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## Recordkeeping Requirements for Private Health Facilities and Services: The statutory perspectives

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### Abstract

The study aims to investigate the implications of Malaysian legislation on recordkeeping requirements. These implications are derived from selected provisions where contexts are determined based on records lifecycle components. Using document analysis approach, the Private Healthcare Facilities and Services Act 1998 is a case to examine the contexts and applications of recordkeeping requirements in medical and health services in Malaysia. Results showed that the Act has various recordkeeping implications either explicitly or implicitly indicated. As this area is least explored, more efforts must be made to establish recordkeeping requirements specially derived from statutes to improve records management policy and governance.

Keywords: Records, Recordkeeping, Law, Legal requirement

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### 1.0 Introduction

Records are legal documentation (Smith, 2016) that preserves organizations' corporate memory. They do not merely support evidence-based decision-making and executions but also document rights and responsibilities, provide proof of transaction, and establish rights and responsibilities between parties (Huang *et al.*, 2023). Thus, records become the official instrument to show compliance with legal requirements and considerations set by statutory provisions (Skupsky, 1990).

Efforts must be made to prepare a recordkeeping framework consisting of policies and guidelines that are consistent with the relevant laws (Dikopoulou & Mihiotis, 2012) to ensure records possess integrity and authority (Farrell *et al.*, 2023; Franks, 2018), minimizing or eliminating risks associated to records, information, and document (Marutha, 2019). Determining the records requirement is daunting as the process requires various considerations, including resources, cost, time, and expertise (Skupsky, 1989). Determining legal requirements related to records from the identified legislation requires searching and researching, assigning context and implication of recordkeeping, and sorting them into the discernable relationship to the context and applications.

### 2.0 Literature Review

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As critical resources to organizations' operations and functions (Megill, 2005; Brunskill & Demb, 2012), records must be managed and regulated as they contain both value and risk. Thus, record-related resources must be managed appropriately by taking into consideration legal requirements enunciated in legislation. Previous studies mainly focused on the impacts and applications of records for services, work efficiency, and organizational objectives, as indicated by Tracey *et al.*, (2023); Farrell *et al.*, (2023); Lawan & Henttonen (2023); Chandler, (2022). Huang *et al.*, (2023); Haraldsdottir *et al.*, (2023), on the other hand, focused on the application of certain methods and technologies on specific scenarios and during constraint and limitation (Wendelken, 2023). Studies determining the ambit and applying statutory law on recordkeeping are the least conducted.

## 2.1 Records, records management process, and lifecycle

Records are primarily defined based on common terminology and the context they serve. Some are defined in statutes, while many can be found in literature. For example, section 2 of the National Archive Acts (2003) defines "records" as *materials in written or other form setting out facts or events or otherwise recording information...electronically produced records regardless of physical form or characteristics and any copy thereof*. International Organization for Standardization (ISO, 2016) defines a record as information created, received, and maintained as evidence and as an asset by an organization or person in pursuit of legal obligations or the transaction of business. Records management, on the other hand, is referred to as a field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use, and disposition of records, including processes for capturing and maintaining evidence about business activities and transactions in the form of records (ISO, 2016). Records management involves systematic control of records through their lifecycle from the creation or receipt, processing, distribution, organization, storage, and retrieval to their ultimate disposition (Read & Ginn, 2007).

Similarly, Brunskill & Demb (2012) view the record life cycle as the life span of records as expressed in the five phases of creation, distribution, use, maintenance, and final disposition. The definitions indicate the composition of various elements, including related resources, processes, outcomes, and capacity building, while the regulatory framework is one of the guiding principles. Knowledge, expertise, availability of information, professionalism, attitude, internal and external roles, and clear assignment of responsibilities are also cited as critical factors (Lanin & Hermanto, 2019). The whole set will positively impact business growth (Mintah *et al.*, 2022).

## 2.2 Recordkeeping and regulatory control

Records enable the organization to perform business and are inevitably linked to the law, as they can be trusted to what they purported to be (Franks, 2018). Works of literature agree that legislation is the core component that forms regulatory frameworks (Marutha, 2019). The organization's standards, policies, and recordkeeping guidelines must meet legal requirements to ensure that actions taken are lawful (Setijaningsih *et al.*, 2022, 2022), and some of the legal provisions are found in legislation. However, most of the legislation provisions do not explicitly establish legal requirements. At the same time, some only need to be considered in developing the regulatory recordkeeping framework. Legal requirements and considerations include laws and other legal concerns that may impact the legal retention period (Skupsky, 1990), accountability, human rights, and social justice (Farrell *et al.*, 2023).

## 2.3 Records management outcomes-legal compliance

Managing records serves multipronged advantages to organizations and entities belonging to them. The availability of records supports good governance and information security, as records and documentary evidence are strongly connected to compliance, transparency, and integrity (Farrell *et al.*, 2023; Chandler, 2022). Records are no longer seen merely as valuable historical resources. They are considered corporate assets that support core functions and other administrative tasks (Dikopoulou & Mihiotis, 2012), protect legal rights, and prevent human rights violations (Barata *et al.*, 2000). Failure to manage records and related information resources may go against the laws, premature disposal of active records, and information security breaches. These adversaries may result in untoward consequences like costs, civil and criminal suits, loss of trust, and disruption to activities and operations (Kautto & Henttonen, 2020). Thus, well-designed recordkeeping procedures and observing legislative and regulatory frameworks protect organizations and individuals against unlawful acts, including violation of privacy and confidentiality (DeRenzo *et al.*, 2020) and other risks (Wendelken, 2023).

## 3.0 Methodology

The study adopts a qualitative approach where the document analysis is used to allow interpretation to be made to the main document, namely the Private Healthcare Facilities and Services Act 1998. The analysis determines the meaning and contexts (Bowen, 2009) of recordkeeping requirements from the identified statutory provisions, which are searched using the keywords of records, information, documents, and reports. Assigning context to the transcript is almost like analyzing data in other qualitative research, which involves preparing data for analysis, understanding the data in-depth, representing the data, and interpreting the more significant meaning of the data (Creswell, 2003). Altogether, 30 sections and 50 occurrences of the keywords in the texts require analysis. It is presumed that the keywords found in the texts suggest the presence of recordkeeping properties in the statute. The following are the primary considerations in the analysis:

- 1) Identifying related statutory provisions using the keywords.
- 2) Contextualizing record requirements from the text to determine the degree of implications on records lifecycle management and business activities.

## 4.0 Findings

The results include a descriptive analysis of the Act and the legal provisions therein, recordkeeping requirements for core business and housekeeping, records lifecycle, confidentiality and accessibility, legal compliance, and the consequences for non-compliance.

#### 4.1 The Background of the Act

Private Healthcare Facilities and Services Act 1998 regulates and controls private healthcare facilities and services and other health-related facilities and services, and for matters related hereto. "Private healthcare facility" and "healthcare services" are defined in section 2 of the Act. It consists of 19 parts and 122 sections, plus many subsections. In identifying recordkeeping requirements, statutory provisions are searched using keywords, namely "record," "information," "document," and "report," where relevant sections and subsections are identified and eventually analyzed. The results are shown in the table below:

Keyword	The occurrence of keywords in sections	Remarks
Records	13	The repetition of the keywords in the provisions occurs 50 times in 30 sections and subsections. It is still premature to implicate the provisions to recordkeeping requirements based on the presence of the keywords until the contexts of these provisions are duly analyzed.
Information	19	
Document	13	
Report	5	
Total 50		

(Source: Private Healthcare Facilities and Services Act 1998)

#### 4.2 Recordkeeping Requirements- Housekeeping purposes

The housekeeping matters are found primarily in Parts 3-6, which involve Section 3 to Section 36 of the Act. They regulate matters for the approval to establish or maintain private healthcare facilities or services, license to operate facilities or services, registration, and responsibilities of a licensee, holder of the certificate of registration, and person in charge. Although only a few statutory provisions have explicitly indicated requirements for recordkeeping (as will be found in all other parts of the Act), closer scrutiny of the statutory provisions proposes various implications, especially for housekeeping purposes. Those implications are explained in the following subsections.

##### 4.2.1 Records lifecycle

The statutory provisions in the sections and subsections suggest the requirement for care records in their lifecycle, i.e., creation, retention, and availability to serve purposes before the disposition. Section 16 requires the retention of the documents, records, and information mentioned therein for inspection, as in section 85, which requires information relating to the organization to be kept as required by the Director General. Section 25 (1), (2), and (3) state, among other things, the failure to abide by the requirements set on the creation, retention, and availability to submitting records, documents, and information as prescribed may render the rejection of the application or the license may be quashed or revoked.

##### 4.2.2 Recordkeeping responsibility

Section 31 (1) and (2) set responsibilities on a licensee or the registration certificate holder to ensure the maintenance of healthcare facilities and services, facilitate inspection, qualified personnel, and compliance with duties and responsibilities as prescribed by the Act. Concerning this, section 31 (2) urges different persons to be appointed to manage and assume the duties and responsibilities relating to non-clinical matters, which include managing records and other functions like administration of non-clinical resources.

##### 4.2.3 compliance with quality and standards

Several sections set responsibilities on parties involved to comply with standards and qualities in recording and documenting information relating to the approval of establishing healthcare facilities, services, and the conditions for licensing. Sections 8 and 15 require standards and quality of information and documents to be observed and exercised within stipulated times. Although not explicitly stated, the quality of information is concerned with its content and format besides the stipulated periods. Section 3 states that failure to abide by the requirements stipulated in the Act in submitting information and documents may render the application unsuccessful, as it is tantamount to a withdrawal.

#### 4.3 Recordkeeping requirements- Functional purposes

Recordkeeping requirements can be established through required documentation, supplying information, record processing, and transactions carried out by private healthcare facilities and services. These compulsory processes establish the following requirements:

##### 4.3.1 Responsibility to care for patients and medical records

The requirements to keep or to maintain records, information, and documents are due to specific functions and to meet the requirements of certain proceedings or incidents. The functions may involve various medical and clinical services and facilities, blood bank and transfusion services, mortality assessment, and other incidents like the transfer of records or, in a case, the ceasing of business operations.

Whether directly or otherwise stated, requirements set on records, information, and documents are spelled out in the Act, or at least through interpreting its contexts. The Act states that the Minister has the power to make regulations. Sections 107 (1) and 112(1)

require private healthcare facilities and services to furnish information, making it compulsory to keep, retain, and dispose of records according to their lifecycle. To this regard, Section 112 (1) states the Director General may, from time to time, direct the holder of an approval, licensee, holder of a certificate of registration, or holder of a certificate to furnish such information on the private healthcare facility or service or the clinic as he may require relating to (a) its staff; (b) any apparatus, appliance, equipment or instrument used or to be used; (c) the condition, treatment or diagnosis of any of its patients or any person to whom the facilities or services thereof are or have been provided; (d) any analytical method or procedure used in carrying out any test; or (e) its operation. Similarly, Section 53 (3) makes the accommodation and care of the patient and the medical records compulsory before closing down, transferring, selling, or otherwise disposing of the licensed or registered private healthcare facility or service. Failure to comply is an offense punishable with a penalty not exceeding 10k for individuals and not exceeding 30k for corporations or partnerships, as prescribed in Section 117.

Observation of recordkeeping and record care is also required in several incidents. For instance, Parts 9 to 15 of the Act lay down requirements that may influence the recordkeeping process in the specified tasks, namely blood bank, blood transfusion, and reporting of assessable deaths. The parts also regulate the provision of information by medical and dental practitioners, the publication of information by private healthcare facilities and services, and the consequences of non-compliance.

Even though more sections could be involved, the following sections are sampled in providing summaries of recordkeeping requirements. Section 61 requires records indicating the receipt and disposition of all blood and blood products provided to patients to be retained. Sections 67, reporting of assessable deaths, and Section 68 require medical and dental practitioners to provide information or report by the person in charge of the private medical facility and services to ensure notification about assessable death is made to the Director General as soon as practicable but not later than 72 hours after the death. The information in the reports includes medical, anesthetic, or dental procedures, the technology used in relation to assessable death, the clinical and medical records, and other materials as prescribed in Sections 67 and 68. Both sections express the need to comply with the quality and specific aspects of records and information created, namely content, time, and formatting requirements. The supply of this specified information is compulsory, notwithstanding subsection 112(4) or any rule of law, custom, or practice to the contrary. Contrary to the requirements, section 68 (3) has classified three categories of information related to assessable death as privileged and must not be disclosed.

Section 69 requires the publication of information to persons concerned with anesthesia, anesthetic procedures, medical technology, medical procedures, surgery or surgical procedures, and to such other persons or classes of persons as the Director General may specify, any conclusion and recommendations it reaches concerning the performance of its functions. Despite that, Section 69(2) treats the name of or any information that could lead to the identification of any person whose death has been considered by a Committee or any medical practitioner or dental practitioner, or any other person who has in any way been involved in the care or treatment of the deceased person as confidential, similar to Section 72.

#### 4.3.2 Confidential information versus public information

Confidential information, records, or documents will make them inaccessible except under exceptions given by the laws. Public records, on the other hand, are accessible with specified considerations. Several provisions in the Act categorize information, records, or documents into such status and, in tandem, set the degree of accessibility in most cases or to the functions conducted. Information, records, and documents stated below are confidential:

- All information obtained by a Committee or a mortality assessment committee during the exercise of the functions of such committee or person shall be treated as confidential, albeit with few exceptions under subsections (a), (b), and (c). The breach of subsection (1) is an offense. It shall be liable on conviction to a fine not exceeding one thousand ringgit- s70 (1).
- Patients' records in the event of the inspection by the authority or from the information furnished by the private healthcare facilities and services- Section 112 (6).
- All information that comes to the knowledge of every person employed, retained, or appointed for the administration or enforcement of this Act shall preserve secrecy concerning all information that comes to his knowledge in the course of his duties and shall not communicate any information to any other person except with few exceptions provided in this section- Section 115 (1).

Other than confidentiality, public documents are declared in Section 42(2). They include a register of all private healthcare facilities or services licensed under this Act and a register of all private medical clinics and private dental clinics registered under this Act as public documents and shall be open for public inspection. The public may search on and obtain extracts from the registers upon payment of a prescribed fee.

#### 4.3.3 Assisting investigation and inspection.

They involve requirements to produce information, records, and documents to assist in investigation and inspection. Books, records, documents, apparatus, equipment, or instruments are examples of materials mentioned several times in the Act. Sections involved are 16, 31, 88, 89, 90, 91, 92, 93, 94 and 112. The documents and records are inspected and referred to ensure that functions carried out in medical and clinical processes and procedures follow the rules. They are functional in their nature.

Regarding housekeeping needs, records indicate that the management and administration of the organization's resources comply with the available legislative and regulatory control. The availability of these materials can be secured through a diligent retention and disposition strategy, which is part of the records management lifecycle processes.

#### 4.3.4 Non-compliance to recordkeeping requirements and the consequences.

Eight sections spell out offenses and penalties for non-compliance in handling records, information, and documents. The following are the nature of the offenses.

- Disclosure of confidential or privileged information or documents as stipulated in Sections 70(4); 107(2)(ii); 112(6); 115(2).
- Failure to report or refuse to supply information to the authorities for the purpose of inspection or other purposes specified intentionally or unintentionally. The sections involved are 84(2) and 85(2) failures to furnish information; 89(2) investigations under a search warrant; 92(2) refuse to comply; 94 (a) willfully delays, impedes, or obstructs an investigation; 94(b) fails to provide the facilities or assistance, or refuses to furnish the information, required by an Inspector in the investigation; 94(c) without reasonable excuse; and s112 failure or refusal to produce searched materials required by the Inspector.
- False or misleading information; Section 84(1) and s112.
- Premature disposal of information. This situation requires records, information, or documents to be retained for various specified purposes, such as Section 115(1).
- Failure to take care of medical records. It is an offense and punishable under s117 for a failure to take care of medical records not exceeding RM10,000 for individuals and not exceeding RM30,000 for corporations or partnerships.

## 5.0 Discussion

This study is critical in indicating the method to analyze the recordkeeping implications of statutes that are not commonly associated with records or information law. Recordkeeping requirements are indeed embodied in legal provisions. They are, however, incoherent, and most of the requirements on records lifecycle components are not explicitly stipulated. The study on the current case indicates that even the statute, which is not commonly associated with recordkeeping and management, embodies many regulatory implications on recordkeeping and records management. However, they are not literally exhibited in the texts. Only after these legal provisions are examined and viewed through the lenses of the records lifecycle the context of recordkeeping requirements and other applications to the records management lifecycle is demonstrated. The results from the study can be used in constructing the organization-wide records management program, consistent with the current best practices, complying with existing laws and regulatory framework, and practically applicable. The analysis also indicates that keywords, i.e., records, information, and documents in the text, do not necessarily connote recordkeeping requirements. Some are not applicable as far as recordkeeping is concerned.

Figure 1 below illustrates the properties of recordkeeping requirements derived through analysis from the statute. The components in the ring furthest from the center would influence the recordkeeping requirement on the elements clustered in the circles moving closer to the center.

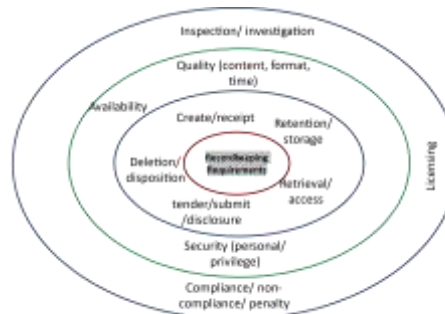


Fig.1: Illustration of the properties and landscape of recordkeeping requirements in accordance with the provisions of the Act

## 6.0 Conclusion

Legal provisions in the statute or legislation are always presented in general statements, overarching matters under its purview. Recordkeeping and records management are detailed processes requiring applications, techniques, methods, and resources that, in most cases, are not explicitly found in the statute but are impliedly reflected. These properties, however, can only be established through analysis and interpretation, deploying records management principles as reference. The recordkeeping requirements established through this process will further contribute to developing organizations' legislative and regulatory framework of records management and information governance. It is recommended that the determination of recordkeeping requirements be further explored on statutes in the healthcare industry or across disciplines like banking and finance or beyond. As the current study narrowly deploys four keywords namely records, information, document, and report to search the relevant provisions, there could be possibility there are other sections in the statute that may involve. The recordkeeping requirements and contexts are mostly assigned arbitrary as no specific measurement has been established.

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