CHAPTER 4

ANALYSIS OF REGULATOR'S PERSPECTIVE ON SUSTAINABILITY CONCEPT AND PRACTICES OF SOCIAL-BASED HEALTHCARE INSTITUTIONS IN MALAYSIA

4.1 Introduction

This chapter discusses the sustainability concept and practices of social-based healthcare institutions from the perspective of the Ministry of Health Malaysia (MOH). The interview questions related to the definitions, standard procedures, and guidelines in the Private Healthcare Facilities and Services Act 1998 (Act 586). The primary information gathered in this chapter came from an interview session with officers at the Division of Medical Practice and Private Services (CKAPS), while secondary resources came from documentary analysis of Act 586 and other related documents. CKAPS was interviewed because of its role as the regulator of the private health sector, including social-based healthcare institutions. The interviews were conducted to accomplish the following research objectives:

i. To examine the understanding of CKAPS on the sustainability concept of social-based healthcare institutions.
ii. To investigate the sustainability practices for social-based healthcare institution from CKAPS perspective

Before conducting the interview, the researcher had to follow certain protocols and guidelines:

i. Obtain approval from the faculty and the university ethics committee.

ii. Online research registration on the National Medical Research Register (NMRR) system.

iii. Proceed through the Medical Research Ethics Committee (MREC) approval procedure.

These procedures must be followed to conduct research in Ministry of Health Malaysia (MOH) facilities, as outlined by the National Institute of Health (NIH). Each process of ethics committee approval is interrelated and compulsory. The process to obtain the approval of MREC through the NMRR website can only be carried out after gaining the approval of USIM's ethics committee. The NMRR website is a tool designed to support the implementation of National Institute of Health (NIH) guidelines in performing any research related to the MOH.

4.2 Interview with Regulator - CKAPS, MOH

Interviewing the regulator is important to examine their understanding on the establishment and sustainability issues of social-based healthcare institutions. This research also aims to investigate the sustainability practices of social-based healthcare institutions in Malaysia as outlined by the regulator. As Olsen (1998) explained, the government administrative setup and its policy related to cooperation with NGOs and voluntary organizations are general contextual factors for the sustainability of social-based healthcare institutions. Data were collected using two methods: interview with representatives of the regulator and document analysis to strengthen the validity of the findings. The interview session with CKAPS in Putrajaya was held on January 2020. CKAPS was represented by three officers (Table 4.1).

Table 4.1: Interviewee Profile

Interviewee	Representative Name	Designation
Interviewee 1	Dr Aliza Ali	Deputy Director, UD56
Interviewee 2	Dr Siti Zufina Abd Samah	Senior Assistant Director, UD54
Interviewee 3	Dr Siti Khadijah Hawari	Senior Assistant Director, UD54

4.3 Document Analysis: Malaysia Act 586 – Private Healthcare Facilities and Service Act 1998

The legal basis for the authority of CKAPS is the Private Healthcare Facilities and Services Act 1998 (Act 586), as explained by Interviewee 1:

> So our main Act is the Private Healthcare Facilities and Services Act 1998. For secretary cross referral with the Mental Health Act 2001. And in term of professionally, we need to cross refer to it. So when we want to enforce this

> Act, it will also relates with other Acts in terms of establishment, operation and so on. As for the Act itself, if I were to explain briefly because we now have 13 facilities that we regulate under this Act. That is all was included in sections 4 & 5 of Act 586. This Act called 586 shortly. Because it's full length, "Private Health Facilities and Services." So it should be simple. My scope is related to Act 586.[1]

Act 586 has been comprehensively designed to ensure the sustainability of private healthcare institutions. Specifically, it intends to achieve the following purposes:

i. Impose and ensure minimum standards in private healthcare facilities and services (PHFS).
ii. Ensure integrity and professionalism of healthcare professionals.
iii. Ensure quality of PHFS e.g., Quality Assurance, Mortality Review, etc.
iv. Address social and national interests.

Besides Act 586, there are several other documents related to the establishment and sustainability of private healthcare facilities used as references for this research:

1. Guidelines on the application process for certificates of approval and licenses for private hospitals.
2. CKAPS Governance Framework.
3. Documents or forms related to the procedures of CKAPS.

[1] Dr Aliza Ali, Deputy Director, Cawangan Amalan Perubatan Swasta, Ministry of Health Malaysia, Putrajaya branch. Interview session on 20 January 2020 (9.00 am)

4.4 CKAPS, MOH Understanding on Sustainability Concept for Social-based Healthcare Institutions

4.4.1 Social-based Healthcare Concept

To define social-based healthcare institutions in Malaysia, it is important to understand the reality of social-based healthcare concept from the regulator's perspective. It is necessary to determine whether the definition is in line with the conceptual definition of this research, that a social-based healthcare institution is that which places social benefits as its main objective. Therefore, at the start of this interview, the interviewees were asked about their understanding on the concept of social-based private healthcare and its differences with for-profit healthcare. Interviewee 1, Dr. Aliza Ali, begun her answer by explaining the types of healthcare providers in Malaysia. According to her, there are two types of healthcare provider in Malaysia, which are public and private.

i. Definition of private healthcare facility based on Act 586

Interviewee 1 explained that the establishment, maintenance, and license to operate a private healthcare facility or provide healthcare services are governed by the Private Healthcare Facilities and Services Act 1998 (Act 586) and its subsidiary regulations. This Act was enacted in 1998 and enforced in 2006. The MOH is the administrator and implementor of this Act, while CKAPS is the government agency responsible to enforce

the Act. According to Section 2 of Act 586, there is no distinction, in terms of definition, between a social-based and profit-based private healthcare provider:[2]

> "**private healthcare facility**" means any premises, other than a government healthcare facility, used or intended to be used for the provision of healthcare services or health-related services, such as a private hospital, hospice, ambulatory care centre, nursing home, maternity home, psychiatric hospital, psychiatric nursing home, community mental health centre, haemodialysis"[3]
>
> (Section 2, Act 586: Private Healthcare Facilities and Services Act 1998)

According to interviewee 1, the concept of social-based healthcare should be understood based on the Act itself. The term private health sector includes all privatized and corporatized government establishments, whether for-profit or not-for-profit, and whether an NGO or NPO. Meanwhile, interviewee 2 perceived the social-based healthcare concept as either purely nonprofit, waqf, or anything established under the same concept but still profit-generating. However, the profit itself is not returned to the shareholders but used to operate the hospital and subsidize healthcare costs. The nonprofit aspect refers to non-distribution of profit to shareholders. But the amount of profit retained by the healthcare institution cannot be measured.

Meanwhile, interviewee 3 stressed that social-based healthcare initiatives cannot be equivalent to philanthropic initiatives in other industries. According to her, in the healthcare industry, there are some aspects whose standards cannot be lowered. The main concern of healthcare is patient safety and quality of care. Therefore, the basic principles of healthcare should remain the same, regardless of whether the private healthcare provider is social-

[2] Ibid pg:196

[3] Act 586: Private Healthcare Facilities and Services Act 1998, Section (I) 2.

based or profit-based. Healthcare facilities, services, and personnel must comply with the standards and quality outlined by the regulator. Therefore, the cost incurred by the profit-based healthcare institution should be similar to the cost borne by its social-based counterpart. She also reminded that a healthcare operator, especially a philanthropic or social-based one, cannot provide cheaper or free healthcare cheaper just because it is established based on the philanthropic or social-based concept. The philanthropic or social-based institution is likely to bear more costs just to provide free or cheaper healthcare services.

ii. Categories of private healthcare facility based on Act 586

Act 586 does not differentiate between the different types of private healthcare facilities. The stipulations regarding the establishment of private healthcare institution, according to Section I(3) of Act 586, apply to every type of healthcare facility:

> No person shall establish or maintain any of the following private healthcare facilities or services without approval being granted under paragraph 12(a) or operate or provide any of such facilities or services without a licence granted under paragraph 19(a):[4]
>
> (a) a private hospital;
>
> (b) a private psychiatric hospital;
>
> (c) a private ambulatory care centre;
>
> (d) a private nursing home;
>
> (e) a private psychiatric nursing home;
>
> (f) a private maternity home;
>
> (g) a private blood bank;

[4] Act 586: Private Healthcare Facilities and Services Act 1998, Section (II) 3.

(h) a private haemodialysis centre;

(i) a private hospice;

(j) a private community mental health centre;

(k) any other private healthcare facility or service or health-related service as the Minister may specify, from time to time, by notification in the Gazette; and

(l) a private healthcare premises incorporating any two or more of the facilities or services.

iii. Differences between nonprofit and for-profit healthcare providers

The interviewees were asked to specify the differences between a nonprofit and for-profit healthcare provider. Interviewee 1 responded that according to Act 586, they are treated as equivalent, except for hemodialysis centers and hospices. Both can be registered by a partnership with at least one medical practitioner or company whose BOD member(s) is a medical practitioner. Additionally, they can also be licensed to a civil society organization registered under the Societies Act 1966 as a nonprofit healthcare institution.

iv. Registration of private hemodialysis center and hospice services as a nonprofit organization

Act 586 specifies that private hemodialysis centers and hospices under the administration of a civil society organization, such as a voluntary or charitable organization, can be registered as a nonprofit healthcare facility. However, Act 586 does not differentiate between for-profit and nonprofit institutions for hospitals, care centers, or clinics. In other words, these facilities cannot be legally recognized as nonprofit healthcare

institutions. Only private hemodialysis centers and standalone hospices can be legally recognized as a nonprofit. Section 6(4)[5] of Act 586 stipulates:

> "(4) Notwithstanding subsection (1), approval to establish or maintain or a licence to operate or provide a **private hospice or a private haemodialysis centre, on a voluntary or charitable basis,** may be issued to a society registered under the Societies Act 1966 [Act 335]"

Interviewee 1 explained that, based on the above provisions, CKAPS as the health regulator in Malaysia only recognizes hemodialysis centers and hospices as nonprofit institutions. Interviewee 3 added that any healthcare institutions established by any institutions, including social-based ones, are still considered as private healthcare institutions licensed by CKAPS.

v. Recognition of healthcare facility as a nonprofit organization

The next question intended to obtain more details about the philanthropic or social-based healthcare concept. The interviewees were asked how CKAPS recognize a nonprofit healthcare provider. According to interviewee 1, in the application process for approval certificates and licenses for private hospitals, there are several clauses that identify whether the healthcare institution is a nonprofit organization:

i. In the process of license application or renewal and application for transfer of title or submission of approval certificate or license, lists 5.1.4 (vii), 5.2.4 (vii), and 5.4.4

[5] Act 586: Private Healthcare Facilities and Services Act 1998, Section (II) 6(4)

(vii) require the applicant to provide two copies of supporting documents confirming its status as a nonprofit organization.

ii. In the license application or renewal process, list 5.2.4 (xxii) requires the applicant to provide two copies of supporting documents confirming the latest social or welfare contribution.

However, in practice, the applicant will usually declare the status of the organization before they submit the relevant documents to strengthen their application, although CKAPS is not strict about it. For dialysis centers, if the applicant promised to CKAPS that it would provide free or pro bono services, the likelihood of its establishment would be higher. The applicant can declare since the pre-establishment phase that the dialysis services, either free or at minimum cost, are intended for the poor by declaring sponsorship from a third party that supports or subsidizes the cost of operations. However, neither CKAPS nor Act 586 considers the declaration of sponsorship as compulsory. Nonetheless, Act 586 only allows the registration of a philanthropic or social-based hemodialysis center and hospice by a nonprofit organization.

But in certain cases, according to interviewee 1, applications for hemodialysis centers by a company will still be considered based on social issues if it promises CKAPS that it will provide pro bono services to the poor. As for the establishment of a hospital and other healthcare facilities other than a hemodialysis center and hospice, they are legally identical. CKAPS will make note only if the applicant declares so, because the main focus of CKAPS is the healthcare services provided by the healthcare institutions. From CKAPS' standpoint, regardless of whether the healthcare institution provides its services to the rich or the poor,

it must still follow the minimum standards set by the authorities in terms of services, medication, facilities, and patient safety. As the regulator, CKAPS expects the institutions to provide similar services to patients regardless of their charges because Act 586 applies to every private healthcare institution in Malaysia. The Act does not lower healthcare standards just because the operator is an NGO, NPO, or a waqf institution. Therefore, CKAPS recognizes a healthcare institution as either philanthropic or social-based based on the applicant's self-declaration and submitted documents.

Interviewee 1 also added that CKAPS will sometimes inspect other documents, such as a letter or notice of tax exemption from the Inland Revenue Board (LHDN) or a report or document from the National Audit Department. These two agencies have more accurate information on the status of the organization. Moreover, the documents provide strong evidence to confirm the status of the organization. CKAPS can also recognize the status of the healthcare institution through patient or public complaints, such as charges that are higher than those declared during the application process.

4.4.2 Sustainability Concept for Social-based Healthcare Institution

This interview session explored in-depth the sustainability concept for healthcare institutions, especially social-based ones.

i. Sustainability concept for social-based healthcare from the regulator's perspective

According to interviewee 1, the sustainability concept for healthcare institution should begin since its establishment. Social-based healthcare should be defined according

to Act 586, the regulation for private healthcare institutions. In her opinion, among the factors that contribute to the sustainability of social-based healthcare institutions are planning, strong proposal, and knowledge of healthcare operator.

ii. Important features for the establishment of healthcare facility

Interviewee 1 revealed that, according to Act 586, there are three important elements that must be considered by a healthcare institution operator: 1) the healthcare services that it intends to provide; 2) facility and hospital equipment; and 3) healthcare professionals. A party that intends to establish a private healthcare facility should consider these three important features from day one.

iii. Fulfill the requirements upon registration and pre-establishment

Based on Section 6, Part II of Act 586,[6] the sustainability concept for social-based healthcare institutions has been considered since their initial registration. The regulator not only considers the establishment of the healthcare institution but also its maintenance or sustainability. The institution may be managed by a sole proprietor, partnership, or body corporate:

> **Approval to establish or maintain,** or a licence to operate or provide may only be issued to-
>
> (a) a sole proprietor who is a registered medical practitioner;
>
> (b) a partnership which consists of at least one partner who is a registered medical practitioner; or

[6] Act 586: Private Healthcare Facilities and Services Act 1998, Section (II) 6

(c) a body corporate whose board of directors consists of at least one person who is a registered medical practitioner.

Based on Act 586, the sustainability process of private healthcare facilities, including social-based healthcare institutions, begins since the establishment process. Act 586 highlights the human and financial resources of the applicant. Although it does not specifically mention the elements of sustainability (i.e., financial, environmental, and social), Act 586 examines all those elements to determine the sustainability of the healthcare facilities. In the pre-establishment phase, the healthcare facility operator is inquired about its financial, human resources, environmental, and social aspects. Its social aspect relates to the suitability of the services that the operator intends to provide to the surrounding population.

iv. Comprehensive planning and pre-establishment proposal

According to interviewee 1, based on the proposal of and interview with the healthcare operator, CKAPS will evaluate and review two aspects. First is the suitability of the proposed healthcare service to the proposed location. Second is to consider other healthcare facilities that already operate in the proposed location to prevent unhealthy competition among private healthcare service providers. This strict procedure, especially the requirement to prepare a comprehensive proposal, is to ensure that the healthcare operators or providers know and are aware of what they want. Such a procedure can prevent the establishment of halfhearted hospitals or healthcare facilities, and to prevent current healthcare facilities from operating poorly or facing future problems.

v. Comprehensive planning for healthcare establishment

Through this rigorous procedure, the healthcare operator or provider should be aware of how to ensure its sustainability since the planning phase. Although the sustainability process is not directly mentioned in Act 586 and the applicant is under no obligation to declare it, in practice the elements of sustainability have already been indirectly applied and reviewed. To obtain a license to operate and maintain a healthcare facility, the applicants must comply with the procedures set by CKAPS. All requirements determined by CKAPS must be fulfilled and completed in the proposal. The elements of sustainability are already implied within the procedure and requirements of CKAPS. Fulfilling them can help the healthcare institutions to sustain.

vi. Human resources capabilities

Interviewee 1 added that the sustainability concept for healthcare institutions is not solely restricted to the financial aspect, but they should also have strong human resources capabilities. The qualifications, training, and experience of the personnel are directly related to service quality. Unfortunately, when discussing waqf, the top priority is typically given to free services instead of professional personnel. Interviewee 3 agreed with this statement, commenting that sustainability is not about how to build or operate a hospital, but it is about how healthcare providers intend to sustain, as they have to bear every cost without neglecting their social initiatives.

4.5 Sustainability Practices for Social-Based Healthcare Institution in Malaysia

i. Underlying principles of social-based healthcare

The sustainable practices of private social-based healthcare institutions are similar to their profit-based counterparts. The reason is that both are regulated by Act 586. Therefore, any laws or regulations that govern private profit-based healthcare institutions will also apply to social-based ones. Both types of organizations are subject to the same procedures and minimum standards laid down in Act 586. As interviewee 3 pointed out, the healthcare industry cannot lower its standards regardless of profit orientation or purpose, as its main concerns are patient safety and quality of care. Therefore, the underlying principles are the same regardless of whether the private healthcare institution is social-based or profit-based. Healthcare facilities, services, and personnel must adhere to the same minimum requirements and quality defined by the regulator. Therefore, there is no distinction in terms of practice between both types of organizations.

ii. Sustainability practices in CKAPS' procedures

Interviewee 1 recalled the statements of interviewee 3 regarding the procedures and minimum requirements set by CKAPS and the law. In terms of procedures, any person or organization, whether private, NGO, or NPO, that intends to establish a private healthcare facility can find the required information from CKAPS' website. The website hosts the relevant procedures, checklists, related forms, and flow charts. These will guide and help the applicant to meet all the requirements.

iii. Collaboration program with stakeholders in the healthcare industry

In addition, CKAPS also jointly organizes seminars and programs with relevant stakeholders to ensure the viability and development of private healthcare institutions, particularly social-based ones. For example, CKAPS commonly conducts joint workshops and seminars with the Malaysia Production Corporation for private healthcare industry players, focusing on how to plan and develop a hospital or healthcare facility.

iv. Roadshow and engagement with related health associations

CKAPS also holds roadshows and engagements with several associations. Usually, interviewee 1 is invited to provide information about the procedures and legal matters related to the role of the regulator and Act 586.

v. Discussion and consultation

CKAPS is always open to any discussion with or provide consultation for applicants who are having trouble with the application process. If an application is rejected, the applicant may appeal to CKAPS. However, according to interviewee 1, CKAPS does not allocate a specific time for consultation. The applicant needs to make a consultation appointment with CKAPS' representative. During consultation, CKAPS will provide assistance to the interested parties. The applicant has the freedom to choose which type of health facilities they intend to operate, and CKAPS will show the rules relevant to the application.

vi. Knowledge on related laws and regulations in the healthcare industry

Interviewee 1 stressed that every party interested in developing a hospital or health facility should be knowledgeable on relevant laws and regulations. This is because the regulations related to the establishment of hospitals or health facilities are not limited to Act 586. Many other laws are also relevant, such as laws under local authorities concerning building planning requirements. Therefore, the process of building and maintaining a hospital or other health facility not only involves CKAPS but also various other agencies. To disseminate information to industry players, CKAPS has collaborated with the Malaysia Productivity Corporation to establish a Private Healthcare Productivity Nexus (PHPN).

vii. Awareness among healthcare industry players

Awareness among industry players is important so that all information related to changes in requirements and regulations can be conveyed without miscommunication. According to interviewee 2, every year, CKAPS will host a dialogue session for healthcare providers, typically hemodialysis operators. During the dialogue session, it will explain and discuss current issues related to the health facilities involved. CKAPS typically disseminates any additional information or modification of existing rules and procedures to industry players through a regulatory impact assessment, which it conducts via a unified public consultation and townhall. According to interviewee 1, this practice has been carried out for a few years. However, sometimes, a few industry players still fail to receive new information.

4.5.1 Financial Sustainability Practices

i. Implied financial sustainability in Act 586

Interviewee 1 said that Act 586 implies the financial sustainability of private healthcare institutions. Therefore, it is essential that the applicant or social-based healthcare institution to be aware of its financial sustainability to ensure its health services remain accessible. However, in practice, some applicants remain unaware of the actual costs of operating a health facility, to the point that some have closed due to financial problems. She explained that this situation happens when some applicants are just following the trend and market demand. For example, they establish cancer treatment centers without being aware of their high operating costs. Thus, applicants should be aware that the development of health facilities is a complex issue: It involves the care of patients and their myriad issues and treatments, as well as various healthcare technology and equipment that directly and indirectly influence the cost of establishment and operations.

ii. Fees to establish and maintain a healthcare institution

Applicants should also be aware of the large amount of funding needed to develop and maintain a health facility since the first day of application to prevent withdrawal of application or termination of operations. Sections 8 and 22 of Act 586 specify that the application to establish or maintain a healthcare facility requires a mandatory fee. The fee, determined by the MOH, differs by healthcare facility. Application for license renewal must be made no later than six months before the expiration of the current license. Late renewals will be charged with twice the original fee. Section 8 of Act 586 is shown below.

An application for approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic shall be made to the Director General-

(a) in the prescribed form and manner;

(b) accompanied by the prescribed fee; and

(c) by submitting together with the application-

(i) a comprehensive plan for the establishment or maintenance of the proposed private healthcare facility or service including the site plan, building layout plan, design, construction, specification, the type of facility or service to be provided and the proposed arrangements for manpower recruitment including arrangements for manpower training;

(ii) if the applicant is not a natural person but a company, partnership or society, a copy of its constituent document, duly verified by a statutory declaration made by an authorized officer of the applicant; and

(iii) such other information, particulars or documents as may be deemed necessary for the purpose of determining the application and the suitability of the applicant.

Interviewee 1 revealed that financial sustainability is required, as the healthcare operator has to pay the initial license fee during the pre-establishment phase and renew it biennially. The renewal period is based on Section 22:

A licence to operate or provide a private healthcare facility or service other than a private medical clinic or a private dental clinic shall, unless sooner suspended or revoked, remain in force **for a period of two years from the date on which it is issued**, and may by application in the prescribed form and on payment of the prescribed fee be renewed for a similar period by the grant of a new licence.

The fee is subjected to the schedule as mentioned in Section 106, Fee Schedule of the Act 586 as below:

Section 106. Fee schedule.

(1) The Minister may make regulations prescribing a fee schedule for any or all private healthcare facilities or services or health related facilities or services.

(2) The Minister may, from time to time, after consulting the Director General, amend the fee schedule by order published in the Gazette.

(3) A private healthcare facility or service for which a fee schedule has been prescribed under this section shall comply with such fee schedule.

(4) A private healthcare facility or service which fails to comply with any fee schedule prescribed under this section commits an offence.

iii. Financial statement document

Section 42 requires financial statement of the healthcare facility during the registration and renewal process. The healthcare entity should be established, maintained, and regulated on the basis of this provision. Subsection 2 of Act 586 also compels the healthcare institution to be transparent:

(1) The Director General shall cause to be kept and maintained in such form and manner as may be prescribed -

(a) a register of all private healthcare facilities or services licensed under this Act;

(b) a register of all private medical clinics and private dental clinics registered under this Act; and

(c) such other register or registers as he deems that the private healthcare facility or service should maintain.

(2) The registers in paragraphs 1(a) and (b) **shall be deemed to be public document within the meaning of the Evidence Act 1950 [Act 56] and shall be open for public inspection and the public may make a search on and obtain extracts from the registers upon payment of a prescribed fee.**

iv. Budgeting during the application process

The application must include the budgeting and financial statement documents required by CKAPS. The healthcare institution, whether nonprofit or for-profit, should be aware of the gross establishment and maintenance costs. It should declare its budget in the proposal, including any subsidies granted by a third party, and regularly publish a financial statement to ensure its sustainability.

v. Detail on financial sources

According to interviewee 1, the applicant is responsible to provide information about the financial source(s) for the establishment of the healthcare institution. Information on the financial statement and budget estimation should be consistent to fulfil the application requirement.

4.5.2 Environment Sustainability Practices

i. Availability and suitability of area/ location setting

Part of environmental sustainability is inspecting the location of a healthcare institution. Before CKAPS can endorse the establishment of a healthcare facility, it will investigate its proposed location to ensure no overlap between healthcare providers. Section 9 of the Act, under "matters to be considered before approval to establish or maintain is granted", has included the location and surrounding area of the healthcare institution as one of the criteria for approval:

> In deciding whether or not to grant approval to establish or maintain a private healthcare facility or service other than a private medical clinic or a private dental clinic, the Director General shall consider the following matters:
>
> (a) the nature of the healthcare facility or service to be provided;
> (b) the extent to which the healthcare facilities or services are already available in an area;
> (c) the need for the healthcare facility or service in an area;
> (d) the future need for the healthcare facility or service in an area; or
> (e) any other matter which in his opinion is relevant.

However, interviewee 1 said that CKAPS may give special consideration if the healthcare facility, specifically a hemodialysis center or hospice, is philanthropic and

willing to offer pro bono services. Thus, even if an area already has one or more hemodialysis centers, CKAPS may still allow a nonprofit center to open. This is in line with the policy of the MOH.

ii. Nature of the healthcare facility

CKAPS has implicitly require environmental sustainability since the pre-establishment phase. The applicant or healthcare provider is asked to specify the type of facility that it intends to open. CKAPS then assesses the proposal by inspecting the area: whether a hospital is already present nearby; whether there is enough hospital in the area; whether the services offered there are appropriate; or whether the provider only wants to cater to the foreign population. It is therefore necessary for the applicant to provide CKAPS with its planning in the pre-establishment proposal.

iii. Compliance with regulatory framework set by Act 586

Interviewee 1 explained that CKAPS observes and enforces the regulations through many approaches. Private healthcare institutions are expected to comply with the regulatory framework defined by Act 586 (Appendix). A simple approach is the biennial license renewal, which the healthcare provider must apply for six months before expiry. This requires CKAPS to visit every licensed healthcare facility.

iv. Observation and enforcement by CKAPS

Observation and enforcement are also conducted based on complaints received from patients. CKAPS will only visit the institution when necessary. The applications are

various, each with a particular perspective. A visit is necessary before license expiry and during the approval process (registration inspection). Monitoring activities, on the other hand, depend on state CKAPS. Visitation will depend on the number of healthcare facilities in a given state. In a state with many clinics, CKAPS cannot visit them periodically. But in states with few clinics, CKAPS can conduct annual inspections. However, if CKAPS needs verification, for example in an application for additional healthcare services, it will visit the healthcare facility.

v. Floor plan

If a healthcare facility intends to offer additional services, it is necessary to renovate the facility, and the healthcare provider must resubmit the floor plan. The healthcare provider must inform CKAPS of the type of additional services and the healthcare professionals in charge. This whole process refers to the regulatory framework. Act 586 is very comprehensive: it applies from the pre-establishment phase until closure. This process was explained by interviewee 1 during the interview.

vi. Healthcare quality

Interviewee 1 emphasized the importance of avoiding low-quality services. She stated that healthcare providers cannot simply ignore the quality of healthcare services, as they concern the safety of human lives. Maintenance of healthcare facilities and equipment should be carried out every year. Neglecting the maintenance procedure will impair the quality of healthcare services. Poor maintenance of equipment results in low-quality and

ineffective services. Nonprofit healthcare institutions have similar responsibilities. Section 74 Act 586 specifies the healthcare quality requirements:

> Act 586, Section 74. Quality of healthcare facilities and services.
>
> (1) Every private healthcare facility or service shall have programmes and activities to ensure the quality and appropriateness of healthcare facilities and services provided.
>
> (2) Information regarding such programmes and activities shall be furnished to the Director General as and when required by him.

Healthcare institutions of any type must prioritize the quality of care. Section 76 of Act 586 has conferred power to the Director General (DG) to issue directives, orders, and guidelines relating to the quality assurance of healthcare institutions:

> Section 76. Power of Director General to Issue Directives, Orders or Guidelines Relating to Quality Assurance.
>
> The Director General may issue directives, orders or guidelines relating to the quality and standards of private healthcare facilities or services as he deems necessary.

vii. Healthcare equipment and instrument

Matters relating to the standards and requirements for healthcare facilities, services, equipment, and instruments are subject to the authority and directions of the Director General:

> Section 75. Power of Director General to give directions.
>
> (1) Where the Director General is of the opinion that any **prescribed requirement or any prescribed standard which applies to a private healthcare facility or service is not being observed by that facility or service, the Director General may give to the holder of the approval, licensee or the holder of a certificate of registration in respect of such facility or service such directions** in writing as he thinks necessary for the observance of the requirement or standard and shall state in the directions the period within which

the holder of the approval, licensee or the holder of the certificate of registration is required to comply with the directions.

(2) Where in the opinion of the Director General **the use of any apparatus, appliance, equipment, instrument, substance or any activity in a private healthcare facility or service** or the manner in which any blood, blood product, human tissue or fluid or any product of the human body, substance or sample is used, collected, handled, stored or transported, or any other activity conducted is detrimental to the health and safety of any person therein or is otherwise unsuitable for the purpose for which it is used, the Director General may, by notice, **direct the holder of the approval, licensee or the holder of a certificate of registration in respect of such facility OR service to stop using the apparatus, appliance, equipment, instrument or substance or to stop the activity.**

(3) The Director General may, by notice, further direct the holder of the approval, licensee or the holder of a certificate of registration to install or replace such apparatus, appliance, equipment, instrument, substance or any activity therein, and to adhere to such procedures as may be specified in the notice.

viii. Relationship with multiple parties and practitioners

To prevent nonprofit healthcare facilities from becoming substandard, interviewee 1 drew attention to strategic preparation in the operation of a healthcare institution, which involves multiple parties and practitioners. She said that a thorough planning is necessary for the establishment of a healthcare institution. Every aspect relating to the operation of the healthcare institution requires an input. She provided an example: To build a hospital, the healthcare provider not only requires a doctor but also an architecture planner, a hospital building engineer, a financial expert for financial planning and budgeting, a lawyer who understands the regulatory requirements, and a runner who knows who to contact.

ix. Board of management and advisory committee

Sections 78 to 80 of Act 586 have also included the guidelines for the establishment of individual advisory committees in medical or dental, obstetric, and nursing care clinics.

These provisions indicate the comprehensive structure that a healthcare institution must implement for its sustainability. The relevant clauses are included in the annex.

> PART XIV - BOARD OF MANAGEMENT AND ADVISORY COMMITTEE
>
> Section 77. Board of Management.
>
> (1) The licensee of a private hospital, private maternity home, private ambulatory care centre, private hospice, private psychiatric hospital or any other private healthcare facility or service as the Minister may specify, **shall establish a Board of Management of whom two members shall be from the Medical Advisory Committee established under paragraph 78(b) or 79(b).**
>
> (2) Where a private hospital, private maternity home, private ambulatory care centre, private hospice, private psychiatric hospital or any other private healthcare facility or service as the Minister may specify, **provides or intends to provide both medical and dental services, the licensee of such facility or service shall establish a Board of Management of whom two members shall be from the Medical and Dental Advisory Committee established under paragraph 78(c).**

x. Strong leadership and teamwork

Other factors related to the sustainability of healthcare institution, as interviewee 1 said, are teamwork and strong leadership. However, she continued, in practice, someone who wants to develop a hospital may not care about planning. This attitude (in fact, ignorance) will not bring success, as the development of the healthcare facility has not been considered comprehensively. To be sustainable, the initiator must be well-prepared, and a good and comprehensive proposal should be drafted from day one. The sustainability of healthcare institutions does not solely relate to maintaining their operations, and it should begin since the planning phase. Interviewee 1 stressed that, to be sustainable, the organization needs to have a good team of experts in their respective fields who can work together. Unfortunately, according to her, it is not that easy for different groups of

individuals, each with their own idea, to cooperate. She also stressed that it is not an easy task to come together as a team without strong leadership. Good leadership can bring everyone to cooperate as a team.

xi. Relationship of healthcare professionals with management

The interviewer then continued with the question of whether CKAPS enforces the minimum wage of volunteers or waqf healthcare professionals, who are influenced by the rate of pay or reimbursement. Interviewee 1 responded that CKAPS does not determine the salaries of healthcare professionals. According to her, Malaysia's private healthcare sector is regarded as an independent contractor, and healthcare providers also charge for their services. Therefore, CKAPS does not regulate the pay system for private healthcare practitioners. Volunteerism or waqf of skills by private healthcare professionals is their personal choice. As far as the law is concerned, it is not illegal to provide free services.

4.5.3 Social Sustainability Practices

In this research, social sustainability refers to the institution's engagement with and impact on its surrounding society. One of the most important social sustainability practices of healthcare institutions is patient engagement.

i. Patient grievance mechanism

One of the social sustainability practices of healthcare institutions is patient grievance mechanism or patient complaints. This complaint process relates to the relationship between social-based healthcare institutions and their patients. Patients can

also make complaints directly to CKAPS, which would affect the sustainability of healthcare institutions. Patient grievances to CKAPS are specified in Section 36 of Act 586. As interviewee 1 mentioned earlier, upon receiving a complaint, CKAPS will decide whether it needs to visit the healthcare institution. During this visit, if CKAPS discovers any conducts, it will close the institution or even revoke its operating license. The Section clearly outlines patient rights and complaint mechanism. A healthcare facility needs to have a patient grievance mechanism plan and procedure to deal with any issues relating to the healthcare services rendered.

> Section 36. Patient grievance mechanism.
>
> The licensee of a private healthcare facility or service or holder of a certificate of registration shall establish a plan for grievance mechanism for patients using the premises of the private healthcare facility or service. A grievance mechanism plan and grievance procedure shall be as prescribed.

ii. License and policy statement

A clause in Section 35 of Act 586 protects the rights of patients by compelling the display of a license and policy statement at healthcare premises:

> Section 35. Policy statement.
>
> (1) A licensee of a private healthcare facility or service or the holder of a certificate of registration or the person in charge of a private healthcare facility or service shall make available, upon registration or admission, as the case may be, its policy statement with respect to the obligations of the licensee or holder of the certificate of registration to patients using the facilities or services.
>
> (2) A policy statement shall cover such matters as may be prescribed.

iii. Monitoring procedure

In addition to dealing with patients' complaints, CKAPS monitoring procedures also include scheduled visits, reviewing complaints on social media, and collecting information or complaints from the top management of health facilities. Visits are made either on the basis of public concern or at least once or twice a year.

iv. Engagement with the surrounding society

Section 105 of Act 586 includes social or welfare contributions of healthcare institutions as one of their social responsibilities:

> The Minister may prescribe the type of social or welfare contribution or the quantum of social or welfare contribution that shall be provided, and the manner in which it shall be provided, by any private healthcare facility or service.
>
> The Minister may, from time to time, amend the type of social or welfare contribution and the quantum of social or welfare contribution imposed under subsection
>
> A private healthcare facility or service shall provide the social or welfare contribution of the type and quantum prescribed under this section.
>
> Any private healthcare facility or service which fails to comply with subsection commits an offence.

v. Attitude of initiators and management team

Another factor that contributes to social sustainability, according to interviewee 1, is the good attitude of initiators and management of healthcare institutions. This is especially important for institutions established on a social initiative. Attitude is the first thing that needs to be fulfilled, as she pointed out.

vi. Experience and competence of healthcare experts

Interviewee 1 opined that social-based healthcare institutions must be operated by a group of practitioners who are experienced in their respective fields. The practitioners should not only be experts on the *duniawi* (worldly) side but also the *ukhrawi* (metaphysical) aspect. She also added that both the operator and provider must be experienced. The operator should understand and know how to operate and handle a healthcare organization in terms of accounts, activities, and operating expenses, while the provider should know how to distribute the benefits of healthcare services. These require experienced and competent personnel.

4.6 Analysing and Findings

Based on the interview and document review, a number of themes and category concepts were developed based on the conceptual structure in Chapter 2. These are shown in Table 4.2:

Table 4.2: List of Themes from the Findings

Research Objective	**Regulator (In-depth Interview)**
Research Objective 1 Regulator perspective on the sustainability concept for social-based healthcare institution	**Social-based Healthcare Concept** i) Private healthcare facility definition based on Act 586. ii) Private healthcare facility categories based on Act 586 iii) Non-profit and for-profit healthcare provider differencess iv) Private hemodialysis and hospice registration under non-profit organization. v) Recognition of healthcare facility category for a non-profit organization. **Sustainability Concept for Healthcare** i) Comprehensive planning, ii) Strong proposal iii) Healthcare operator knowledge. iv) Important features for healthcare facility establishment (healthcare services, facilities and professional) v) Fulfill the requirement upon registration and pre-establishment based on Act 586 vi) Human resources capabilities

Table 4.2 continue

Research Objective	**Regulator (In-depth Interview)**
Research Objective 2 Sustainability practices for social-based healthcare institution	**Financial Sustainability Practices** i) Financial sustainability element implies in Act 586 ii) Fees to establish and maintain iii)Financial statement document iv)Budgetting for application process v) Detail on financial sources **Environment Sustainability Practices** i) Availability and suitability of area/ location setting ii) Nature of the healthcare facility iii) Comply with regulatory framework set by Act 586 iv) Observation and enforcement from CKAPS v) Floor plan vi) Healthcare quality of care vii) Healthcare equipment and instrument viii)Relationship with multiple parties and practitioners ix) Board of management and advisory committee x) Strong leadership and teamwork xi) Healthcare professional relationship with the management **Social Sustainability Practices** i) Patient grievance mechanism ii) License and policy statement iii)Monitoring procedure iv)Engagement with the surrounding society v) Attitude among the initiator and management team vi)Healthcare expertise experience and competence

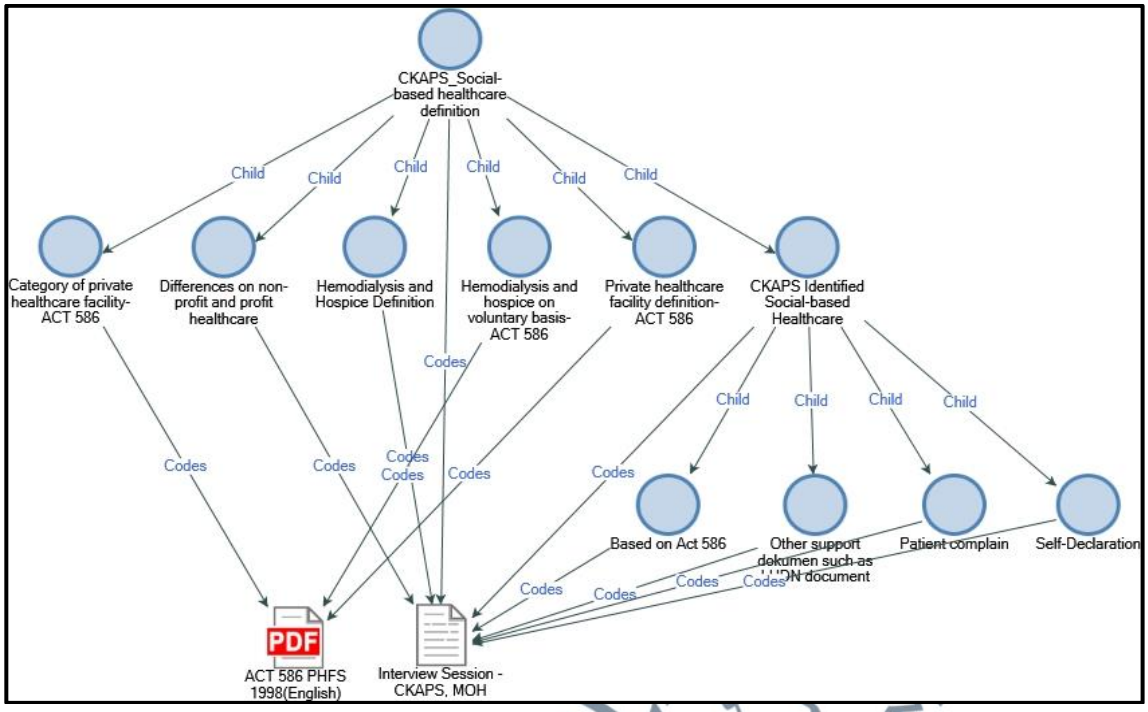

Figure 4.1: CKAPS Understanding on Social-based Healthcare Concept

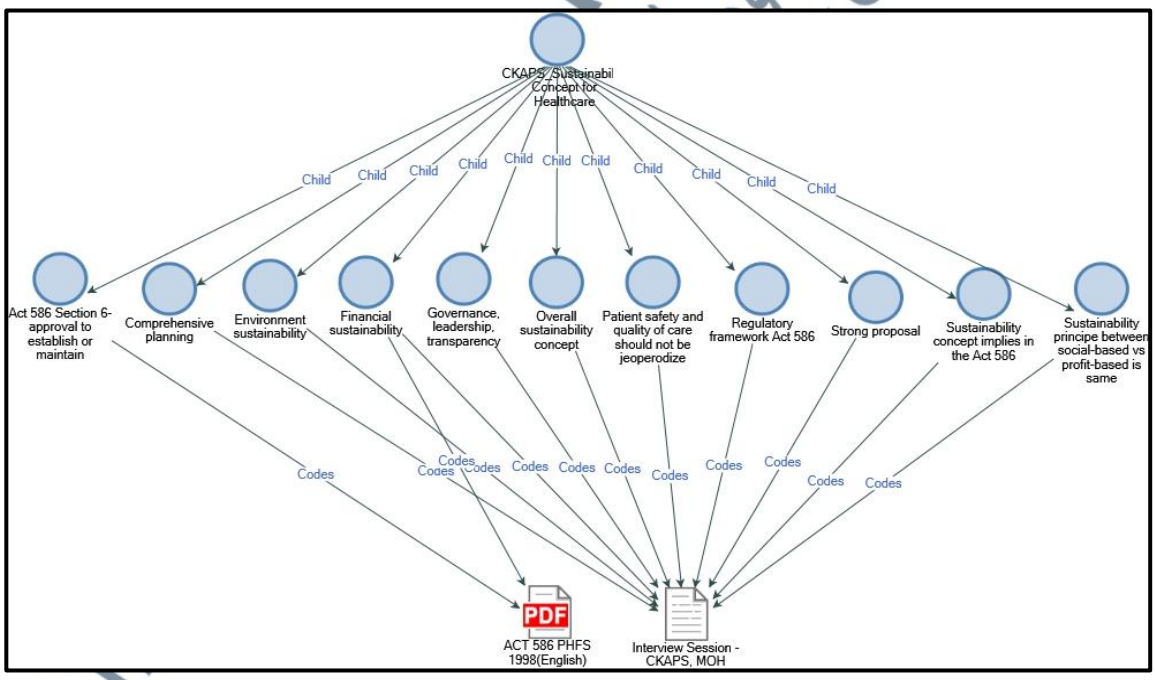

Figure 4.2:CKAPS Understanding on Sustainability Concept for Healthcare Institution

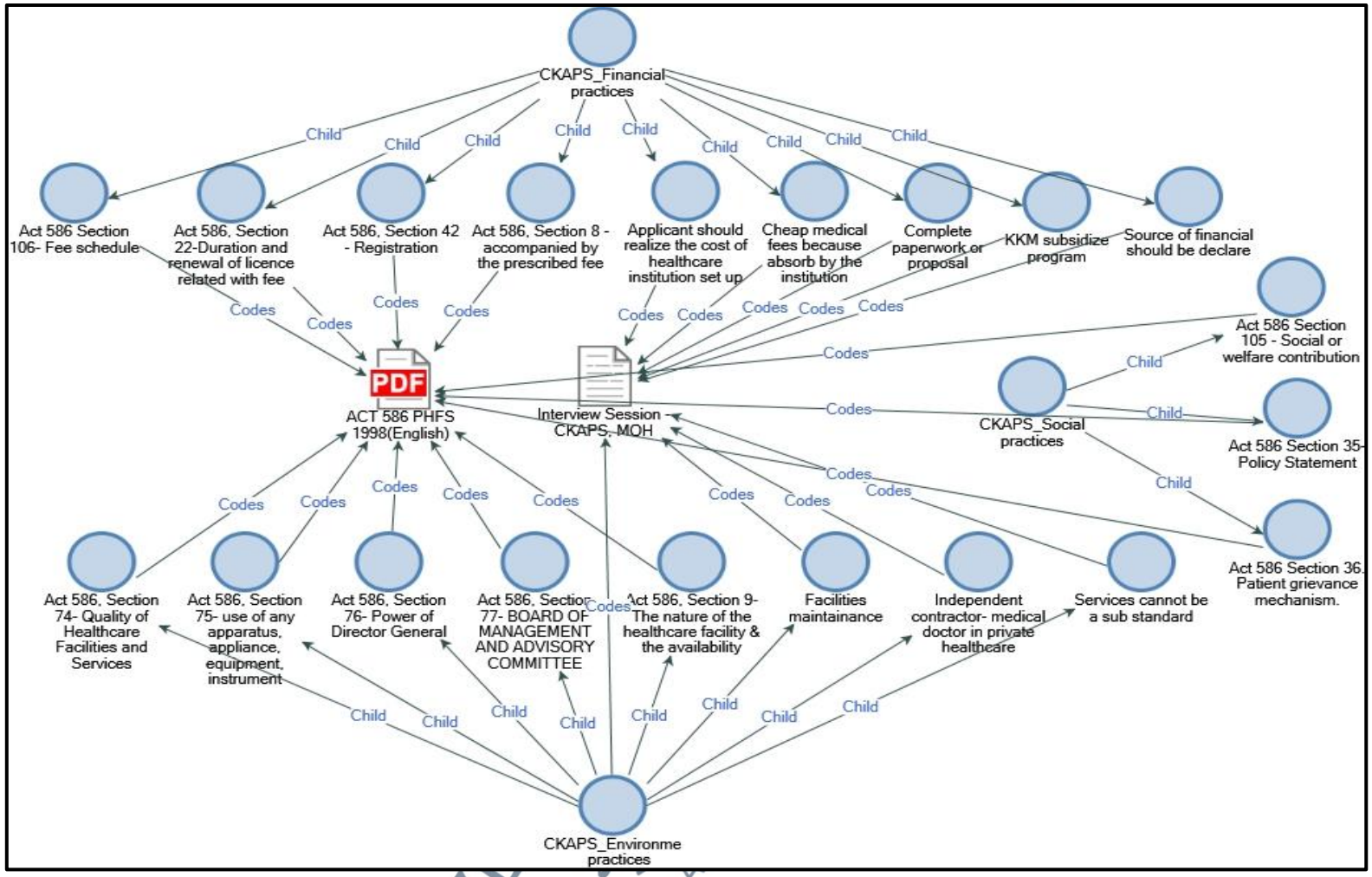

Figure 4.3: Sustainability Practices by Social-based Healthcare Instition from CKAPS, MOH Perspective

4.7 Conclusion

Overall, the sustainability concept for social-based healthcare institutions should be based on the principles outlined in Act 586, which emphasizes comprehensive planning and proposal. The pre-establishment proposal should prioritize three important aspects: 1) types of service; 2) facilities and equipment; and 3) healthcare professionals. Additionally, the party who intends to develop or operate the healthcare facility must be knowledgeable on the operations of the facility. There are three ways to determine whether a healthcare institution is social-based: 1) self-declaration from the social-based healthcare institution; 2) documents such as tax exemption letter from LHDN or National Audit Department; and 3) information from the public. To sustain, these healthcare institutions should not only be financially, socially, and environmentally robust, but they should also have a management team and leadership with pertinent qualifications and experience. Healthcare quality is the top priority and should not be foregone to reduce the cost of healthcare in the attempt of serving the poor.