Healthcare Services (General) Regulations FAQ

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General

1.	**Where can I find the Healthcare Services (General) Regulations?**

- Please refer to (http://www.hcsa.sg) to find out more about the Healthcare Services (General) Regulations (HCSA General Regulations).
- Once it is implemented, the Regulations will also be available on Singapore Statues Online at http://sso.agc.gov.sg.

Part III Governance of Licensees

2.	**Who can be appointed as the licensee?**

- Under HCSA, the licensee may be the corporate entity or a natural person (e.g. CEO of the licensable healthcare service). There is no restriction on who may be appointed as the licensee, nor is there any requirement for the licensee to have clinical expertise.
- For example, an acute hospital may appoint its CEO as the licensee, or the licence may be held by the corporate entity (e.g. company) that owns the acute hospital. This similarly applies to other services, such as a medical clinic group, a clinical laboratory or a nursing home. In a much simpler business set-up, such as a solo GP clinic, the licensee may be the sole doctor who owns and practises at the clinic.

3.	**What is the difference between the roles of the Principal Officer (PO) and Key Appointment Holders (KAHs)?**

- The role of the PO under HCSA is akin to that of the "manager" under the PHMCA. The oversight provided by the PO is to do with direct day-to-day management of the licensable healthcare service. It is the PO's duty to ensure operational compliance with the regulations, and assist the licensee to review any risks to patient safety and welfare.
- While the role of the "KAH" is now formalised under the HCSA, it is not a new concept. The KAHs are the governing body and generally the controlling mind and will of the licensee, and to be determined based on the business structure as registered with the Accounting and Corporate Regulatory Authority (ACRA). KAHs generally comprise the Board of Directors (BOD) for companies, the partners for partnerships, or the owner for sole proprietorships. They are responsible for the strategic leadership and corporate management oversight of the organisation, but they have limited direct influence over the day-to-day operations on the ground as compared to the PO.
- Examples of typical KAHs in different settings include:

- Board of Directors for acute hospitals and community hospitals, large medical / dental clinic chains, clinical laboratories and large nursing homes, as these are typically complex set-ups owned by companies;
- Partners in partnerships, which typically own less complex set-ups, such as a small multi-doctor clinic;
- The business owner of sole proprietorships, which typically own simple set-ups, such as a solo GP clinic. Where a clinic is owned by an individual and the business is not registered with ACRA as a sole proprietorship, that individual is the KAH.

- For subsidiaries of a corporate entity without their own Board of Directors, e.g. clinical laboratories in a hospital cluster, the Board of Directors of the owner corporate entity are the KAHs of the subsidiaries.

4. Do KAHs have a duty to be involved in day-to-day operational issues?

- KAHs are responsible for approving policies and SOPs for both corporate and clinical aspects of the healthcare service. The PO and, where required, CGO remain responsible for overseeing the day-to-day operational management.
- As such, KAHs should take reasonable steps to apprise themselves of the implementation of policies and SOPs, and to identify any gaps or deficiencies in its implementation.

5. What does "day-to-day" operational management refer to?

- The phrase 'day-to-day' is a broad term, which entails the executive involvement of the PO/CGO, but it does not mean that they are required to be personally or directly involved in every task or function on the ground.
- The PO/CGO may delegate tasks to other personnel deemed competent and suitable for the functions, although the overall responsibility and accountability to ensure operational compliance with HCSA remain with the PO/CGO.
- This is akin to the Chief Executive Officer (CEO) or Chief Operating Officer (COO) retaining executive/operational responsibility over the day-to-day running of their institution even though they are typically supported by a team.

6. Why is there a need to formalise the role of KAHs? Are the KAHs always held accountable in the event of a breach?

- KAHs are the governing body of the licensee responsible for the strategic leadership and general management oversight of the licensable service. However, they do not have statutory roles under the PHMCA. Formalisation of the roles of KAHs under HCSA makes it clear that they are accountable for the directions they give.

- The licensee will always be culpable in the event of the breach. KAHs may not always be culpable whenever there is non-compliance. Their degree of culpability will turn on the facts of each case.

7. Why are KAHs required to have clinical expertise?

- At least one KAH is required to have clinical qualifications and experience relevant to the healthcare service(s), to ensure appropriate clinical oversight and guidance for the service(s) being provided. This is especially the case as there is no requirement for the licensee or the PO to have such clinical qualifications or experience.
- However, to provide greater flexibility for healthcare service providers, the clinical qualification/governance requirements for the KAH will be waived if these clinical requirements are met instead by the PO, or where there is a mandatory appointment of a Clinical Governance Officer (CGO) for the licensee's service.
- Please refer to the consultation slides for the Code of Practice for KAHs and its FAQs for more details.

8. Can one person be appointed as the CGO for more than one licensee?

- Yes, a person with suitable skills and competencies can be appointed as the CGO for several licensees simultaneously, subject to them meeting the specific requirements on skills and competencies of the CGO stipulated in the specific service regulations.
- However, in appointing such persons as the CGO, licensees are responsible for taking into consideration their bandwidth and capacity as part of assessing their suitability and ability for the role.

9. If the PO consults the CGO for clinical matters but eventually makes a decision that deviates from the CGO's advice, who would be held responsible if a non-compliance occurs?

- Under HCSA, the licensee is ultimately responsible for safeguarding patient safety and welfare, and ensuring compliance with the Act and Regulations. The licensee is the default party that will be culpable for non-compliance with HCSA.
- However, if MOH investigates and determines that key officeholders such as the PO and CGO are also responsible for the non-compliance, MOH may also hold these other officeholders accountable. Their degree of culpability will depend on the specific facts of the case.
- Using the above example, the investigation will look into, among others, the nature of the non-compliance, and whether the licensee, PO and/or CGO are reasonably expected to identify and avoid or rectify the non-compliance based on their respective competencies, to ascertain their culpability.

Part IV Employees of licensees

10. What are the things a licensee should do to meet the requirements to ensure adequate supervision of employees?
• The licensee could have an organisation chart that clearly states the reporting line of every employee. • The licensee could also put in writing (e.g. Letter of Appointment) the responsibilities, duties and reporting line of each employee. • The licensee can have an appraisal system, which institutes systematic and regular review of the performance of the employees by the supervisors. Discussions during the appraisals should be documented. • The head of the group of employees or the supervisors may be held accountable if the employee's performance is not up to standard due to the lack of supervision.

Part V Committees appointed by licensees

11. Can I appoint a QAC for a service that is not listed in the HCSA General Regulations?
• Yes, the licensee can appoint a QAC for any service as deemed necessary to ensure quality and safety. • The requirements stipulated under HCSA for the respective committees would similarly apply when setting up such committees.
12. What is the definition of "clinical appropriateness" that a QAC is responsible for?
• Appropriateness of clinical care is determined by the extent to which the relevant and required clinical care plans and procedures are executed properly; patients are subject to healthcare resources and procedures based on evidence that such resources and procedures can help the patients subjected to them; and healthcare practices with proven benefits to patients are employed, as required.
13. Can I appoint medical practitioners who are not employed by the licensee as QAC members?
• Yes, the licensee can appoint non-employees who are assessed to be appropriate to be a QAC member.

14. How does a licensee ensure the QAC carries out its functions and duties when the members are appointed by the licensee and there may be conflict of interests?

- It is the QAC's duties and responsibilities to evaluate and monitor the quality, safety and clinical appropriateness of the licensable healthcare service provided by the licensee in a fair manner.
- The licensee must appoint a QAC supervisor, who may or may not be a member of the QAC, to oversee the QAC activities and ensure the QAC's duties and responsibilities are fulfilled.
- In case of a conflict of interest when a case being reviewed by the QAC involves a QAC member, the licensees should put in place processes to resolve the conflict of interest, and ensure transparency and fairness, including requiring the implicated person to recuse himself from the QAC review, and appoint another qualified person to take over that role in fulfilling the QAC obligations.

15. [Updated on 26 Jan 2021] What is the requirement of qualifications and competencies for the QAC Supervisor? Can a CGO be the QAC Supervisor?

- The licensee can also appoint a member of the QAC or an independent person as the QAC Supervisor. This can be the CGO, if the licensee deems it appropriate. The licensee should assess whether the person could effectively perform the role of a QAC Supervisor, taking into consideration his/her qualification, competencies and experience.

16. I'm a licensee of a service for which QAC is not mandated. Why do I need to participate in the QAC activities?

- A non-QAC licensee may be directed by the Director to participate in the QAC activities of a QAC licensee, or to provide information as requested by the Director. This will ensure an independent review of the clinical quality of the non-QAC licensee.

17. Why is it necessary to have both QAC and key officeholders such as KAH/PO/CGO?

- The appointment of key officeholders strengthens the governance of the licensee, and is applicable to all licensees. They ensure organisational processes of the licensee comply with all laws and regulations, including day-to-day operations and various aspects of the clinical services.
- On the other hand, QACs are set up to evaluate and monitor the quality and appropriateness of the healthcare services provided by the licensee, and are only required for prescribed licensees. QACs review incidents such as Serious Reportable Events (SREs) and recommend corrective actions.

- The requirements on key officeholders and the QAC complement each other to enhance patient safety.

18. Can key officeholders such as the KAH/PO/CGO take on concurrent appointments in the QAC?

- Yes, key officeholders can be appointed as members of the QAC.
- The QAC members are required to carry out their reviews impartially. If the QAC is reviewing incidents that involve any QAC members, the implicated member should recuse himself from the review. Under HCSA Section 40(6), if there are reasonable grounds to believe that a QAC member is not performing any function or discharging any duty in a proper or satisfactory manner, the DMS may direct the licensee to (a) remove or replace any member of that committee; (b) appoint one or more additional members to that committee; or (c) dissolve that committee and appoint another such committee in its place.

Part VI Licensed premises and licensed conveyances

19. Why is the licensee accountable for any misconduct/mistreatments by the co-located non-licensed healthcare service provider?

- The aim of the HCSA and its Regulations is to safeguard patient safety and welfare. Therefore, if licensees wish to have non-licensed services co-located within the same premises as licensed services, the licensee remains responsible for ensuring that patient safety and welfare are not compromised by any of these services.

Part VII Handling of medicinal products, health products and specimens

20. Whose responsibility is it if the specimen is compromised/destroyed during the transport? Licensee or the outsourced transportation provider (e.g. the courier)?

- Licensees should have protocols in place to ensure safe packaging, handling and transport of specimen.
- Licensees should also take steps to ensure there is no mix-up or contamination of the specimen, as well as proper labelling of the nature of the specimen to ensure public safety is not compromised.
- If the specimen is compromised/destroyed during transport, MOH will investigate and hold the licensee culpable if it has not complied with HCSA's requirements.

Part VIII Service standards

21.	**There are requirements for licensees to ensure patients are protected from abuse and negligent, but how can licensees protect their staff from being abused by patients/family members?**
•	Protection of staff is governed under the Protection from Harassment Act (POHA), and there is also recourse available under the Penal Code against the abusive patients/family members.
•	HCSA focuses on safeguarding the safety and welfare of patients, including protecting them from abuse and neglect.
22.	**What information must be given to patients to help them make an informed decision?**
•	Licensees must ensure that patients are adequately informed of their conditions and options for treatment, and also put in place systems to obtain the corresponding consent from patients thereafter.
•	These requirements complement existing requirements stipulated in the Directive on Consent Taking Practices for Procedures Performed by All Registered Medical Practitioners issued by MOH in 2016, as well as the guidelines on consent taking set out by the Ethical Code and Ethical Guidelines published by Singapore Medical Council (SMC ECEG).

Part IX Price transparency

23.	**How detailed do I need to be when displaying the "common charges" on the premises or websites? I may be providing many services, and there are too many to be displayed.**
•	Licensees should ensure price transparency by providing information on fees and charges to patients and/or their representatives. The purpose is to facilitate informed decision-making. Therefore, common charges (e.g. consultation) and fees of treatments/procedures that are relevant to a significant segment of patients of the service must be prominently displayed on the premises/conveyance or website.
•	MOH will provide further guidance on the details of common charges to be displayed in different services at a later date.
24.	**Am I required to always provide an itemised bill to patients?**
•	Licensees are required to provide a bill that itemises the charges minimally by the generic categories stipulated in the General Regulations.
•	Licensees that are able to generate a more detailed line item bill may also choose to do so, as appropriate.

25. Is financial counselling required for every service and visit?
• Financial counselling will be mandated for licensees providing selected licensable services which will be listed in General Regulations during their respective implementation phases (notwithstanding that, licensees of services not within the list may also carry out financial counselling if deemed appropriate.). • In general, the licensee should verify whether the patient is aware of the charges, and counsel or re-counsel the patient if the fee information is new to the patient. • Some examples of when financial counselling should be carried out: a. During the first visit or consultation for a particular care episode b. When the patient is advised on a treatment or procedure for the first time c. For longer-term care, when there is a change in fee or estimated charge range earlier counselled to the patient (e.g. the price of doctor's consultation or treatment has increased from $x to $y with effect from a certain date)
26. Am I expected to provide the historical and national price ranges for all my services and charge items?
• The provision of historical and national price ranges is mandated if they are published by MOH, such as on MOH's website for fee benchmarks and bill amount information for surgeon fees, inpatient bill sizes, and dental fees. • In such instances, licensees may include these published price ranges in the financial counselling process, e.g. by informing patient of the relevant diagnosis-related group (DRG) or table of surgical procedures (TOSP), or point their patient to the website where they can access the information.

Part X Infection control, incident management and emergency preparedness

27. [Updated on 22 Jan 2021] Why is vaccination against measles and diphtheria incorporated as requirements under HCSA? Will MOH be including other vaccination as requirement under HCSA?
• Measles and diphtheria are serious infectious diseases, and vaccinations against the two diseases are mandated under the Infectious Diseases Act for all children residing in Singapore. • There is a need to ensure high vaccination coverage or immunity among workers in healthcare, to minimise the risk of disease outbreak and spread of the diseases to patients, and other healthcare workers.

- The measles outbreaks in 2019 globally further point at the vulnerability of not being protected against the disease. It is important to ensure that all healthcare workers who are clinically eligible for the vaccines are protected against these serious infectious diseases through vaccination.
- There are currently no plans to include other vaccinations as a HCSA requirement.

28. [Updated on 22 Jan 2021] Can self-declaration of immunity or vaccination be accepted?

- No, self-declaration is not accepted as proof of immunity.
- For measles, acceptable evidence of immunity includes documented proof of vaccination (2 doses); or serological evidence of immunity; or laboratory confirmation of past infection.
- For diphtheria, acceptable evidence of immunity includes documented proof of vaccination with Tdap or Td in the last 10 years.

29. [Updated on 22 Jan 2021] We understand that there are exemptions for certain age groups to meet the requirement. Who is exempted/not exempted? Why are there exemptions?

- For the requirement on measles vaccination, all Singaporeans or Permanent Residents (PRs) born in Singapore before 1975 are exempted from the requirement.
- Serological studies had showed that there is high level of immunity (~100%) in these cohorts.
- There is no exemption for the diphtheria vaccination requirement.

30. [Updated on 22 Jan 2021] Why is the exemption (Singaporeans or PRs born before 1975 are exempted) not extended to foreigners?

- The immunity of these persons/groups of persons cannot be established a priori.

31. [Updated on 22 Jan 2021] On measles vaccination, for staff who have taken one dose, can they continue working while waiting to take the second dose?

- Yes, they can continue working while waiting for the second dose.
- The dose interval for the measles vaccine is 4 weeks, and staff who had commence work should take the 2nd dose based on the minimum dose interval.

32. [Updated on 22 Jan 2021] How can the licensees assess the exemption criteria?

- The intent is to ensure that all staff working within the licensees' premise or offsite in a patient are setting on behalf of the licensee are vaccinated/immune and are not conduit of spread of diseases to patients (and other healthcare workers) in the healthcare setting. Licensees that do not offer patient-facing services and

are not located within the premises of any healthcare institutions can be exempted from the requirement.

- At the individual level, staff who work offsite in non-patient care settings can be exempted from the requirement if they do not return to the healthcare institution premise.
- In addition, staff who are clinically not suitable for the vaccination are exempted from the requirement.

33. [Updated on 22 Jan 2021] How should persons who refuse the vaccinations be managed?

- Licensees should derive measures to ensure high vaccination coverage is maintained, in keeping with the intent of the HCSA requirements. For example, new potential hires should be informed of the requirement before confirming employment.
- MOH recognises that licensees may need some lead time to ensure all existing staff are immune and would allow for licensees to progressively increase the vaccination rates in these groups following the introduction of the requirements.

34. [Updated on 22 Jan 2021] Will this vaccination requirement among healthcare workers be extended to COVID-19 vaccination?

- For now, COVID-19 vaccination is voluntary for healthcare workers. However, healthcare workers are at high risk of exposure to the disease in their workplace. It is, therefore, important that they are protected from the disease, so that they can in turn protect their loved ones and their patients. Healthcare workers are therefore, strongly encouraged to be vaccinated.

35. [Updated on 3 Mar 2021] What is the timeline for licensees who are transiting to HCSA in the other Phases (i.e. Phases 2 and 3) to meet the measles and diphtheria vaccination requirements?

- MOH plans to introduce the vaccination requirements via the HCS General Regulations and PHMC LTCs, which are planned to be issued in June 2021. Licensees will be required to ensure their staff have undergone the measles and diphtheria vaccinations by 1 Sep 2021 unless they have been exempted.
- PHMC licensees will be subjected to the vaccination requirements through the PHMC LTCs until they transit to HCSA in their respective phases (e.g. Phase 2 for clinics and Phase 3 for hospitals), after which the HCS General Regulations will apply.

36.	**[Updated on 15 Mar 2021] We have outsourced partners and vendors, volunteers, who provide services in our premises with different frequency. For example, aircon serving are done quarterly, while couriers enter our premises either daily or weekly. Are the vaccination requirements applicable to such outsourced partners and vendors?**

- All staff, including those from outsourced partners/vendors, and volunteers, who regularly enters/work in the licensee's premise, will need to meet the vaccination requirement.
- This would include scheduled services, regardless of frequency, that the licensee engages (e.g. maintenance of equipment, infrastructure etc.)
- For those providing one-off service/visit (e.g. catering, event organiser), they are not required to meet the requirement.

37.	**[Updated on 15 Mar 2021] Will the staff be eligible for the National Adult Immunisation Schedule (NAIS) subsidy for the measles and diphtheria vaccination?**

- All Singapore Citizens (SCs) and Permanent Residents (PRs) who meet the criteria for vaccination under the NAIS are eligible for subsidies for nationally-recommended vaccinations. Under the NAIS, MMR vaccination is recommended for adults who have not been previously vaccinated, or lack evidence of past infection or immunity, while Tdap is recommended for pregnant women during 16-32 weeks of each pregnancy.

Part XI Miscellaneous

38.	**If my clinic specialises in treating a certain disease, can I include the disease in the name of my clinic? Do I need to apply for special permissions to do such?**

- Generally, the name must accurately reflect the service(s) that the licensee is licensed to provide. It should not contain terms that may misrepresent the licensee's capability, or purport to be a different specialty or licensable service.
- In the same vein, the name of the licensed service(s) should not include mention of disease conditions or treatments that the licensee is not qualified and/or competent to manage or provide. For example, at least one medical/dental practitioner working in that licensed service must be a specialist (certified by SAB or DSAB) for that disease condition or treatment, or the medical/dental practitioner is credentialed by a professional body to provide treatment for that disease condition, where they are mentioned in the licensed name.
- During the evaluation of licence applications, or if complaints are lodged against licensees with alleged inaccurate names, MOH can require licensees to furnish proof of their competency/credentials to provide treatment for that particular

disease condition. There is no need to specially apply for permission for naming of the service.

39. As businesses who have built brands around their names may lose brand equity, will there be grandfathering of existing providers with names that will not be approved under the HCSA?

- Existing licensees will be exempted and may continue to use their present name.
- However, this exemption will cease where there is a transfer of ownership or substantial change in the governing body (e.g. Board of Directors) of the licensee.

40. If I outsource a licensable healthcare service, do I need to ensure the facilities and equipment used by outsourced service providers meet the requirements? Who is responsible if the requirements are not met?

- Where the outsourced service is a licensable healthcare service, the contracted provider that the licensee engages must be a HCSA licensee holding a licence for that service. The contracted service provider is responsible for ensuring its facilities and equipment meet requirements under HCSA and its various Regulations.
- The licensee should also implement measures to ensure the outsourced service provider meet the requirements under HCSA, as the licensee retain overall oversight for any outsourced service and remain ultimately responsible for compliance with HCSA. This could be done via a formal contractual agreement which states clearly the obligations of the outsourced service provider. Licensees may also wish to consider random audits and checks by the on the facilities, equipment and services by the contracted service provider.
- In case of a breach, both licensee and the contracted provider (who is also a licensee) remain accountable, and degree of culpability will turn on the facts of each case.