MINISTRY OF HEALTH
SINGAPORE

FAQ ON HEALTHCARE SERVICES ACT (HCSA)

Contents

FAQ on Introduction of Healthcare Services Act (HCSA)

1.Q Where can I find the Healthcare Services Act (HCSA)?

A Please refer to **https://sso.agc.gov.sg/Bills-Supp/37-2019** to find out more about the Healthcare Service (HCS) Bill. The Ministry of Health (MOH) will update the FAQ once HCSA is available on Singapore Statues Online.

2.Q Why is there a need for a new HCSA to replace the current Private Hospitals and Medical Clinics Act (PHMCA)?

A In recent years, **there have been significant changes to the healthcare landscape in Singapore**.

While almost all healthcare services were previously provided from physical 'brick-and-mortar' locations, there are emerging **new healthcare services and models**, in response to changing care needs and patient expectations. Some examples include home and community-based care and telemedicine services. Further, **new technological advancements** such as proton beam and cell, tissue and gene therapy as well as clinical genetic testing services have emerged.

Therefore, it is timely to **update the regulatory framework to ensure that it remains relevant to current and emerging models of care and that patient safety and welfare are safeguarded**.

3.Q What are the objectives of HCSA?

A The main objective of HCSA is to **better safeguard the safety and welfare of patients** and to **ensure continuity of patient care**.

This is done through ensuring regulatory clarity, strengthening governance and accountability of licensees and introducing new and enhanced safeguards for patient safety, welfare and continuity of care. HCSA will also allow a more flexible and modular services-based licensing regime that caters to the licensing of different healthcare services, while enabling the development of new and innovative services, centred around patient needs.

4.Q How is "healthcare service" defined? What is the rationale for this definition?

A "Healthcare service" is defined in Clause 3 of the HCS Bill*.

The definition encompasses the range of services that can be provided within the healthcare sector and will remain relevant in future.

This will allow MOH to continue oversight of services that are clinical in nature, whilst ensuring patient safety, welfare and continuity of care.

**The HCS Bill can be found here.*

5.Q What are the benefits of the new framework under HCSA as compared to PHMCA? Are there any overseas countries that utilise a similar licensing framework?

A PHMCA is premises-based whereas HCSA adopts a service-based licensing structure. This is similar to the legislative framework in the United Kingdom (UK) and Malaysia.

It allows licensees the flexibility to provide a range of services, and take on new licences in a modular fashion.

A licensee also has the flexibility to hold one or multiple licences for the provision of the same service across different premises depending on the organisation's governance or business models.

FAQ on Regulatory Scope of HCSA

1.Q Why are allied health, nursing, Traditional Chinese Medicine (TCM) and Complementary and Alternative Medicine (CAM) services in the scope of HCSA but not licensed for now?

A HCSA allows for a phased approach to progressively license healthcare services.

Hence, MOH is adopting a calibrated and risk-based regulatory approach. While MOH has no current plans to license these services, the Ministry will closely monitor the landscape of such services. As the service complexity evolves and there is evidence of impact and risks to patient safety and welfare, MOH can take steps to license these services.

Before any new services are licensed, MOH will engage and consult the relevant stakeholders on proposed standards to ensure that they are contextualised for that particular service.

2.Q Why are beauty and wellness services not within the scope of HCSA?

A Beauty and wellness services are not within the scope of HCSA as they do not diagnose, treat or manage a medical condition, disease, injury or disability, and the risks to patient safety are low.

The public can lodge a complaint with MOH via email (**MOH_QSM@moh.gov.sg**) or phone (63259220) if they feel that these providers are providing or advertising any form of licensable healthcare services.

3.Q Why are Government entities, e.g. SCDF ambulances, SAF clinics, excluded from the scope of HCSA? How do we ensure the safety of care in these settings / services?

A Government entities like SCDF-owned ambulances and SAF clinics have critical national functions and are subjected to a separate set of governance structure and stringent internal standards. As SCDF serves highly-critical cases, they apply equivalent or higher standards and these include six-monthly paramedic skills certification test and quarterly Continual Professional Education sessions to improve and broaden the knowledge, skills and competence of the SCDF emergency medical services crew.

4.Q Will community care entities, e.g. Adult Disability Homes, Shelters, Boys' Home, and Girls' Home, Assisted Living Facilities, Senior Care Centres, Senior Activity Centres and Social Day Care Centres, need to be licensed under HCSA?

A These entities provide services that are predominantly social in nature, and to that extent, will not be regulated under HCSA.

However, if these entities also deliver services that are clinical in nature, then the clinical services will have to be licensed. For example, if the senior activity centre has a doctor providing clinical services, either the doctor will require a medical clinic licence, or the doctor has to be employed by a clinic licensee.

5.Q How will non-doctor led home care services be regulated under HCSA?

A Non-doctor led home care services provides direct nursing, allied health and personal care to clients at home (i.e. not doctor-led visits).
Safe care is ensured through the professional regulation of the healthcare professionals providing such services.
This sector is growing and will continue to play an increasingly important role in the aged care landscape. MOH will monitor the patient safety risks from these emerging models of care before deciding to introduce any forms of licensing or regulations for these services.

6.Q Why are concierge services, e.g. managed care organisations (MCOs) or third party administrators (TPAs), not regulated?

A The current scope of HCSA is limited to regulating direct healthcare service provision. Concierge services, that involve third party providers who are essentially an administrative coordinating service. They are not engaged in direct patient care, and thus will not be regulated.

Professional guidelines, such as Singapore Medical Council's Ethical Code and Ethical Guidelines (SMC ECEG) provide guidance for medical practitioners contracting with such MCOs or TPAs to ensure objectivity of their clinical judgement and the provision of the required clinical standard of care.

MOH will continue to monitor the patient safety risks and study the landscape of these concierge services further, before deciding on the appropriate regulatory framework, should important patient risks emerge.

Additionally, if TPAs should advertise licensable healthcare services, they are subject to Clause 31 of the HCS Bill*. This means that they can only advertise on a licensee's authorisation and must still comply with all relevant advertising rules. If they also directly provide a licensable healthcare service in the course of their operations, they will need to hold the relevant HCSA licence.

**The HCS Bill can be found here.*

7.Q Will HCSA be able to take an errant healthcare service provider located overseas treating a local patient to task?

A HCSA requires that local or foreign entities providing healthcare services in Singapore be licensed and that all foreign doctors working for the provider be registered with SMC. HCSA will not have extra-territorial powers. **[Section 4 of the HCS Bill]***

The provision of healthcare services to local patients who travel overseas will also be outside the jurisdiction of HCSA.

**The HCS Bill can be found here.*

8.Q How will HCSA interact with other Professional Acts that currently govern the different categories of healthcare professionals, e.g. Medical Registration Act?

A MOH recognises the central role that healthcare professionals play in the provision of healthcare services.

HCSA will not affect the operation of any of the Acts regulating healthcare professionals.

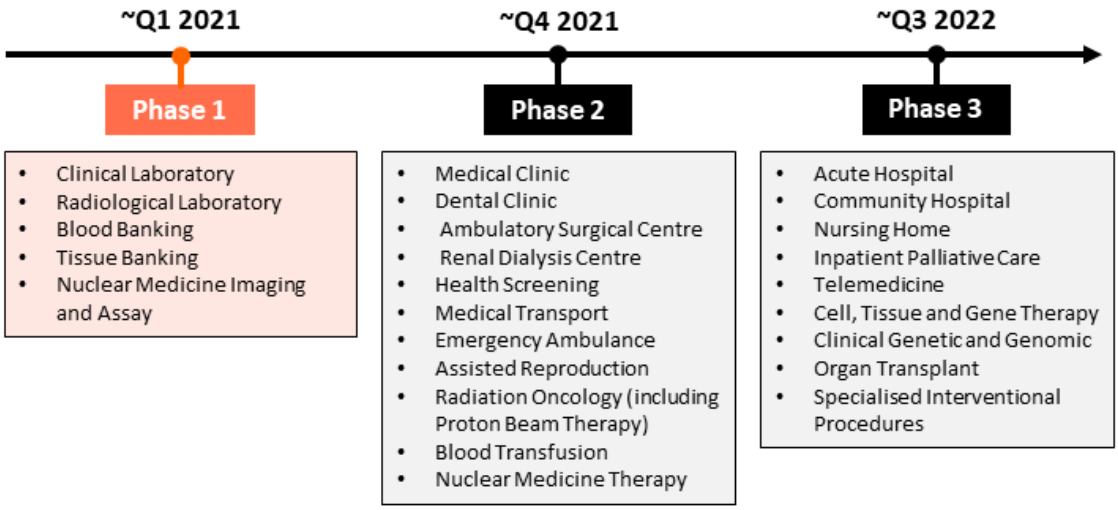
HCSA stipulates requirements pertaining to licensing and governance of services such as processes, facilities, safety standards required, and complements the Professional Acts in protecting the safety, welfare and continuity of care of patients.

FAQ on Implementation of HCSA

1.Q When will HCSA be implemented?

A HCSA will be implemented over 3 phases from early 2021 to end 2022. This progressive approach is to provide the existing and new licensees with a reasonable sunrise period to meet any new regulatory requirements under the new HCSA regime.

The first phase, estimated to port over in Q1 2021, will involve clinical laboratory licensees while the second phase in Q4 2021 will bring in the medical and dental clinic licensees, and private ambulance and medical transport service providers. The final phase in Q3 2022 will cover all remaining hospital licensees (including the nursing homes) and special care services, as well as the other newly unregulated services, such as telemedicine and clinical genetic testing services.



2.Q I am a current existing PHMCA licensee. What should I do to prepare for HCSA?

A MOH will be conducting a service mapping exercise to confirm the services in your licensed premises, so that we can facilitate the portover of your service licensees at the implementation date.

The service mapping exercise for Phase 1 HCSA licensees will be in January/February 2020. We will announce the dates for the subsequent phases at a later timing.

MOH will engage the licensees a few months prior to their implementation phases to define the specific service regulations and support the licensees with their transition into the new regulatory regime.

MOH will also be consulting on the set of general regulations which will be applicable to all licensees; and these include general licensing matters, details of the qualified personnel and committees that will need to be set up, general requirements for service provisions (such as infection control and fire safety), etc.

3.Q Do I need to make any additional licensing application or pay any additional licensing fees at the point of implementation for my licensed services?

A Licensees are not required to make any additional licensing application nor pay any additional licensing fees if you are providing the same licensable services under HCSA.

If you are providing any new licensable services previously not regulated under PHMCA, then additional licensing application and fees will be required. Nevertheless, MOH will guide you through the application if it is needed.

4.Q What happens on the day of portover for my HCSA licence?

A On the day of portover, your PHMCA licence will be changed to a HCSA licence for the remaining period of your existing licence. It will be done seamlessly and there is no need for you to take any action.

5.Q Will we still use the current e-licensing system or will there be a new licensing system?

A MOH is currently developing a new e-licensing system that will support HCSA licence applications and inspections. The new system will be more user-friendly and responsive. It will also contain new features, such as a repository of your past and present licences, the ability to track your licence expiry electronically, the ability to retrieve your inspection report and respond to non-contraventions electronically, etc. We will be issuing you the user guides for the new system and conducting training for you to be familiar with the new system closer to the implementation date.

FAQ on Licensing Fees

1.Q What is the licensing fee for my existing services under HCSA? Will I need to pay additional licensing fees under HCSA?

A Licensing fees are pegged at a level commensurate with the costs of manpower and resources incurred from inspections and audits.

Based on our preliminary assessment, more than 95% of existing providers will see no change or in fact a decrease in the amount of fees to be paid. The change in licensing fees, if any, will only take effect at the next licence renewal cycle.

You will only need to pay additional licence fees at the point of portover if you are providing a new licensable service previously unregulated under PHMCA.

The schedule of licensing fees will be made known to you closer to the implementation date.

2.Q If I am providing a new service and need to pay additional licence fees, will there be any concession?

A For licensees providing a new service and will need to pay additional licensing fees at the point of portover, MOH will put in place mitigating measures to support the transition, which includes implementing the fee increase gradually over three licensing renewal cycles.

MOH has and will continue to streamline our licensing processes to keep our regulatory costs down, as well as reduce excessive regulatory burden on licensees.

FAQ on Enhanced Governance

1.Q **Can the licensee, Principal Officer (PO) and Clinical Governance Officer (CGO) be the same individual?**

A Yes, as long as the individual can concurrently take on the role of the licensee, PO and CGO, and can fulfil all relevant prescribed requirements.

The appointed individual should also have the sufficient organisational authority for these roles as he or she will be held accountable for these roles.

2.Q **With the new requirements for the CGO, what happens to existing licensees who do not have personnel that can fulfil the stipulated qualifications?**

A The licensee will have to **engage a person who has the necessary skills and competency to act as the CGO**. This can be done by either hiring a new CGO or entering into contractual arrangements with an independent contractor (e.g. one who belongs to another licensee).

The requirements are essential to ensure more competent, effective, and consistent clinical or technical governance over these complex clinical services.

Going forward, MOH will continue to engage with the stakeholders to ensure the qualification requirements for CGOs are appropriate for the specific services.

3.Q **Why are there no specific requirements for a PO to be a medical doctor? If the PO is not a medical doctor, who will be held responsible for medical decisions?**

A The PO is an individual who is the authorised person representing the licensee and involved in the day to day management of the provision of the licensable healthcare service. **[Section 2 – definition of "Principal Officer"]*** The PO has to have sufficient organisational authority to adjust operations and make decisions to assist the licensee to ensure compliance to the Act e.g. a hospital CEO or COO or Chief Compliance Officer.

However, there will be safeguards to ensure appropriate medical decisions are made in the interests of the patients. For example, MOH will require that POs act on the medical opinions and recommendations surfaced to them by their CGOs, designated medical advisors or healthcare professionals in the area of patient safety, welfare and continuity of care.

At the same time, licensees are expected to empower clinical staff to carry out their clinical duties in accordance to safety standards and ethical codes that they are required to abide.

**The Act can be found here.*

FAQ on New Services to be Regulated

1.Q What are the new services that will be regulated?

A Under HCSA, the newly regulated services are:

1. Non-premises based services such as ambulance services and telemedicine services.
2. Standalone health screening services.
3. Certain complex services that have come about because of technological advancement, such as Cell, Tissue and Gene Therapy and Clinical Genetic Testing services.

FAQ on Telemedicine

1.Q Which aspects of telemedicine will be regulated under HCSA?

A MOH takes a risk-based approach towards regulations and will focus on licensing medical practitioner-led tele-consultation* for a start, as doctors diagnose and treat patients, and such activities are assessed to have a higher impact on patient safety.

MOH will continue to assess other aspects of telemedicine services (e.g. tele-monitoring) to determine if there is a need to regulate them going forward. For reference, tele-monitoring medical devices are regulated by the Health Sciences Authority (HSA) under the Health Products Act.

More details about telemedicine in the health sector can be found in the National Telemedicine Guidelines (NTGs) at **https://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/national-telemedicine-guidelines.html**.

**Tele-consultation refers to interactions between remote healthcare professionals and patients for the purposes of direct clinical care e.g. triage history, diagnosis and treatment.*

2.Q When does telemedicine begin? What about duty of care?

A Telemedicine begins when the patient enters the telemedicine application and initiates a consultation with the medical practitioner. This is akin to a patient entering into a clinic for an in-person consultation with a medical practitioner.

Doctors providing services using telemedicine modalities must endeavour to provide the same quality and standard of care as in-person medical care as stipulated in the SMC ECEG. The doctor should clearly indicate the limitations of his telemedicine services at the start of the consultation and refer the patient for an in-person consultation when he is unable to form a sufficient judgment from the tele-consult to discharge the expected standard of care.

3.Q How will MOH ensure that patient safety and welfare are not compromised with the practice of telemedicine?

A Medical practitioners providing telemedicine have to abide by the SMC ECEG which states that they must endeavour to provide the same quality and standard of care as in-person medical care.

In addition, medical practitioners providing telemedicine have to abide by the National Telemedicine Guidelines, which cover 4 domains such as clinical standards and outcomes, personnel, organisational and technology and equipment. MOH has also rolled out the Regulatory Sandbox for telemedicine providers to participate in. With the lessons learnt through the sandbox, MOH will be working with the telemedicine providers to co-develop the appropriate and "fit-for-purpose" regulations for telemedicine under HCSA.

Where a medical practitioner determines that he is unable to meet the expected standard of care for his patient via telemedicine, he should refer the patient for an in-person consultation. A patient can choose to stop a telemedicine consult and visit the physical clinic as well.

More FAQ will be published with regard to the other provisions of HCSA, such as background checks, step-in provisions, co-location, etc.

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