MINISTRY OF HEALTH
SINGAPORE

24 May 2018

PUBLIC CONSULTATION ON THE DRAFT HEALTHCARE SERVICES (HCS) BILL

SUMMARY OF KEY FEEDBACK AND RESPONSES

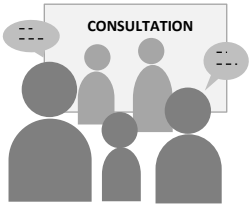
The Ministry of Health (MOH) invited licensees and members of the public to provide feedback on the draft Healthcare Services (HCS) Bill from 5 Jan to 15 Feb 2018. The draft HCS Bill is intended to replace the current Private Hospitals and Medical Clinics Act (PHMCA), and put in place better safeguards for patient safety and well-being, and strengthen continuity of care.

2 MOH held 18 consultation sessions at various locations and timings over the six weeks of public consultation. At the close of the exercise, MOH received over 2,000 written comments, email enquiries and clarifications, as well as face-to-face Q&As at the consultation sessions from our stakeholders - current and prospective licensees, professional bodies[1], academia, relevant Ministries, and members of the public.

3 Since May 2016 when MOH first started engaging relevant stakeholders on HCS Bill policies, over 2,300 individuals have attended our roundtables, focus group discussions, and most recently our town-hall-style public consultation sessions.

AT A GLANCE

HCS Bill enhances safeguards for patient safety & welfare, and strengthens continuity of care



6-week consult period
18 consultations from 5 Jan – 15 Feb 2018

Engagement began in Aug 2016.
To-date over 2,300 individuals consulted

[1] *These include the Singapore Medical Council, Singapore Medical Association, College of Family Physicians, Academy of Medicine, Singapore Dental Council, Allied Health Professional Board*

Ministry of Health, Singapore
College of Medicine Building
16 College Road
Singapore 169854
TEL (65) 6325 9220
FAX (65) 6224 1677
WEB www.moh.gov.sg

Stakeholder Feedback

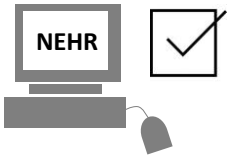
4 There was broad recognition for the need to update the current PHMCA, given the evolving healthcare landscape with the introduction of new technologies and healthcare delivery models. Feedback on the move from "premises-based" to "services-based" licensing was also generally positive.

Generally, stakeholders are supportive of the HCS Bill

5 While most licensees felt that this approach gave them more business flexibility, some were concerned if this would increase regulatory burden and cost. Licensees also sought clarifications on the scope of the new Bill, plans to help existing licensees transition from PHMCA to HCSA, as well as definitions of newer services under the HCS Bill.

Queries on implementation of HCSA

6 Mandatory data contribution to the National Electronic Health Records (NEHR) by all HCS licensees drew considerable comments and feedback. There was general agreement from both licensees and the public that mandatory NEHR data contribution would improve continuity of care for patients.



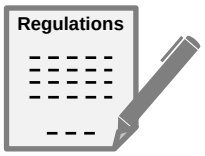
Wide agreement that NEHR contribution is worthwhile

7 Some healthcare professionals were concerned about their lack of technical know-how and cost of acquiring and maintaining an electronic medical record system. The majority of licensees and public were supportive of legally prohibiting the use of NEHR for insurance or employment purposes. Stakeholders also raised questions on the relevance of NEHR for foreign patients, data security, medico-legal implications and confidentiality of patients' medical data.

Concerns with medico-legal issues & adoption

Next Steps

8 MOH will consider the feedback gathered and assess where and how to address the issues raised. The proposed HCS Bill draws from the experience of regulating under the PHMCA as well as good practices across other sectors and jurisdictions. It seeks to strike a fair balance between allowing the introduction of new and innovative service models, and the need for effective and efficient patient safeguards.



Majority of implementation concerns to be addressed via Regulations

9 Around 80% of the issues raised by stakeholders were on HCS Bill implementation (e.g. port-over and operational details), which will be addressed through the HCS Regulations. The Regulations will outline the requisite standards (including personnel, premises and service requirements) that licensees will need to fulfil in order to obtain and retain service licences under the new HCS Bill. These will include responsibilities of key personnel, the listing of Point of Care Tests (POCT) allowed in clinics, and the scope and roles of the various committees required in the new Bill. MOH will be seeking feedback on all the HCS Regulations with the relevant affected licensees from early 2019.

On-going engagement with expert panels to develop Regulations.

10 MOH has also heard the concerns regarding NEHR. We will consider practical suggestions that retain the key outcome of continuity of care for patients. In the coming months, MOH will also work with providers to support NEHR adoption through various means. These include a phased implementation to allow time for sectoral adoption of IT and digitalisation grants to support licensees in the transition. MOH, through the Integrated Health Information Systems (IHiS), will be working with IT vendors to explore the feasibility of developing simpler systems for licensees who are less familiar with electronic records. IHiS will also be conducting medico-legal workshops and creating a set of guidelines for proper contribution, access and use of NEHR.

MOH will be working to address <u>providers'</u> concerns with NEHR by:
- Introducing grants
- Updating adoption schemes
- Holding Medico-legal workshops

11 The Ministry will take into consideration patients' suggestions for their summary record to be made available in HealthHub. On data security, MOH would like to reassure that system integrity remains paramount and MOH will continue to develop technical solutions for safe access. Finally, MOH will take in feedback on opt-out options and review how these options can be operationalised.

MOH will be working to address <u>patients'</u> concerns with NEHR

- Patient access to their own health records
- Data security to remain paramount
- Updated opt-out options

Preparing for HCSA

12 MOH is mindful that there should be sufficient time and support for licensees to adjust and transit smoothly into the HCS Bill. Most respondents supported the proposed 18-month phased approach starting a year after enactment of the new Act. MOH will continue to actively reach out to licensees through briefings and regulatory visits.

Good support for 18-month phased implementation of the HCS Bill

13 MOH thank all stakeholders and members of the public for participating in this public consultation exercise. It has helped the Ministry develop a greater understanding of your priorities and concerns. MOH looks forward to refining the draft HCS Bill in response to the constructive feedback given. Together with all our stakeholders, MOH can improve patient safety, welfare and continuity of care across the sector.

Thank You

Your feedback made a difference

14 If there are further clarifications needed, please feel free to write to hcsa_enquiries@moh.gov.sg.

Ministry of Health, Health Regulation Group

----------Thank you for your feedback----------

ANNEX

DETAILED RESPONSES TO THE KEY FEEDBACK ON HCS BILL

(i) Queries on HCSA Service Licensing Framework

MOH has proposed to move from regulating physical healthcare premises to regulating healthcare services delivered out of those premises. For most licensees, it will mean that their licences will no longer be tied to the premises where they deliver their healthcare, but will be granted based on the services they deliver.

2 This move will also enable MOH to impose safety standards on businesses that have been providing their services from non-brick-and-mortar settings (e.g. those providing standalone telemedicine, mobile community-based medical or home care services without a base clinic).

3 There were concerns that it would be administratively burdensome for medical or dental clinics to manage three or four additional licences (e.g. telemedicine, health screening and/or mobile medical) in addition to their general medical/dental license. The Ministry recognise that these services are already part of a General Practitioner's practice. MOH will take this feedback into account when developing the HCSA licence fee framework (e.g. exploring the option of bundling licences as a package), so that the regulatory cost impact to the existing licensees will be minimised at the point of port over.

4 In terms of transitioning licensees from PHMCA to HCSA, MOH will focus on reducing administrative burden on the licensees and enabling a smooth port-over to the new Act. To do this, the Ministry recently conducted a service mapping exercise for the existing licensees to match their PHMCA and potential HCSA service licenses. To ensure the validity of the mapping, MOH will ask licensees to confirm their mapping of services closer to the HCSA implementation date.

(ii) Queries on HCSA Service Definitions

5 Stakeholders raised queries on some of the definitions for new services that will be licensed under the HCSA. MOH's clarifications are as follows:

6 Telemedicine: The purpose of a telemedicine service license is to ensure that telemedicine services are provided in a safe and appropriate manner. The regulatory standards will take reference from the existing National Telemedicine Guidelines. Currently, only the tele-treatment domain where doctors provide direct clinical care to patients remotely over an electronic platform will be licensed. Other domains such as tele-collaboration (interactions between healthcare professionals), tele-monitoring (vital sign monitoring of patients) and tele-support (educational or administrative support), will not be regulated at the moment. In unforeseen emergency situations where tele-treatment is sought from a doctor without a telemedicine service licence, the doctor may respond to the best of their professional capacity in accordance with the Singapore Medical Council's Ethical Code and Ethical Guidelines (ECEG).

7 Specialised interventional procedures: Specialised interventional procedure service is a licence category reserved for complex and high-risk interventional procedures that require specialised expertise, equipment or techniques. Most of these procedures involve more complex image-guided interventional neurological (e.g. gamma knife), cardiac, pulmonary, hepatic and vascular procedures. MOH is working with expert committees to finalise the list of these procedures and will consult licensees when this review has been completed.

8 Radiology: Some clinic providers had queried the need to apply for a separate radiological service licence if they are providing simple point-of-care-tests (POCT) in the clinic. MOH acknowledges that the purpose of POCT is to facilitate clinic consultations for their own patients. With this in mind, MOH will not be requiring a separate radiological service licence if the tests provided are specified in a scheduled list of point-of-care-tests (POCT) published by MOH. MOH is still in the midst of finalising the list of POCTs and will consult providers once the list has been finalised.

(iii) Queries on Co-Location of Licensed and Unlicensed Services

9 There were a number of questions on Section 82 of the HCS Bill regarding the use of licensed premises or licensed conveyances for other purposes. This provision is intended to prevent the co-location of unlicensed healthcare services with MOH-licensed healthcare services (e.g. a beauty spa co-locating with a general medical/dental clinic). This will reduce public misperception that such unlicensed services are providing healthcare services licensed by MOH. Several providers highlighted that there are certain health-related services (i.e. those not listed in the First Schedule – licensable healthcare services) which should be allowed for co-location as they facilitate care continuity (e.g. physiotherapy services with an orthopaedic specialist clinic). Based on this feedback, MOH is proposing to allow co-location for a list of health-related services with specific HCSA service licensees. MOH is developing the list. We will review the operational details of this policy, and update service providers when the review has been completed. Licensees who wish to seek further clarification on the type of unlicensed services they can co-locate with may write to MOH to seek clarification.

(iv) Queries on the Scope of the Draft Bill - Regulating Third Party Administrators (TPAs) / Managed Care Organisations (MCOs) / Medical Concierge

10 Some healthcare providers called for TPAs, MCOs and Medical Concierge businesses to be regulated under the draft Healthcare Services Bill. They were concerned that the charging practices adopted by some TPAs and Medical Concierge businesses may (i) constrain doctor practices and result in sub-optimal care for patients (particularly for those under primary care practitioners) or (ii) encourage overcharging, over-servicing (particularly for patients under specialist care) and unnecessary medical referrals.

11 The latest SMC Ethical Code and Ethical Guidelines (ECEG) already provides a framework of expected practice of doctors with respect to such referral arrangements. In addition, to empower patients and provide them with better bill transparency, licensees will be required to provide itemised bills for their services

(including a breakdown for TPA fees where relevant) under the proposed HCS Bill. MOH will monitor the situation, before determining if service regulation is necessary.

(v) Queries on the Stipulated Qualifications for Principal Officers (POs)

12 Under PHMCA, there are stipulated qualifications required for the role of Manager under clinical labs, clinics and nursing homes. For better clarity, the role of the current Manager would be clearly delineated between the Principal Officer (PO) and Clinical Governance Officer (CGO). The PO would take on the role of ensuring overall compliance in the day-to-day operations of the healthcare institution, while the CGO would be responsible for the higher risk and more complex services, such as assisted reproduction and clinical laboratory services – a role requiring specific medical qualifications. For clarity, a CGO would only be required for selected specialised services and not for all the services in the HCS Bill.

13 With this delineation, the PO would not require stipulated qualifications under HCSA. Generally, even if the PO is not a medical professional, all decisions relating to patient's clinical care must take into account healthcare practitioners' views, to ensure patient safety and welfare.

(vi) Concerns with Readiness and Long-Term Cost of NEHR Contribution

14 Some healthcare professionals who were less familiar with electronic clinic management systems or who had a relatively low patient volume, highlighted that it would be challenging for them to adopt a NEHR compliant Electronic Medical Record System (EMRS). Many currently only keep "pen-and-paper" records and expressed concern about their lack of tech know-how and the high cost of acquiring and maintaining an EMRS.

15 In addition to extended training, assistance and funding support programmes, MOH will also be working with the IT vendor community from mid-2018 to explore alternative technical solutions for NEHR data contribution.

(vii) Concerns Penalties for Non-Contribution to NEHR

16 Licensees were of the view that criminal liability for a failure to contribute to NEHR was too harsh and suggested that regulatory action, such as revoking or suspending a licence or issuing a fine, would be more appropriate. Licensees highlighted that a failure to contribute could result from situations beyond the licensees' control, such as an IT system error.

17 While MOH understands the concerns expressed, the Ministry would like to clarify that the intent for this penalty is to specifically address recalcitrant licensees who intentionally or persistently fail to contribute health information to NEHR, thereby compromising continuity of care for their patients.

18 MOH would like to assure licensees that the Ministry looks into all circumstances of each case and the reasons for the non-contribution, before considering appropriate enforcement actions. Nevertheless, MOH will consider whether more clarity is necessary and feasible in the legislation.

(viii) Concerns with Usage of NEHR for Insurance and Employment Purposes

19 Use of the NEHR for insurance and employment checks was debated widely during consultations. Majority of licensees and public were supportive of legally prohibiting the use of the NEHR for such purposes. However, several stated that patients would still be obligated to release their medical information before being able to proceed with claims or an employment assessment.

20 MOH is mandating contribution to NEHR to enhance the quality of patient care. In response to the feedback provided, MOH will explore if additional provisions are required to be introduced into the draft Bill to legally prohibit licensee access and use of the NEHR for insurance and employment purposes.

(ix) Concerns with Unauthorised Access to NEHR Information

21 Members of the public raised concerns on possible unauthorised access and/or use of data in NEHR. Others asked if there were mechanisms to detect unauthorised access of their personal medical records in NEHR.

22 Several measures have been put in place to ensure that NEHR remains secure, such as performing security tests on the system, conducting regular cyber security audits, enabling a two-factor authentication system for licensees/individuals to access NEHR and features to detect suspicious access and usage. MOH will continue to enhance the access and security measures for NEHR.

23 With respect to Sensitive Health Information (SHI), MOH is of the view that provider access to this type of health information is important for patient safety and welfare. Healthcare decisions in emergency and non-emergency situations are guided based on such information. Safeguards are already built into NEHR to ensure that access to SHI is not abused or misused, and that all SHI access is tracked and subjected to a full audit.

24 Concerns were also raised that there could be unintended disclosure of NEHR information following authorised access, for example if NEHR printouts were not properly disposed and picked up by other persons. MOH has taken note of this concern and is exploring adding in necessary safeguards and penalties to address these concerns.

(x) Concerns with the Relevance of NEHR for Foreign Patients

25 Licensees suggested that the NEHR would be more relevant for the provision of continuity of care for those who resided or spent significant time in Singapore. There were also concerns that including foreign patient information in the NEHR could be a potential barrier for promoting medical tourism in Singapore. Several suggested the need for a simpler opt-out process for this group of foreigners.

26 MOH agrees that for foreigners on long-term visit pass, care continuity is important. MOH has also noted stakeholders' concerns on NEHR's impact on medical tourism. A holistic approach is necessary, and we will take these points into consideration when we review the matter.

(xi) Concerns with the Clarity of Available NEHR Opt-Out Options and Processes

27 Some stakeholders were concerned with the contribution of patient data into NEHR and asked for further clarity on opt-out options. Several private healthcare providers shared that some of their patients had expressed strong interest for their data not to be included in NEHR, so as to protect their confidentiality. While MOH acknowledges this feedback, the sentiment was somewhat different from the views shared by members of the public during the public consultations. The majority indicated that they would remain opted-in to NEHR given the value to their continuity of care and the built-in confidentiality safeguards and controls.

28 The proposed contribution of patients' summary medical records to NEHR is to support continuity of care and patient safety. However, MOH recognises that some patients may wish not to have their records in NEHR due to particular concerns. To address these concerns, MOH will be reviewing the various opt-out options (e.g. records stored in NEHR under lock, records not to be stored in NEHR) to meet patients' needs. Those who wished to opt-out asked that the process be made simple and efficient. The Ministry acknowledges the need for a streamlined process for patients who have decided to opt out. However, as this has significant impact on care continuity, a balance has to be struck between the ease of opt-out as and the time and information needed for patients to make a well informed decision. MOH will be studying ways to operationalise the opt-out option efficiently and effectively.

29 For clarity, licensees will still be required to maintain systems that allow for NEHR data contribution.

(xii) Medico-Legal concerns with NEHR

30 With mandatory NEHR contribution, some licensees were worried about their potential medico-legal liability in relation to data contribution, access and usage, which might affect their medical practice. Licensees cited a few possible scenarios of concern:

a) Contribution of inaccurate or wrong data to NEHR;
b) Reliance on inaccurate or wrong data within NEHR to manage a patient;
c) Inappropriate access or data breaches;
d) Unintentional release of sensitive patient conditions; and
e) Failure to refer to NEHR for every patient's consultation, resulting in an error in the management of the patient.

31 To address these medico-legal concerns, MOH and IHiS will collaborate with medico-legal professionals and licensees to develop a set of guidelines for proper contribution, access and use of NEHR. This will be done through a series of educational workshops for licensees, which MOH will be planning to roll out in the 2nd half of 2018.