

# A Paradigm Shift – From Premises to Services: the New Healthcare Services Act

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## Introduction

The Healthcare Services Act 2020 (HCSA), when it comes into force in phases in 2021 and 2022, will repeal the existing Private Hospitals and Medical Clinics Act (Chapter 248 of Singapore Statutes) (PHMCA), and make certain consequential and related amendments to a number of other Acts.

The HCSA introduces a services-based regulatory framework (departing from the current premises-based framework under the PHMCA), expanding the regulatory scope to cover new healthcare services, treatments and models. Significantly, the HCSA will regulate telemedicine services (which are delivered wholly or partially through mobile and online channels) which have become increasingly popular and are poised to become a key feature of Singapore's healthcare system.

In this article, we examine some of the key features of the HCSA and draw some comparisons with the current regulatory regime under the PHMCA.

## What services will be regulated?

The HCSA regulates “**healthcare services**” which mean any of the following services:

- a. assessment, diagnosis, treatment, prevention or alleviation of any ailment, a condition, disability, disease, disorder or an injury affecting any part of the human body or mind;
- b. nursing or rehabilitative care of an individual suffering from an ailment, a condition, disability, disorder or an injury;
- c. conduct of any clinical procedure to change, or that is intended to change, the appearance or anatomy of an individual;
- d. assessment of the health of an individual; and
- e. any other service of a medical or healthcare nature that is prescribed.

The Ministry of Health (MOH) intends to introduce the licensing requirements under the HCSA in three (3) phases:

| Phase 1                              | Phase 2 | Phase 3 |
|--------------------------------------|---------|---------|
| <b>Estimated Implementation Date</b> |         |         |
| Q1 2021                              | Q4 2021 | Q3 2022 |
| <b>Licensable Services</b>           |         |         |

|  |   |   |
|--|---|---|
|  | <p>Ambulatory Care Services</p> <ul style="list-style-type: none"> <li>• Medical clinic services</li> <li>• Dental clinic services</li> <li>• Ambulatory surgical centre services</li> <li>• Renal dialysis centre services</li> <li>• Health screening services</li> </ul> | <p>Hospital Services</p> <ul style="list-style-type: none"> <li>• Acute hospital services</li> <li>• Community hospital services</li> </ul>   |
| <p>Clinical Support Services</p> <ul style="list-style-type: none"> <li>• Clinical laboratory services</li> <li>• Radiological laboratory services</li> <li>• Blood banking services</li> <li>• Tissue banking services</li> </ul> | <p>Non-Premises Based Services</p> <ul style="list-style-type: none"> <li>• Medical transport services</li> <li>• Emergency ambulance services</li> </ul>   | <p>Long-Term Care Services</p> <ul style="list-style-type: none"> <li>• Nursing home services</li> <li>• Inpatient palliative care services</li> </ul>  |
| <p>Special Services</p> <ul style="list-style-type: none"> <li>• Nuclear medicine imaging and assay services</li> </ul>  | <p>Special Services</p> <ul style="list-style-type: none"> <li>• Assisted reproduction services</li> <li>• Radiation oncology services (including proton beam therapy)</li> <li>• Blood transfusion services</li> <li>• Nuclear medicine therapy services</li> </ul>        | <p>Non-Premises Based Services</p> <ul style="list-style-type: none"> <li>• Telemedicine services</li> </ul> <p>Special Services</p> <ul style="list-style-type: none"> <li>• Cell, tissue and gene therapy services</li> <li>• Clinical genetic and genomic services</li> <li>• Organ transplant services</li> <li>• Specialised interventional procedures services</li> </ul> |

MOH has stated that allied health, nursing, traditional Chinese medicine and complementary and alternative medicine services, while falling within the regulatory scope of the HCSA, will not be licensed at this point.

## Transitional Provisions

Existing licensees under the PHMCA will not have to apply for a new licence under the HCSA if:

- they are providing the same licensable service(s) under the HCSA; and
- they are providing such licensable service(s) in a private hospital, medical clinic, clinical laboratory or healthcare establishment.

Subject to the above, licences and approvals granted under the PHMCA will continue in force for the remainder of their validity period.

However, if an existing licensee wishes to provide a healthcare service that was not previously regulated under the PHMCA or wishes to provide the licensable service(s) outside of the premises that the licence under the PHMCA was granted in respect of, the existing licensee will have to apply for a new licence under the HCSA.

## Certain obligations of licensees

### Appointment of Principal Officer and Clinical Governance Officer

Licensees under the HCSA will be required to appoint a Principal Officer who, (a) must be involved in the day-to-day management of the provision of the licensable services, (b) must have the capacity and organisational authority to influence the compliance of the licensee's officers and employees, (c) must have access to and the authority to provide any information relating to the licensee and the licensable services it is licensed to provide, and (d) must be authorised to represent the licensee in providing the licensable services for the purposes of the HCSA. The role served by the Principal Officer is similar to that of a Manager under the PHMCA.

The HCSA introduces a new role – the Clinical Governance Officer. Licensees providing certain prescribed licensable services must also appoint one (1) or more Clinical Governance Officer(s) who will be responsible for the clinical and technical matters relating to the prescribed licensable services and to perform any other prescribed functions in relation to the licensee.

The licensee must ensure that the Principal Officer and the Clinical Governance Officer(s) are suitably qualified for their respective roles.

## Appointment of Specified Committees

Licensees of certain prescribed categories or descriptions will be required to appoint one (1) or more specified committees as may be prescribed, such as Quality Assurance Committees, Service Review Committees and Clinical Ethics Committees.

## Ethics review for certain treatments

Licensees providing certain prescribed medical treatments may provide such medical treatments to an individual only after that individual's case has been referred to and reviewed by at least one (1) or more Clinical Ethics Committee (appointed by the licensee or by another licensee), and every Clinical Ethics Committee that reviewed the individual's case is satisfied that the provision of the prescribed medical treatment to that individual is ethically appropriate.

## Co-location of services

Unless approved by the Director of Medical Services, licensees are not allowed to co-locate licensed and unlicensed services except where the unlicensed service is incidental to the provision to the licensable service being provided at the relevant premises, or the unlicensed service is a prescribed healthcare service that is within the scope of the HCSA.

# Additional regulatory powers of MOH

In addition to the other regulatory powers granted to the Director of Medical Services (including, without limitation the power to shorten, suspend or revoke a license, censure the licensee, modify any condition of a license, etc.), the HCSA will also give the Director of Medical Services the power to make a step-in order (Step-in Order) to take over some or all operations of certain designated licensees.

The Director of Medical Services may make a Step-in Order in certain specified circumstances such as: (a) where one (1) or more of the designated licensee's licenses are suspended, revoked or surrendered, (b) where the designated licensee is financially distressed, (c) the contravention or non-compliance by a designated licensee of the HCSA, (d) where the designated licensee's conduct of operations is, or is likely to be, detrimental to the interest of its patients or customers, or (e) where the Minister of Health considers it is in the public interest to make such an order.

## Further developments

MOH had previously announced that it would conduct consultations in February 2020 in relation to the General Regulations which will set out the key licensing requirements under the HCSA. Additionally, MOH also stated that it would engage the relevant stakeholders in relation to the sector-specific regulations closer to the respective implementation dates (please refer to the table in paragraph 5 above) for each of the licensed services. However, in view of the COVID-19 situation, all consultation sessions have been postponed until further notice.

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