Baker McKenzie Wong & Leow.

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Newsletter

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For more information, please contact:

Andy Leck
+65 6434 2525
andy.leck@bakermckenzie.com

Lim Ren Jun
+65 6434 2721
ren.jun.lim@bakermckenzie.com

MOH releases Summary of Key Feedback and Responses to Healthcare Services Bill

We previously discussed the *Healthcare Services Bill* (the "**Bill**") which will replace the current *Private Hospitals and Medical Clinics Act* ("**PHMCA**"), and the public consultation for the Bill held between 5 January 2018 and 15 February 2018. Our earlier client alert on this topic can be found here.

On 24 May 2018, the Ministry of Health ("**MOH**") released its Summary of Key Feedback and Responses received during the public consultation (the "**Public Consultation Summary**").

The Public Consultation Summary underscores MOH's intent for the Bill to put in place better safeguards for patient safety and well-being, and to strengthen continuity of care. As previously discussed, the Bill modifies the regulatory regime for healthcare services from a "premises-based" to a "services-based" form of licensing, and mandates contributions to the National Electronic Health Record ("**NEHR**").

Significant findings and statements from the Public Consultation Summary include, amongst others:

- As concerns telemedicine, only tele-treatment (i.e. where doctors provide direct clinical care to patients remotely over an electronic platform) will be licensed. Other domains, such as tele-collaboration, tele-monitoring, and tele-support, will not be regulated.
- To provide greater clarity on licensed specialised interventional procedures and radiology services, MOH will finalise two respective lists of the relevant procedures and services, and consult with licensees after such finalisation.
- MOH is proposing to allow co-location of a list of health-related services with specific service licensees under the Bill. MOH will review the operational details of this policy and update service providers once the review has been completed.
- In addition to extended training, assistance and funding support programmes, MOH will also work with the IT vendor community from mid-2018 to explore alternative technical solutions for NEHR data contribution.
- MOH emphasised that the criminal penalty for failure to contribute health information to the NEHR is intended to specifically address recalcitrant licensees who intentionally or persistently fail to contribute health information to the NEHR. MOH will looks into all circumstances of each case and the reasons for the non-contribution, before considering appropriate enforcement actions.
- MOH will explore additional provisions to legally prohibit licensee access and use of the NEHR for insurance and employment purposes, and to add in

necessary safeguards and penalties to address concerns of unintended disclosure following authorised access.

- In view of the particular concerns of certain patients, MOH will review the various options for patients to opt-out of contributing their medical records to the NEHR.
- In response to public concerns about potential medico-legal liability in relation to contribution, access and usage (e.g. inappropriate access or data breaches), MOH and the Integrated Health Information Systems will collaborate with medico-legal professionals and licensees to develop a set of guidelines for proper contribution, access and use of the NEHR. This will be done through a series of educational workshops for licensees, which MOH plans to roll out later this year.
- MOH has taken note of stakeholders' concerns on the impact of the NEHR on medical tourism in Singapore, and will take this into consideration when reviewing the Bill.

The Public Consultation Summary released by MOH can be found here.

Changes to the Medical Device Regulatory Regime to take effect from 1 June 2018

On 22 May 2018, the Health Sciences Authority ("**HSA**") announced that regulatory legislation will be enhanced to facilitate faster access for certain lower risk medical devices and standalone mobile applications. The HSA will also provide greater clarity to existing policies and requirements for telehealth devices and high risk devices for the modification of appearance or anatomy.

These changes will take effect from 1 June 2018.

In summary, under these enhanced regulations:

- Class A sterile medical devices (e.g. sterile examination gloves and intravenous sets) will not need to be registered with HSA. However, importers / manufacturers will be required to list all their Class A medical devices on the HSA's public online database;
- Class B medical devices with (a) no safety issues globally; and (b) two independent regulatory agencies' approval or one reference agency's approval and 3 years of marketing history, will be eligible for immediate market access under the immediate registration route; and
- Class B and C standalone mobile medical applications (e.g. those for insulin dosage calculation or live monitoring of electrocardiograms) that are approved by at least one reference regulatory agency without safety issues globally will be eligible for immediate market access under the immediate registration route.

The HSA also clarified that:

- While telehealth devices intended by its manufacturer to fulfil a medical purpose will be regulated as medical devices, those which are intended solely for well-being or lifestyle purposes (e.g. smart watch heart rate trackers for fitness purposes) and / or not intended for medical purposes will not be subject to regulatory controls. However, such telehealth devices must include a prescribed clarification statement (or equivalent) on their labels and advertisements;
- Certain high risk devices used for modification of appearance or the anatomy will be subject to regulatory controls. Such devices will be included in a "Positive List" developed by HSA to provide clearer guidance to industry players. At present, the list comprises implants, injectable dermal or mucous membrane fillers, and invasive devices for fat removal or fat degradation purposes; and
- HSA will require manufacturers of more complex medical devices (i.e. those requiring users to have the relevant skills and knowledge to use them safely and effectively) to provide training for users. For example, HSA will require physicians using implantable devices to undergo training on implantation techniques before using them on their patients.

The HSA's press release can be found here.

www.bakermckenzie.com

Baker McKenzie Wong & Leow
8 Marina Boulevard
#05-01 Marina Bay Financial Centre
Tower 1
Singapore 018981

Tel: +65 6338 1888
Fax: +65 6337 5100