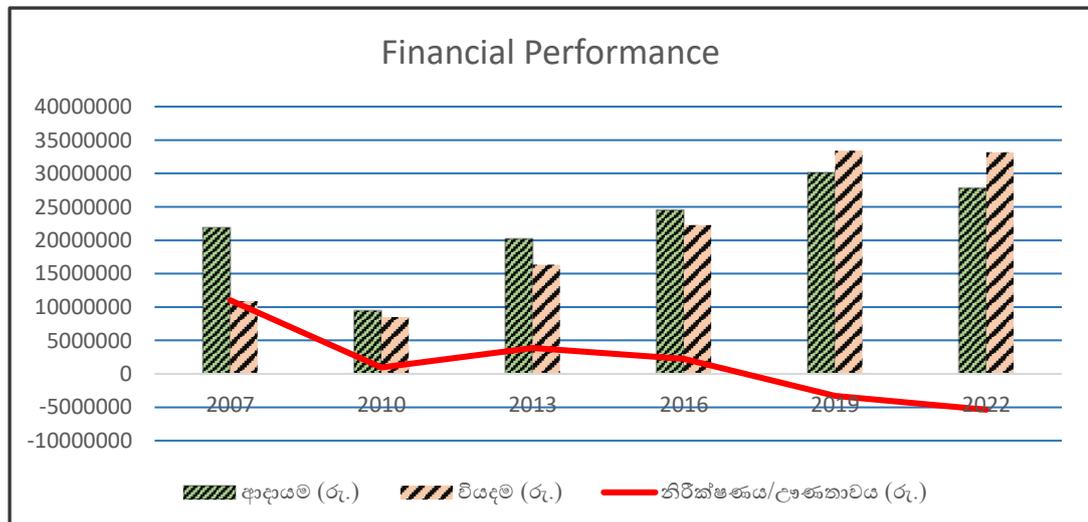
- (b) The registration certificates had been issued for the relevant year after receipt of money in any day for the registration of the medical institutions due to not indicating the specified registration period of time in the Act or pilot consultation and an income to be received to the council at the beginning of the year had been received in delay due to not charge of a penalty .This situation had not been amended until holding the 173rd meeting of governing body on 11 August 2023.
- (c) As per Section 3(5) of the said Act, it had been specified that 50 percent of the fees collected by each Health Services Director should be sent to relevant provincial council. Accordingly, the balance owed to be paid at the beginning of 2023 was Rs.44, 518,057 which is 50 percent of the registration income received to the Regulatory Council to be remitted to the provincial council and the total amount to be paid was Rs. 58,346,307 including the amount of Rs.13, 828,250 to be paid in 2023. The action was taken to settle only Rs.21, 446,466 i.e. 37 percent within 2023.
- (d) The approval of the Cabinet of Ministers had been granted on 09 July to amend the Section 3(5) of the Private Medical Institutions Registration Act No.21 of 2006 having inserted the provisions to be submitted an annual proposal with the annual budget estimate in relation to the private health sector development by Provincial Health Services Director prior to providing 50 percent of the annual registration fee income collected by the Regulatory Council to Provincial Chief Secretaries and to be submitted a report on expenditure and functions at the end of the year. Even though 07 years had elapsed from the receipt of approval of the Cabinet of Ministers, the Act had not been amended and only a part of 50 percent of the annual registration fee income had been provided to Provincial Health Services Directors.
- (d) No provision had not been made in the Act to incur the expenses of the provincial councils and an amount of Rs.1,307,300 had been paid in 2023 for the telephone allowances, transport expenses salaries of the officers attached to Western Province Health Services Director's Office and Rs.1,614,037 had been paid for the salaries of 02 officers in Sabaragamuwa Province by the Regulatory Council. In term of Section 3(5) of aforesaid Act, such amount had been deducted from the registration fee income to be paid to Western and Western Provincial Council.

3.19.3 Financial Performance of the Council

The financial performance of the Council for several years is as follows.

Year -----	Income ----- (Rs.)	Expenditure ----- (Rs.)	Surplus/(Deficit) ----- (Rs.)
2007	21,894,960	10,878,557	11,016,403
2008	16,377,970	10,833,136	5,544,834
2009	11,585,241	10,147,526	1,437,715
2010	9,474,746	8,503,857	970,888
2011	13,514,577	12,209,855	1,304,722
2012	14,178,027	14,572,473	(394,446)
2013	20,197,814	16,346,810	3,851,004
2014	20,585,847	19,415,020	1,170,827
2015	18,056,343	19,995,419	(1,939,076)
2016	24,508,082	22,267,174	2,240,908
2017	25,763,278	28,229,653	(2,466,375)
2018	31,016,270	37,183,440	(6,167,170)
2019	30,122,360	33,402,673	(3,280,313)
2020	27,647,089	33,695,769	(6,048,680)
2021	28,926,842	29,619,036	(692,194)
2022	27,800,707	33,173,163	(5,372,457)
2023	44,579,653	43,074,969	1,504,684

Source: - Annual financial statements of Private Health Sector Regulatory Council



Accordingly, even though a finance surplus had been maintained by incurring expenditure in minimum level than the earned income from 2007 to 2016 (except 2012 and 2015) by the Regulatory Authority, the cumulative fund of Rs.33,719,154 as at 31 December 2016 had gradually decreased to Rs.10,371,883 as at 31 December 2023 by 69 percent and since a negative balance of Rs.48,438,734 had prevailed in net current assets as at 31 December 2023 , it was observed that a short-term bankruptcy had prevailed of the Regulatory Council.

4. Audit Recommendations

- (a) To pass and implement a new Parliamentary Act with a governing body which can take required decisions for implementation a regulation which ensures a safety and efficient health service under affordable charges with fair and responsible to the people by the overall institutions system which render the private health services implemented in the country or amend the composition of Private Medical Services Regulatory Council established by Private Medical Institutions (Registration) Act No. 21 of 2006 to be increased the possibility of the public sector for decision making for the regulation of the private health institutions
- (b) To make precise provisions after carrying out a suitable evaluation on that, since the provisions in relation to audit of Private Health Services Regulatory Council had not been exactly indicated in Private Medical Institutions (Registration) Act No. 21 of 2006. Insert the suitable provisions into the Act having valued on conferring the powers for reporting to the parliament to the Auditor General (not for carrying out audits on private medical institutions) after examining the accuracy of data supplied by those institutions, whether the government officers who examine and certify the information submitted for the registration and whether accurate registration fees had been charged
- (c) To present the regulations prepared so far in terms of the powers conferred to formulation of the regulations by the Private Medical Institutions (Registration) Act No.21 of 2006 to the Parliament and convert it to a law and immediately formulate the regulations which had not been prepared by the minister in charge of subject so far, publish in the government gazette and present to the Parliament and convert it to a law
- (d) To prepare the rules with regard to the facts provided for the preparation of rules by the Private Medical Institutions (Registration) Act No.21 of 2006 and approve by the minister in charge of the subject and publish in the government gazette and empower them
- (e) To pay prompt attention on the formulation of the regulations in relation to a fair charge system which is affordable to the people and having graded the all private health institutions in the country and empower them
- (f) To pay the immediate attention on the facts such as mentioning what are the compulsory duties of the private medical institutions in the amendment of the existing Act or formulation of a new Act, indicating precisely the steps to be taken by the Regulatory Council if a private medical institution had breached a regulation or a rule , assessment and regulation of the technology and address on the ethical issues related to that

- (g) To prepare a formal methodology in order to develop, monitor and evaluate the standards to be maintained by the registered private medical institutions for fulfilling the objectives of the Act, ensure that the minimum qualifications are followed in the recruitment of the workers and the minimum standards are followed in training and ensure the quality of the patient caring services and take action to legalize and implement it. Also certify that the national recruitment criteria are followed in recruitment of professionals.
- (h) To amend the registration fees determined in 2007 suitably to the present situation
- (i) To pay attention on possibility of converting the condition for obtaining the registration of Private Health Services Regulatory Council in registration or renewal of the registration under the companies Act or another provision to a mandatory condition.
- (j) To introduce a method of providing registration without delay to the institutions which had submitted the documents for registration, provide a specified period of time to the private medical institutions which had not fulfilled the minimum requirements for registration and immediately take the legal action against to the institutions which do not take necessary steps to complete such minimum requirements
- (k) To get legal action promptly in relation to the all private medical institutions operating throughout the country without registration in Private Health Services Regulatory Council by using the powers conferred by the Act
- (l) To prepare a registration certificate awarded by Private Health Services Regulatory Council valid for a certain specified period of time and implement a method for charge the suitable penalties in the registration subsequent to the valid period
- (m) To make compulsory the license given after annual examination carried out by Sri Lanka Accreditation Board that the laboratory is in compliance with the specified standards in registration of laboratories
- (n) To make mandatory the fulfillment of the legal requirement for obtaining Environmental Protection License –EPL and Schedule Waste Management License – SWML to be compulsorily taken for the disposal of the clinical waste in the registration of the private medical institutions
- (o) To take prompt action to avoid the shortcomings identified by the Health Master Plan on regulation of the private health services and define more accurately the definition for “Authorized Officer” as indicated in the Health Master Plan

(2016-2025) and Section 14 of Private medical Institutions (Registration) Act No.21 of 2006

- (p) To formulate and implement a suitable and formal mechanism for submission the complaints in relation to the injustices occurred to the people by the private medical institutions and the issues arisen and providing the relief for them having heard the complaints received likewise and providing the opportunity to make the complaints via online
- (q) To provide an understanding on the Private Medical Institutions (Registration) Act and regulations and rules made under such Act to the public from time to time.
- (r) To make under the coordination of an officer who serves in Office of Medical Officer of Health in order to regionally regulate the private medical institutions and appoint the Field Officers in Regional Medical Officer of Health level and collect quarterly the data on human resources, worker qualifications and fees of the private medical institutions through them
- (s) To establish a separate unit consisting with separate staff with the powers for implementation the regulatory activities and registration in Private Health Services Regulatory Council in the all Provincial Health Services Director Office
- (t) To mention the directives on period of time of holding the meetings of Governing Council and number of sittings as well as ensure the active participation for the meetings by the members of Governing Council and take necessary measures to appoint the suitable persons after removing the members who do not participate for the meetings properly
- (u) When the Provincial Health Services Directors cannot participate for the committee meetings due to unavoidable circumstances, to make the legal provisions enabling to participate for the meetings by an officer in the level of District Health Services Director authorized by him and make compulsory for the participation of the meetings by Provincial Health Services Director or his representative
- (v) To appoint the members who have the ability of working independently and objectively for subcommittees as per the nature and the expected objectives to be fulfilled of the subcommittees, appoint the members with the specific knowledge related to each subjects, ensure the determination of the quorum for subcommittees and active participation of the members of subcommittee for the committee meetings

- (w) To pay attention on possibility of formulation and implementation a suitable mechanism in order to co-coordinately work with the institutions such as National Medicines Regulatory Authority, Consumer Affairs Authority and Central Environmental Authority.
- (x) To provide timely information through the integration the data and information in relation to health obtained from the private health sector with national health information system
- (y) To maintain a proper financial stability for the continuous existence of Private Health Services Regulatory Council and obtain the approval of the General Treasury for the staff
- (z) To display the fees charged for the services provided by the Private medical institutions in terms of the regulations prepared by Private Medical Institutions (Registration) Act No.21 of 2006 in the relevant institutions for making aware the public and take necessary actions for the occasions in where the private medical institutions do not act accordingly.
- (aa) To take into account the possibility of inserting a condition of considering the payment of benefits only for the treatments obtained from the private hospitals and the other private medical institutions registered with the Private Health Services Regulatory Council when the benefits are paid under Agrahara Insurance Scheme.
- (ab) To pay attention on possibility of formulating a methodology to pay the claims only for the treatments obtained from the private hospitals and other medical institutions registered in Private Health Services Regulatory Council in paying the claims under health insurance schemes of the private insurance institutions in coordination with the National Insurance Regulatory Commission

Sgd./W.P.C. Wickramaratne
Auditor General

W. P.C. Wickramaratne
Auditor General
On 10 July 2024

Details on Medical Officer of Health Offices (MOH) which had not submitted the information

Province -----	District -----	Number -----	Name of Medical Officer of health Office -----
Central	kandy	05	Doluwa/Kuruduwatta (Ganga Ihala Division)/Ganga Wata Division(Hasalaka) / Minipe) / Thalathuoya (Pathahewaheta)
	Matale	01	Matale (Urban Council)
	Nuweraeliya	06	Kothmale/Mathurata/Walapane/Rikillagakada(Haguranketha)/Ragala/Nuwaraeliya
Western	Colombo	04	Boralessgamuwa/Hanwella/Kaduwela/Colombo(Department of Public Health)
	Kaluthara	02	Beruwela / Kaluthara
Sabaragamuwa	Rathnapura	01	Rathnapura (Urban Council)
Southern	Galle	04	Baddegama/Galle(Urban Council) Karandeniya (Boralanda)/Niyagama
	Hambanthota	02	Hambanthota/Walasmulla
Uva	Monaragala	01	Thanamalwila
Northern	Jaffna	01	Jaffna
	Killinochchi	01	Killinochchi
	Mannar	02	Madu/Ampan(Mannai West)
	Mutaiyu	04	Mulativu/Oddusudan/Mannai(Eastern) Welioya
	Vauniyawa	03	Vauniya (Southern) / Vauniyawa / Cheddikulam

Number of private medical institutions and registered private medical institutions maintained in the Island wide

S.N	Type of private medical institution	Number of institutions identified and maintained up to 30 January 2023	Actual number of registered institutions	Registered percentage
-----	-----	-----	-----	-----
	Private Hospitals	275	162	59
	Private medical Institutions	875	183	21
	Medical Laboratories	1631	469	29
	Other Private Medical Institutions	435	66	15
	Part-time Normal Medical Centers	1795	204	11
	Full-time Normal Medical Centers	556	111	20
	Part-time Dental Surgeries	172	19	11
	Part-Time Dental Surgeries	168	36	21
	Part-Time Specialist Medical Services	37	03	8
	Full-Time Specialist medical Services	27	02	7
	Private Ambulance Services	31	10	32
Total		6002	1265	21
		=====	=====	=====

Survey data on the prices of the laboratory tests carried out in relation to 13 private medical institutions in Colombo District by Consumer Affairs Authority (07 June 2023)

Hospitals included in the sample -----	Fee for one test -----						
	(Rs.)						
	FBS	UFR	TSH	ESR	Lipid Profile	HBA1C	ECG
Durdans Hospitals	500	500	2000	500	2500	2250	575
Lanka Hospitals	510	510	2170	420	1970	2320	-
Hemas Laboratories	540	570	2120	510	2070	2630	-
Nawaloka Laboratories	550	560	2480	520	2480	1880	-
Asiri Laboratories	630	620	2480	590	2770	2870	910
Western Hospital	450	400	1450	425	2200	1900	600
Nwala Cilinic	300	500	2170	400	1500	2320	800
Asia Hospital - Maharagama	370	400	2200	340	1600	1950	500
Medi Help Hospital - Nugegoda	370	450	1790	350	1700	2200	750
Win Lanka Hospital- Kohuwela	390	450	1990	350	1900	1990	600
Kings Hospital- Borella	400	400	1490	350	1500	1800	900
Cemed Hospital- Nugegoda	490	470	1790	460	1900	2200	600
Park Hospital- Colombo 05	520	500	2490	400	2900	3010	1200
Maximum fee	630	620	2490	590	2900	3010	1200
Minimum Fee	300	400	1450	340	1500	1800	500

Imposition of the penalties in charging the money in contrary to the maximum fees by the Consumer Affairs Authority

Date of raid -----	Magistrate's Court -----	Case No. -----	Test -----	Penalty ----- (Rs.)
2022/03/03	Panadura	92161/22	Antigen Test	500,000
2023/03/23	Nuwaraeliya	3114	FBC Invoice	500,000
2023/03/16	Awissawella	90115	Medicine	5,000
2023/02/20	Maligakanda	6399/23	Medical Test	1,000,000
2023/03/22	Homagama	51473	Medical Test	500,000
2023/02/20	Maligakanda	6400/23	Medical Test	400,000
2023/02/22	Mount Lavinia	12380/s/23	Medical Test	1,500,000
2023/02/23	Gangodawila	13533/23	Medical Test	1,000,000
2023/03/08	Kirulapana	87684/05/23	Medical Test	1,000,000
2023/03/08	Kirulapana	87683/05/23	Medical Test	1,000,000
2023/03/23	Homagama	51472	Medical Test	500,000
2023/03/13	Gangodawila	14155/23	Medical Test	500,000
2023/02/03	Kirulapana	85510/05/23	Medical Test	500,000
2023/02/03	Kirulapana	85511/05/23	Medical Test	1,000,000
2023/02/15	Kirulapana	86235/05/23	Medical Test	500,000
2023/02/15	Kirulapana	86236/5/23	Medical Test	500,000
2023/02/23	Gangodawila	13532/23	Medical Test	500,000
2021/08/13	Marawila	75350	Medical Test	10,000