

Bird & Bird ATMD

Legal Update



Singapore Regulatory Update: Healthcare Services Bill

January 2020

*The Healthcare Services Bill (the "**Bill**") was passed on 6 January 2020, replacing the Private Hospitals and Medical Clinics Act ("**PHMCA**"), which was last amended in 1999. The Bill seeks to strengthen the safeguards for the safety and welfare of patients who receive healthcare services, improve the governance requirements for providers of healthcare services, as well as enhance the regulatory powers in relation to providers of healthcare services.*

The Bill will be implemented in three phases from early 2021 to end 2022, with the new provisions first being extended to PHMCA clinical laboratory licensees, followed by clinic licensees and private ambulance operators, and finally hospitals and licensees providing other new services.

Key Changes introduced by the Bill

Broadened Scope of Coverage

Under the Bill, the regulatory scope will be broadened to include healthcare services¹, allied health and nursing services, traditional medicine, and complementary and alternative medicine.

While the scope of the Bill is sufficiently broad to cover allied health and nursing services, traditional medicine and complementary and alternative medicine, the Ministry of Health ("MOH") will not

¹ "healthcare services" is defined in Clause 3 of the Bill to mean any of the following services, whether or not provided for reward:

- (a) assessment, diagnosis, treatment, prevention or alleviation of an 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, disease, disorder or an injury mentioned in paragraph (a);
- (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; or
- (e) any other service of a medical or healthcare nature that is prescribed

be licensing these services for the time being, adopting a risk-based regulatory approach. The MOH currently regulates these professionals such as physiotherapists and traditional Chinese medicine practitioners through existing legislation², to ensure patient safety.

Services-based Licensing

The Bill introduces a services-based licensing regime for providers of healthcare services, replacing the premises-based licensing regime under the PHMCA. The MOH has grouped the licensable healthcare services into six broad service categories – hospital services, ambulatory care services, long-term residential care services, non-premise based services, health support services and special services. A provider may be required to have multiple licenses depending on the services provided. License conditions will depend on the type of service provided and some services will require other licenses as a pre-requisite.

² These include the Traditional Chinese Medicine Practitioners Act and Allied Health Professions Act.

'Step-In' Safeguards for Residential Care Services

The MOH will be empowered under Part 4 of the Bill to take over the operations of certain healthcare service providers who are in serious financial trouble. These step-in provisions will apply only to residential healthcare entities such as nursing homes, hospitals and inpatient palliative care centres, and serve as a transitional measure to be in place until patients can be transferred to other service providers.

These powers are to be exercised as a last resort after measures such as penalties, warnings, or the appointment of a new management team have failed. The requirements to be fulfilled before a step-in order is made include (i) that one or more licences of a designated licensee are suspended, and (ii) the licensee is, or is likely to be, declared bankrupt, has gone, or is likely to go, into voluntary liquidation, or is, or is likely to be, placed under judicial management. The MOH or an appointed 'step-in' operator can also take over if the service provider flouts regulations under the Bill, or is operating in a manner that is detrimental to the interests of its patients or customers.

Refined Roles and Responsibilities of Key Personnel

In addition to the role of the licensee as required under the PHMCA regime, the Bill lays out new enhanced roles under Clause 24 of the Bill – the Principal Officer ("PO"), which is mandatory for all licensed services, and a Clinical Governance Officer ("CGO") which is required for selected services.

The PO must be involved in the day-to-day management of the provision of the licensable healthcare services the licensee is authorised to provide, and must have the capacity to influence the compliance of the licensee's officers and employees with the requirements under the Bill. The CGO is responsible for the clinical and technical matters relating to the relevant licensable healthcare service, and performing the prescribed functions in relation to the license. The CGO will be required to have certain qualifications, depending on the service in question, to be stipulated in the relevant service regulations. The same individual can function as the licensee, the PO and CGO for different service licenses, as long as the individual can fulfil all relevant requirements and can perform all roles adequately.

Augmenting Safeguards for Clinical Quality and Medical Ethics

Pursuant to the Bill, licensees providing higher patient risk services are required to appoint one or more specified committees as may be prescribed in relation to any licensable healthcare service that they provide, namely the quality assurance committees, service review committees and service ethics committees.

The Bill also imposes obligations on licensees to keep and maintain records that are relevant to the monitoring, evaluation or provision of any aspect of any licensable healthcare service.

Measures to Minimise Public Misperception

Similar to the PHMCA, Clause 30 of the Bill places restrictions on the provision of licensable healthcare services together with other unrelated or unlicensed services at a premise or a conveyance. Services of activities unrelated to such licensable services must be situated in a separate premise or conveyance.

Licensees are prohibited under Clause 29 of the Bill from using terms that connote a national body, such as 'National' or 'Singapore', as part of their names or logos without explicit approval from the Director of Medical Services. Additionally, licensees are also prohibited from using names of services that they are not licensed for.

Clause 31 of the Bill also sets out tightened publicity controls relating to the advertisement of licensable healthcare services. Under this provision, only licensees and their appointed agents will be allowed to advertise licensable healthcare services. They will also have to comply with prescribed requirements to prevent advertisements that are false, misleading or laudatory.

The Bill also empowers the MOH to publish a list of non-compliant licensees and unlicensed providers, in order to facilitate more informed decision-making by patients.

National Electronic Health Record ("NEHR")

The mandatory contribution to the NEHR has been deferred as the system will be put through rigorous

independent external review before being used as a national database, in the wake of the cyberattack and data breach on Singhealth in July 2019.

References and Links

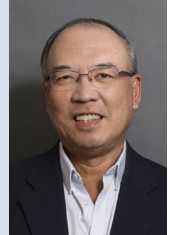
- The Healthcare Services Bill can be accessed [here](#).
- Opening Speech for Second Reading of Healthcare Services Bill by Mr Edwin Tong, Senior Minister Of State, Ministry Of Health, 6 January 2020, reproduced [here](#).

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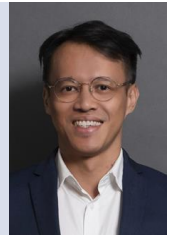
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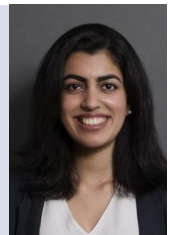
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