

# PANORAMIC HEALTHCARE REGULATION

Singapore



 LEXOLOGY

# Healthcare Regulation

Contributing Editors

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## ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

### Organisation

How is healthcare in your jurisdiction organised? What is the role of government?

Healthcare regulation in Singapore is overseen by the Ministry of Health (MOH), a ministry of the Government of Singapore. The government sets policy directions in relation to healthcare objectives, such as ensuring quality and affordable basic medical services for all and providing everyone with access to different levels of healthcare in a timely, cost-effective and seamless manner.

There are various statutory boards established under the oversight of the MOH, including the Health Sciences Authority (HSA) (established by the Health Sciences Authority Act 2001) and the Health Promotion Board (established by the Health Promotion Board Act 2001).

The HSA, which was formed on 1 April 2001, integrated five highly specialised agencies – namely, the Centre for Drug Evaluation, the Institute of Science and Forensic Medicine, the National Pharmaceutical Administration, the Product Regulation Department and the Singapore Blood Transfusion Service. The HSA has been designated as the authority responsible for the administration of Singapore's health laws and regulations such as the [Health Products Act 2007](#), [Medicines Act 1975](#), [Tobacco \(Control of Advertisements and Sale\) Act 1993](#) and [Poisons Act 1938](#).

Law stated - 17 October 2024

### Key legislation

What key legislation governs the provision of healthcare services in your jurisdiction?

Singapore promulgated the Health Products Act 2007 (HPA) with the intention that the HPA (and all subsidiary legislation promulgated thereunder) would consolidate legislation regulating all health products (including medicinal products). Prior to 1 November 2016, the HPA regulated medical devices and cosmetics only. The Medicines Act and other related legislation regulated the manufacturing, sale and distribution of medicinal products. There is also specific legislation regulating the use of radiation-emitting devices, contact lens substances and condoms. However, as part of the HSA's ongoing initiative to update and streamline the existing regulatory controls for health products and bring them under a single piece of legislation – namely, the HPA – so as to ensure that the controls remain relevant and adequate to different operational and business models, with effect from 1 November 2016, pharmaceutical products, conventionally termed as 'chemical and biologic drugs', are categorised as health products in the First Schedule of the HPA using the term 'therapeutic products'. Therefore, controls under the Medicines Act and the Poisons Act no longer apply to pharmaceutical products.

Further, the provision of healthcare services is governed under the new [Healthcare Services Act 2020 \(HCSA\)](#), which adopts a services-based regulatory framework. This stands in contrast with the previous premises-based regime under which private hospitals and medical clinics were regulated under the [Private Hospitals and Medical Clinics Act](#)

[1980 \(PHMCA\)](#). The HCSA's regulatory scope is broader than that of the PHMCA, and includes healthcare services, nursing and allied health services, traditional medicine, and complementary and alternative medicine. The HCSA has been fully implemented. Phase 1 of the implementation encompassed clinical support services (with the exception of human tissue banking service, nuclear medicine services and preventive health service). Phase 2 of the implementation encompassed inpatient and outpatient clinical support services. Phase 3 of the implementation encompassed nursing homes and commenced on 18 December 2023. Pursuant to the full implementation of the HCSA, the PHMCA was repealed on 18 December 2023. Under the HCSA, certain specified services and non-premises-based modes of service delivery (eg, virtual medical consultations, home medical care) are licensable.

**Law stated - 17 October 2024**

## Financing

### How is the healthcare system financed in the various patient care sectors?

Singapore adopts a mixed financing system that provides multiple tiers of financing for its citizens' healthcare expenditure.

There are four main tiers of healthcare financing:

- The first tier consists of subsidies from the government, which provides a subsidy of up to 80 per cent of the total bill in acute public hospital wards to all Singaporeans.
- The second tier is the MediSave scheme. It is a compulsory individual medical savings scheme where all working Singaporeans and their employers contribute a part of the employee's monthly wages into the account to save for the employee's future medical needs.
- The third tier, MediShield Life (which replaced MediShield from 1 November 2015), is a basic, low-cost catastrophic medical insurance scheme that allows Singaporeans to effectively pool the financial risks of major illnesses. MediShield Life is administered by the Central Provident Fund Board (CPF Board). Singaporeans may also supplement their basic MediShield Life coverage by applying for a MediSave-approved Integrated Shield Plan directly from one of the private insurers under the Private Medical Insurance Scheme. The Integrated Shield Plans are made up of two components – MediShield Life and additional private insurance coverage providing additional benefits and coverage (eg, to cover the cost of private hospitals or Class A/B1 wards in the public hospitals).
- The fourth tier, MediFund, is a medical endowment fund set up by the government to further assist low-income Singaporean patients who cannot afford to pay their medical bills despite utilising the first three tiers.

In addition, ElderShield is a severe disability insurance scheme administered by private insurers that aims to provide basic financial protection to Singaporeans and Singapore Permanent Residents (SPRs) who need long-term care, especially in old age, and is designed to help supplement their savings in the event of severe disability. In 2020, CareShield Life was introduced to replace Eldershield. Singaporeans and SPRs who are under the ElderShield scheme may decide to join CareShield Life instead, and their existing ElderShield policy will be replaced by the CareShield Life policy.

CareShield Life is administered by the CPF Board, and is a long-term care insurance scheme. All Singaporeans and SPRs are eligible to join, and Singaporeans or SPRs born in 1980 or after are automatically covered under CareShield Life once they turn 30. Under CareShield Life, Singaporeans and SPRs will receive financial support and monthly cash payouts, should they develop severe disability.

Separately, the government also administers other subsidy schemes, such as the Community Health Assist Scheme (CHAS), Interim Disability Assistance Programme for the Elderly and the Medication Assistance Fund.

Under the CHAS, general practitioners and dental clinics that have agreed to partner with the MOH will provide common outpatient medical treatment and basic dental services to low-income elderly or disabled patients at subsidised charges. The CHAS covers 23 chronic diseases and medical conditions. All Singapore citizens are eligible to receive subsidies under the CHAS, although enrolment is on an application basis, and subsidies are tiered according to household monthly income per person or, for households with no income, the annual value of the home.

From 1 October 2024, the MOH will make changes to the monthly per capita household income thresholds for its various schemes and grants such as the CHAS and the Interim Disability Assistance Programme for the Elderly. The MOH will also be enhancing its palliative care subsidy framework and revising its community hospital subsidies. Through these changes, the MOH seeks to improve patient affordability and facilitate right-siting of care for Singaporeans.

**Law stated - 17 October 2024**

### **Delivery structures**

#### **What are the basic structures for the delivery of care to patients in your jurisdiction?**

Under Singapore's hybrid delivery healthcare model, healthcare providers in both the public and private sectors offer primary healthcare services, acute hospital services and step-down care services. Private sector providers account for around 80 per cent of the market in the primary care sector, while public sector providers account for around 80 per cent of the market in the acute care sector. Voluntary welfare organisations, which are mostly funded by the government for services provided, account for a majority of the market in the step-down care sector.

**Law stated - 17 October 2024**

### **Access and coverage**

#### **What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?**

Singapore adopts a mixed financing system that provides multiple tiers of financing for its citizens' healthcare expenditure.

There are four main tiers of healthcare financing, which include, but are not limited to, MediSave and MediShield Life.

MediSave can be used for the following purposes:

- to pay for an individual's own health insurance premiums, or those of their approved dependents;
- to pay for an individual's own/approved dependents' hospitalisation expenses in Singapore;
- to pay for certain specified outpatient care uses; and
- to pay for certain specified long-term care uses, such as approved inpatient hospice palliative care services, day rehabilitation centres and home palliative and day hospice care.

However, MediSave withdrawal limits and use conditions apply. This is intended to ensure that Singaporeans have sufficient savings in their MediSave account for their basic healthcare needs in old age. The withdrawal limits are generally adequate to cover most of the charges incurred at subsidised inpatient wards and outpatient treatments.

In turn, MediShield Life can be used for hospitalisation and day surgeries, and outpatient treatments. However, these may be subject to certain daily claim limits and conditions, as well as maximum claim limits.

There are a number of standard excluded treatments and procedures that are not covered by MediShield Life. These include, without limitation:

- ambulance fees;
- cosmetic surgery;
- dental work (except due to accidental injuries);
- vaccination; and
- infertility, sub-fertility, assisted conception or any contraceptive operation, including their related complications.

**Law stated - 17 October 2024**

### **Exclusions from statutory coverage**

**Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?**

Foreigners are generally not entitled to local healthcare schemes and subsidies. Foreigners also do not qualify for MediShield Life.

Foreigners receive health coverage through international health insurance plans provided by their employer or purchased privately.

Working Singapore citizens and permanent residents contribute to the Central Provident Fund, which is a compulsory comprehensive savings and pension plan aimed primarily at

funding their retirement, healthcare, education and housing needs. This in turn contributes to the individual's MediSave fund.

Law stated - 17 October 2024

### **Gaps in cost coverage**

#### **Are there any gaps in cost coverage?**

Various categories of financing under Singapore's tiered healthcare financing model are subject to exclusions, which may take the form of excluded treatments and procedures, as well as claim limits.

Law stated - 17 October 2024

## **HEALTHCARE PRICING AND REIMBURSEMENT**

### **Pricing**

#### **How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?**

The market price of a medicinal product or a medical device is not generally governed by law or regulation in Singapore. However, the Ministry of Health (MOH) administers several drug subsidy schemes, including the Standard Drug List (SDL) Subsidy Framework and the Medication Assistance Fund (MAF).

The SDL Subsidy Framework, which is modelled on the World Health Organization's essential drug lists, consists of drugs assessed to be cost-effective and essential to the provision of medical care to all Singaporeans. Certain revisions to the SDL Subsidy Framework took effect from 1 November 2022. The MAF was set up in August 2010 to provide financial assistance in respect of non-standard, high-cost drugs.

The Drug Advisory Committee also makes recommendations to the MOH as to whether a drug should be subsidised through listing on the SDL or MAF.

Law stated - 17 October 2024

### **Reimbursement**

#### **How is reimbursement for healthcare services structured?**

The national health insurance system in Singapore comprises multiple tiers. In general, there is heavy subsidy of services and medicinal products provided by the national healthcare institutions to qualifying Singaporeans. In addition, generally all Singaporeans must maintain an individual medical savings account under the MediSave scheme. A secondary level of medical insurance scheme, MediShield Life (which replaced MediShield from 1 November 2015), allows Singaporeans to pool against the financial risks of major illnesses, whereas ElderShield and CareShield Life allow Singaporeans to pool against the financial risks of

suffering a severe disability. Integrated Shield Plans are also available as an additional level of insurance for Singaporeans. Further, MediFund is available as a safety net for those who cannot afford the subsidised bill charges, despite coverage under schemes such as MediSave and MediShield Life. The MAF (which was implemented in August 2010) also assists patients who require costly medication. Through the Community Health Assist Scheme, the government has also engaged private general practitioners to provide common outpatient medical services to low-income Singapore citizens at subsidised charges. Lastly, the government has also introduced the Pioneer Generation Package, whereby Singapore citizens who were aged 16 and above in 1965 and who obtained Singapore citizenship on or before 31 December 1986 are eligible for additional subsidies for their healthcare costs for life.

It should be noted that MediSave, MediShield Life, ElderShield, CareShield Life and any Integrated Shield Plans reimburse not only the cost of medicines, but also hospitalisation and certain outpatient expenses.

Claims under MediShield Life can be made through the hospital where the patient is being treated. The hospital will inform the Central Provident Fund Board that the patient is insured under the MediShield Life scheme and submit the claim to the Central Provident Fund Board. After determining the amount payable from MediShield Life, the Central Provident Fund Board will make payment directly to the hospital, and the outstanding amount may be settled with the patient's MediSave or by cash payment, or by a combination of the two. The withdrawal limits for MediSave depend on the type of treatment required by the patient.

MediFund assistance is available to Singapore citizens who are subsidised patients receiving treatment from a MediFund-approved institution. A patient who wishes to apply for MediFund assistance must demonstrate that the patient and family have difficulty affording the medical bill despite the available government subsidies and contributions from MediShield Life and MediSave. These patients (or their family members) may approach a medical social worker at a MediFund-approved institution for assistance. Every MediFund-approved institution has a MediFund committee to consider and approve applications, and decide on the appropriate amount of assistance to provide. The MediFund committee is made up of independent volunteers, most of whom are actively involved in community social work and are familiar with the needs and problems faced by lower-income Singaporeans. The actual amount of assistance provided will depend on the patient's financial and social circumstances, as well as the size of the medical bill incurred.

The MAF is available to patients who face difficulties affording their medical bills after MediShield Life or MediSave claims or deductions. Patients who are prescribed with MAF-listed drugs can apply for the MAF by approaching a medical social worker in the restructured hospitals and institutions or polyclinics.

Under the Community Health Assist Scheme, low to middle-low income or disabled Singaporeans with any of the 23 prescribed chronic diseases or medical conditions enjoy subsidised charges when seeking common outpatient medical treatment or basic dental charges at participating clinics.

**Law stated - 17 October 2024**

## | Adjudication

## If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

The MOH is the competent body for decisions regarding subsidies, including the subsidisation of certain medicinal products under the SDL and the MAF.

Law stated - 17 October 2024

## HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

### Legal authorisation

#### What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

The provision of healthcare services is licensed under a services-based regulatory framework. Under the Healthcare Services Act 2020 (HCSA), the healthcare services to be licensed fall into three broad categories: inpatient services, outpatient services and clinical support services.

Phased implementation of the HCSA has been completed. Phase 1 of the implementation, which encompasses clinical support services (with the exception of human tissue banking service, nuclear medicine services and preventive health service), commenced on 3 January 2022. Phase 2 of the implementation, which encompasses inpatient and outpatient clinical support services, was implemented in June 2023. Phase 3 of the implementation, which encompasses nursing home services, commenced on 18 December 2023. The Ministry of Health (MOH) has also introduced specified services and non-premises based modes of service delivery (eg, virtual medical consultations, home medical care) for various licensable healthcare services.

Law stated - 17 October 2024

### Legal structures

#### What types of legal entities can offer healthcare services?

HCSA licensees may be the corporate entity itself (including companies and sole proprietors) or natural persons (eg, the CEO of a licensable healthcare service).

Law stated - 17 October 2024

### Foreign companies

#### What further steps are necessary for foreign companies to offer healthcare services?

From 3 January 2022, foreign companies intending to offer licensable healthcare services in Singapore must apply for an HCSA licence.

Law stated - 17 October 2024

### **Healthcare arrangements**

**What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?**

The provision of healthcare services is a licensable activity in Singapore. Any person intending to provide healthcare services in Singapore must obtain the requisite licence under prevailing laws.

There is no restriction under the new HCSA on the nationality of the licensee (if a natural person), or persons appointed to fulfil governance requirements imposed on licensees, such as the Principal Officer (PO), Clinical Governance Officer (CGO) or section leader. However, the licensee (if a natural person), PO, CGO or section leader must reside in Singapore in order to discharge their duties and functions effectively.

There is no residency requirement for the licensee's key appointment holders, as long as they are able to fulfil their governance roles effectively.

**Law stated - 17 October 2024**

## **COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES**

### **Authority enforcement**

**Are infringements of competition law by healthcare providers pursued by national authorities?**

Singapore's generic competition laws are contained in the [Competition Act 2004](#). A person who believes that an entity is in breach of competition law may make a complaint to the Competition and Consumer Commission of Singapore (CCCS), which administers and enforces the Competition Act. The CCCS may also choose to initiate its own investigation into alleged anticompetitive behaviour. The CCCS can take action against healthcare providers that enter into anticompetitive agreements; engage in an abuse of their dominant position; or enter into mergers that substantially lessen competition (or are expected to substantially lessen competition) within any market in Singapore. Where the CCCS, upon completion of an investigation, decides that there has been an infringement of competition law, it may, among other things, impose financial penalties, issue directions or take other appropriate measures to remedy, mitigate or prevent the harmful effect of the infringement, and to prevent recurrence of the same.

**Law stated - 17 October 2024**

### **Private enforcement**

**Is follow-on private antitrust litigation against healthcare providers possible?**

Only after the CCCS has found a party to be in breach of competition law in Singapore, and after the expiry of the applicable appeal period, can third parties bring actions under

section 86 of the Competition Act for loss or damage suffered directly as a result of a healthcare provider's infringement of competition law. There is a two-year time limit for the commencement of such private actions from the expiry of the applicable appeal period. To date, there have been no published instances where a party has brought a follow-on private action against a manufacturer.

Law stated - 17 October 2024

## Anti-corruption and transparency

### What are the main anti-corruption and transparency rules applicable to healthcare providers?

There is no specific legislation in Singapore on the anti-corruption and transparency rules applicable to healthcare providers. However, the [Prevention of Corruption Act 1960](#) (PCA) is the primary statute dealing with corruption offences in Singapore. The PCA criminalises corruption in both the public and private sectors and is enforced by the Corrupt Practices Investigation Bureau.

Sections 5 and 6 of the PCA prohibit bribery in general. Under section 5 of the PCA, it is an offence for a person (whether by him or herself or in conjunction with any other person) to corruptly solicit, receive, or agree to receive for him or herself or for any other person, or corruptly give, promise or offer to any person, whether for the benefit of that person or of another person, any gratification as an inducement to or reward for or otherwise on account of:

- any person doing or forbearing to do anything in respect of any matter or transaction whatsoever, actual or proposed; or
- any member, officer or servant of a public body doing or forbearing to do anything in respect of any matter or transaction whatsoever, actual or proposed, in which such public body is concerned.

Any person convicted of an offence under section 5 of the PCA may be liable to a fine not exceeding S\$100,000 or imprisonment for a term not exceeding five years, or both.

Section 6 of the PCA sets out the offence of corrupt transactions with agents. It is an offence under section 6 of the PCA for:

- any agent to corruptly accept or obtain any gratification as an inducement or reward for doing or forbearing to do, or for having done or forborne to do, any act in relation to his or her principal's affairs or business;
- a person to corruptly give or agree to give or offer any gratification to any agent as an inducement or reward for doing or forbearing to do, or for having done or forborne to do any act in relation to his or her principal's affairs or business; or
- a person to knowingly give to an agent a false or erroneous or defective statement, or an agent to knowingly use such statement, to deceive his or her principal.

Any person who is convicted of an offence under section 6 of the PCA may be liable to a fine not exceeding S\$100,000 or imprisonment for a term not exceeding five years, or both.

In addition, the ethical codes of the Singapore Medical Association, the Singapore Medical Council, the Singapore Association of Pharmaceutical Industries and the Singapore Manufacturing Federation's Medical Technology Industry Group promulgate the principle that the relationship between the pharmaceutical industry and healthcare professionals must always be seen to be impartial and honest.

Law stated - 17 October 2024

## REGULATION OF HEALTHCARE SERVICES

### Licensing authority and process

#### Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

Under the new services-based regulatory framework for the provision of healthcare services, operators of patient care facilities will be required to apply for a Healthcare Services Act (HCSA) licence based on the relevant healthcare services provided. An application for a HCSA licence together with the requisite licence fee must be made to the Ministry of Health (MOH) through the new Healthcare Application & Licensing Portal (HALP) no later than two months before the intended practice commencement date. When all licensing requirements are met, the MOH will issue an e-licence on HALP. Licences must be renewed no later than two months before their current validity expires.

Medical practitioners in Singapore must be registered under the [Medical Registration Act 1997 \(MRA\)](#). The Singapore Medical Council (SMC), constituted under the MRA, governs all registered medical practitioners. In September 2016, the SMC issued the 2016 edition of the Ethical Code and Ethical Guidelines (SMC Ethical Code) together with the 2016 Handbook on Medical Ethics, which contains additional materials on the SMC Ethical Code and explains their applications and provides advice on best practices. The SMC Ethical Code came into effect on 1 January 2017 (except Guideline H3(7), which came into force on 1 July 2017). All registered medical practitioners are required to adhere to the SMC Ethical Code.

Dentists, nurses and midwives, pharmacists, optometrists and opticians, and traditional Chinese medicine practitioners are also subject to registration requirements under various local legislation.

Law stated - 17 October 2024

### Cross-border regulation

#### What requirements and restrictions govern the mobility of licensed health professionals across borders?

Industry-specific restrictions may apply. For illustration, medical practitioners trained overseas (also referred to as 'international medical graduates', such graduates holding a degree from a university specified in the Second Schedule of the MRA or a registrable postgraduate medical qualification recognised by the SMC) may apply for medical registration, provided they meet the SMC's prevailing criteria for registration. International medical graduates who do not hold qualifications that are recognised by the SMC, as stated

above, will not be eligible to apply for medical registration to be a medical practitioner in Singapore.

**Law stated - 17 October 2024**

### **Collaboration between healthcare professionals**

**What authorisations are required for collaboration between healthcare professionals? How is this regulated?**

There is no specific authorisation required for collaboration between healthcare professionals. However, the engagement of such collaborations must not contravene any local legislation, and the industry-specific codes of conduct and ethical guidelines may apply – for instance, the SMC Ethical Code and the Allied Health Professions Council's Code of Professional Conduct, which set out standards of conduct expected of medical practitioners and allied health professionals respectively.

**Law stated - 17 October 2024**

### **Collaboration between patient care facilities and healthcare professionals**

**What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?**

There is no specific authorisation required for collaboration between patient care facilities and healthcare professionals. However, the engagement of such collaborations must not contravene any local legislation. HCSA licensees must continue to abide by their licence conditions. Industry-specific codes of conduct and ethical guidelines may apply for healthcare professionals – for instance, the SMC Ethical Code and the Allied Health Professions Council's Code of Professional Conduct, which set out standards of conduct expected of medical practitioners and allied health professionals respectively.

**Law stated - 17 October 2024**

### **Training of healthcare professionals**

**What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?**

Educational and training requirements are set out under the respective local legislation that pertain to the applicable healthcare professional industry. To illustrate, for medical professionals, one of the criteria for a provisional and conditional registration with the SMC is a primary qualification, typically an MD or MBBS from a recognised medical school.

**Law stated - 17 October 2024**

## **Discipline and enforcement**

**What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?**

For patient care facilities, under the HCSA, the MOH has the power to issue fines and imprisonment terms, as appropriate, for non-compliance with the regulations. The MOH may also revoke a licence granted to the licensee.

For healthcare professionals, the sanctions and penalties are issued by the respective healthcare professional industry organisation. To illustrate, for doctors, the SMC has the power to issue a range of sentences, depending on the severity of the non-compliance, such as: censure and written undertaking, financial penalties, changing the registration status or imposing conditions or restrictions on the healthcare professional's registration, suspension and removal of a doctor's name from the registrar.

**Law stated - 17 October 2024**

## **Patient complaints**

**How are patient complaints processed and adjudicated?**

For complaints against a healthcare provider, the MOH has outlined several procedures that assist patients with lodging specific concerns or complaints with the healthcare service providers or the MOH itself. The patient should first raise the complaint with the specific healthcare provider (ie, person dealing with the case). However, if this is not possible, the individual may ask for the issue to be considered as an official complaint. At this stage, the individual may lodge their complaint with the healthcare institution either in writing by letter or e-mail. Next, if the individual is not satisfied with the reply from the healthcare institution complained against, the individual may write to the MOH, SMC, Singapore Nursing Board, Singapore Dental Council, Singapore Mediation Centre or private healthcare institutions listings, according to the nature of the complaint. Depending on the circumstances, cases may be referred to for mediation or other private means of dispute resolution, including litigation.

Complaints against a medical professional relating to professional misconduct of registered medical doctors shall be referred to the SMC, which will make the relevant inquiries into the complaints.

**Law stated - 17 October 2024**

## **DATA PROTECTION, PRIVACY AND DIGITAL HEALTH**

### **Responsible authorities and applicable legislation**

**Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?**

The [Personal Data Protection Act 2012 \(PDPA\)](#) is Singapore's main personal data protection legislation, and is administered and enforced by the Personal Data Protection Commission (PDPC). The PDPA prescribes baseline standards relating to the collection, use, disclosure, access, protection, retention and transfer of personal data to which all organisations must adhere.

[The Personal Data Protection \(Amendment\) Act 2020](#) permits disclosure of personal data about an individual who is a current or former patient of a licensee under the Healthcare Service Act (HCSA), and a prescribed healthcare body to a public agency for the purposes of policy formulation or review.

**Law stated - 17 October 2024**

## Requirements

**What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?**

The PDPA prescribes baseline standards relating to the collection, use, disclosure, access, protection, retention and transfer of personal data to which all organisations must adhere.

Under the PDPA, organisations are required to protect personal data in their possession or under their control by making reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks, as well as prevent the loss of any storage medium or device on which personal data is stored.

Additionally, the PDPA generally requires organisations to seek consent from an individual before collecting, using or disclosing his or her personal data. In seeking such consent, the organisation is required to notify the individual of the purposes for such collection, use or disclosure, which must be what a reasonable person would consider appropriate in the circumstances. The organisation may not, as a condition of providing a product or service, require an individual to consent to the collection, use or disclosure of personal data about the individual beyond what is reasonably required for the provision of the service.

The PDPA also requires organisations to designate one or more individuals to be responsible for ensuring the organisation's compliance with the PDPA. These individuals are typically known as data protection officers (DPOs). Key responsibilities of a DPO include:

- ensuring compliance with the PDPA when developing and implementing policies and processes for handling personal data;
- fostering a personal data protection culture among employees;
- communicating personal data protection policies to stakeholders;
- handling access and correction requests to personal data;
- managing personal data protection-related queries and complaints;
- alerting management to any risks that might arise with regard to the personal data handled by the organisation; and
- where necessary, liaising with the PDPC on personal data protection matters.

Further, under the general regulations to the HCSA, healthcare providers have several obligations in relation to patient health records.

First, HCSA licensees must ensure every patient's privacy is respected and every patient is treated with dignity and respect. Next, HCSA licensees must keep and maintain an accurate, complete and up-to-date patient health record of every patient for a specified period. The regulations stipulate certain information which is mandatory (eg, name, National Registration Identity Card, gender), and which is mandatory if the information is available to the licensee (eg, medical information, vaccinations, allergies, laboratory test results, etc). HCSA licensees must keep every patient health record confidential and ensure that the confidentiality, integrity and security of every patient health record is maintained at all times and all personnel handling any patient health record is aware of his or her role and responsibility in maintaining the confidentiality, integrity and security of the records. In addition, HCSA licensees must implement (and periodically monitor and evaluate) adequate safeguards and appropriate protocols and processes to protect the patient health records.

**Law stated - 17 October 2024**

### **Regulatory guidance**

#### **Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?**

The PDPC has also issued the Advisory Guidelines for the Healthcare Sector, which aim to address the unique circumstances facing the healthcare sector in complying with the PDPA.

Other regulatory instruments relating to data protection and privacy in the healthcare sector include the following:

- the Medicines Act and the Health Products Act, which contain regulations relating to pharmaco-vigilance, adverse event reporting and the conduct of clinical trials;
- the HCSA, which contains provisions relating to the protection of confidential information such as patients' medical records, diagnosis or treatment;
- the 2015 Guidelines for the Retention Periods of Medical Records issued by the MOH;
- the SMC Ethical Code and the Allied Health Professions Council's Code of Professional Conduct, which set out standards of conduct expected of medical practitioners and allied health professionals respectively, such as those relating to patient confidentiality;
- the Healthcare Cybersecurity Essentials, which was developed by MOH and meant as a 'guidance document' for licensees under the HCSA, as well as entities providing intermediate and long-term care services, in adopting basic safeguards for their IT assets and data; and
- the proposed Health Information Bill (HIB), which sets out the basic data security and cybersecurity requirements that healthcare providers must comply with.

**Law stated - 17 October 2024**

## Common infringements

### What are the most common data protection and privacy infringements committed by healthcare providers?

Organisations are required to protect personal data in their possession or under their control by making reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks, pursuant to the PDPA.

The PDPC has stated that among the various data protection obligations under the PDPA, breaches of the above protection obligation is the most common in its reported decisions. Notably, in January 2019 the PDPC fined the Integrated Health Information Systems, the central national IT agency for Singapore's public healthcare sector, and Singapore Health Services Pte Ltd, one of Singapore's three public healthcare clusters, S\$750,000 and S\$250,000 respectively for failing to comply with that obligation, in respect of a data breach in which the non-medical personal data of around 1.5 million patients and the outpatient prescription records of around 160,000 patients were exfiltrated in a major cyberattack.

**Law stated - 17 October 2024**

## Digital health services

### Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

Telemedicine services are regulated under the MOH's 2015 National Telemedicine Guidelines (NTG), as well as the SMC Ethical Code and the 2016 Handbook on Medical Ethics. The NTG provides guidance to healthcare providers on clinical standards and outcomes, human resources, organisational issues, and technology and equipment. The SMC Ethical Code, to which all registered medical practitioners are required to adhere, sets out how such services are to be provided responsibly. For instance, it provides that doctors engaging in telemedicine must endeavour to provide the same quality and standard of care as in-person medical care, otherwise they must state the limitations of their opinion.

Under the HCSA, telemedicine services are licensable healthcare services. That said, the MOH has stated that it will adopt a risk-based approach in regulating telemedicine, and that only direct doctor and/or dentist-led teleconsultation will be licensable for a start. This refers to consultations with a doctor or dentist without seeing them in-person, and via apps, video calls, phone calls or texts. At the time of writing, the MOH was not set to license indirect telemedicine providers. Indirect telemedicine providers refer to those who do not provide direct medical care, and only offer the technology support for telemedicine, such as platforms offering software-as-a-service for teleconsultation, directory listings and payment solutions.

In May 2023, the MOH issued guidelines on appropriate use and access to the [National Electronic Health Records \(NEHR\)](#). The NEHR is a centralised repository of health information established in 2011 and is intended to serve as a source of information for users of the system who contribute to patient care. The NEHR has been progressively deployed to both public and private healthcare institutions across Singapore. The key thrust of these guidelines is to issue guidelines on the contribution of medical records to the NEHR, as well

as certain principles surrounding accessing medical records, maintaining confidentiality and using NEHR information.

The MOH seeks to introduce the Health Information Bill (HIB) in 2024, which aims to facilitate and regulate the proper collection, use and sharing of patient information via the NEHR. Under the HIB, all licensed healthcare providers would be required to contribute summary data of patients' key health information to the NEHR. Licensees would also be required to comply with the HIB when sharing information with other care providers.

At the time of writing, the HIB has not yet been passed.

**Law stated - 17 October 2024**

## UPDATE AND TRENDS

### Key developments

**Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?**

The Private Hospitals and Medical Clinics Act (PHMCA), which adopts a premises-based regulatory framework, has been repealed, and healthcare services providers are licensed under a services-based regulatory framework under the Healthcare Services Act (HCSA).

The Ministry of Health (MOH) also launched the Licensing Experimentation and Adaptation Programme (LEAP) in 2018, a regulatory sandbox initiative for telemedicine and mobile medicine to facilitate the development of innovative healthcare models in a controlled environment. As of February 2021, MOH has closed the sandbox for telemedicine and mobile medicine after successfully reaching the objectives it had set. Due to the increasing number of telemedicine providers, the MOH had listed direct telemedicine service providers online under a voluntary listing in 2021. From 26 June 2023, with the HCSA taking effect, direct doctor and/or dentist-led teleconsultations are licensable healthcare services, and the voluntary listing has been discontinued. Information relating to licensees providing telemedicine services are not listed on HealthHub.

**Law stated - 17 October 2024**