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 I 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.

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. [Updated on 7 Jan 2022] 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 (e.g. Section Leader), although the overall responsibility and accountability for their duties and functions as stipulated in the regulations 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 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 or licensable service?

Yes, a person with suitable skills and competencies can be appointed as the CGO for several licensees or licensable services 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. [Updated on 7 Jan 2022] Can a licensee appoint multiple CGOs?

It is up to the licensee to decide whether to appoint one or more CGOs. A licensee may decide to appoint more than one CGO if a single CGO is not sufficient to fulfil the duties and responsibilities of the CGO role as stipulated in the General Regulations, and individual service regulations for the entire scope of services provided by the licensee. When multiple CGOs are appointed, the licensee must make clear the delineation of responsibilities amongst the CGOs.

10. [Updated on 7 Jan 2022] Can a licensee appoint an individual who is not employed by the licensee as the CGO?

Yes, the licensee can appoint non-employees who are assessed to be appropriate to be a CGO.

11. 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.

12. [Updated on 9 Jun 2021] Does the PO report to the licensee?

Under HCSA, the PO should be sufficiently empowered in his role to assist the licensee in ensuring operational compliance with the regulations, while remaining accountable to the licensee since the latter is ultimately responsible. The organisation can determine the reporting structure and arrangements that will allow this outcome to be best achieved.

13. [Updated on 7 Jan 2022] Can foreigners be licensee, PO, CGO or Section Leader?

There is no restriction under HCSA on the nationality of the licensee (if a natural person), PO, CGO or Section Leader. However, the licensee (if a natural person), PO, CGO or Section Leader must reside in Singapore in order to discharge their duties and functions effectively.

There is no residency requirement for KAHs, as long as they are able to fulfil their governance roles effectively.

Part II Employees of licensees

14. 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.

15. [Updated on 7 Jan 2022] Am I required to retain employment records of my employees?

Yes. Every licensee shall keep records of all personnel engaged in the management or provision of licensable healthcare services, with the following particulars: a) name, sex, date of birth, identification card or passport number and residential address; b) qualifications, professional registration (where available, including duration of validity) and duties; c) period of employment.

In addition, a licensee should be responsible for ensuring that the registrable healthcare professional has a valid practising certificate while serving in their professional capacity during his/her period of employment.

16. [Updated on 7 Jan 2022] Does HCSA stipulate the number of suitable personnel required for a licensable healthcare service?

Under HCSA, service-specific manpower standards and requirements (if any) are stipulated within the corresponding Service Regulation(s). The licensee is responsible for meeting these service-specific standards and requirements in the provision of the licensed service(s).

In addition to these service-specific standards and requirements, and as a general principle, the licensee is responsible for making the appropriate staffing decisions (e.g. staffing levels, skill-mix, deployment patterns) as are necessary to ensure the delivery of safe, effective, and good quality service, as part of a HCSA licence. This principle applies to all requisite personnel for the operationalisation of the licensable healthcare service(s), including personnel types that are not explicitly addressed within the Service Regulation(s).

Appropriate staffing decisions will vary from licensee to licensee, and will depend on factors including (but not limited to) each licensee's unique operational needs, service delivery model, as well as nature and quality of the healthcare service provided. In undertaking staffing decisions, licensees should exercise reasonable judgement, and consider service-wide interdependencies to ensure that staffing decisions remain relevant, responsive, and fit-for-purpose.

Licensees should consider the following good practice guidelines for implementing appropriate staffing decisions:

a. **Plan.** Develop a staffing plan to ensure that the right number of personnel with the right skillsets are deployed to the right place at the right time, to facilitate the delivery of safe, effective, and good quality service.

b. **Prepare.** Prepare contingency staffing arrangements and countermeasures (e.g. as part of the licensee's Business Continuity Planning) to support service continuity and minimise operational disruptions, in case of an unforeseen staffing shortage and/or inadequacy.

c. **Review.** Review staffing plans at regular timepoints (e.g. once every six months) and make adjustments in response to operational data and/or feedback on service outcomes and quality. In cases where a staffing shortage and/or inadequacy has occurred, or where concerns of such have been highlighted to the licensee (e.g. by staff, patient, member of public), the licensee should examine gaps in existing staffing plans and make the necessary improvements.

Part III Committees appointed by licensees

17. [Updated on 7 Jan 2022] Can I appoint a QAC for a service that is not listed in the HCSA General Regulations?
Yes, the licensee may appoint a QAC for a healthcare service that is not listed in the General Regulations, and take reference from the QAC requirements stipulated under HCSA, in the interests of ensuring quality and safety. However, please note that the protection from personal liability offered under HCSA section 55 is not applicable to such QACs, as the licensee is not legally required to set these up.
18. [Updated on 9 Jun 2021] Can a hospital have one hospital-level QAC to cover all QAC requirements for the various services provided by the hospital, including renal dialysis, nuclear medicine, day surgery, blood transfusion etc.?
Licensee can choose to have separate QACs (with different member compositions) for each service or have the same QAC cover all services. The licensee will need to ensure that the QAC(s) meet all the requirements for the various services and that the composition is appropriate for the areas covered.
19. [Updated on 9 Jun 2021] Do clinical laboratories offering laboratory genetic testing require at least one Mortality and Morbidity (M&M) QAC?
No, clinical laboratories offering genetic testing do not need M&M QAC at this juncture.
20. 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.
21. Can I appoint individuals 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.
22. [Updated on 9 Jun 2021] Must the QAC include external parties?
QACs are not required to have external members. In the 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.

23. 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.

24. [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.

25. [Updated on 7 Jan 2022] Can I appoint one QAC Supervisor to oversee multiple QACs?

Every QAC licensee must appoint, for each QAC appointed by the QAC licensee, a suitably qualified and competent QAC supervisor. However, licensee have the flexibility to appoint the same person as the QAC supervisor for multiple QACs, if the licensee has assessed that this person can effectively perform the role of a QAC Supervisor for all the QACs that he is appointed to supervise, taking into consideration his/her qualification, competencies and experience.

26. 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.

27. 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.

28. 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.

29. [Updated on 9 Jun 2021] If I operate a medical practice as a solo practitioner (e.g. private specialist), am I required to assemble a QAC for the healthcare service(s) I provide?

If you are not providing any licensable healthcare service(s) prescribed in the General Regulations that require a QAC, you are not required to establish a QAC. However, you may set up processes or engage qualified individuals to review the clinical quality of the service(s) provided.

However, if you are offering special licensable healthcare services that require a QAC, a QAC must be appointed as a pre-condition to offering these services, as this is deemed necessary to ensure quality and safety for patients. You are allowed to tap on relevant existing QACs. This can be appointed by the hospital involved in the patient's care, or by another licensee. Multiple services can be overseen by the same QAC if the members of the QAC are appropriate for the evaluation of the healthcare services under its purview.

30. [Updated on 7 Jan 2022] Can a cluster appoint an overarching QAC to oversee services provided by all the healthcare institutions across the cluster?

Each licensee that provides the prescribed licensable healthcare service is required to formally appoint a QAC for their own institution to discharge their duties under HCSA section 25.

If each healthcare institution under the cluster holds its own licence (i.e. is a s25 licensee), it is required to appoint a QAC for itself. Nevertheless, the same individual can sit in multiple QACs. This means that it is possible for multiple licensees to appoint the same members to their QACs. Most importantly, each licensee's QAC should discharge their duties in relation to each licensee e.g. the QAC should make findings/recommendations for each licensee's service.

However, if the cluster holds HCSA licences for all its healthcare institutions (i.e. the cluster is a s25 licensee), the cluster can appoint an overarching QAC, and the QAC can review matters that may be relevant to both the cluster and the healthcare institutions under the cluster, while enjoying protections afforded to the QAC for all these matters. However, there are broader governance issues (e.g. direct legal responsibility, appointment of key appointment holders, etc.) that the cluster needs to consider to determine if the cluster should hold one licence for all its healthcare institutions.

Part IV Licensed premises and licensed conveyances and equipment

31. [Updated on 7 Jan 2022] What services are allowed to be co-located with licensed services?

The following non-licensable healthcare services (stipulated in the Fourth Schedule of the General Regulations) can be co-located with a licensed service, without the need for specific approval from MOH:

Healthcare services provided by healthcare professionals registered under the following Acts:

- Nurses and Midwives Act
- Pharmacists Registration Act
- Optometrists and Opticians Act
- Traditional Chinese Medicine Practitioners Act (**only** acupuncture services)

Healthcare services provided by the Allied Health Professionals listed in the Second Schedule of the Allied Health Professions Act:

- Occupational Therapist / Ergotherapist

- Physiotherapist / Physical Therapist
- Speech Therapist / Speech Pathologist
- Radiation Therapist / Therapeutic Radiographer
- Radiographer / Diagnostic Radiographer / Radiologic Technologist

For any other non-licensable healthcare services not listed above, MOH's prior approval is required before they can be co-located with a licensed service.

32. [Updated on 7 Jan 2022] Do I need to seek approval for co-located retail shops?

Licensees are required to seek approval for any co-located non-licensable services not listed in the Fourth Schedule, including co-located retail shops.

Licensees licensed to operate residential facilities, such as hospitals, nursing homes and hospices, would be given standing approvals to provide certain retail and F&B services (e.g. florist, foodcourts). Once approved, the licensee does not need to seek approval again if the tenant is changed subsequently for the same retail service. However, if the type of retail service changes, the licensee would need to re-apply for approval from MOH (e.g. if a co-located coffee shop changes to a hairdresser).

For all other licensees not given a standing approval, the licensee will need to seek approval if the tenant or the type of retail service changes.

33. [Updated on 7 Jan 2022] Do I need to physically separate co-located non-licensable services from my licensed healthcare service?

For all co-located non-licensable services, regardless of whether they are categorically permitted to co-locate under the Fourth Schedule or require prior approval from MOH, we will impose conditions in the following instances:

(i) If the co-located non-licensable services only serve the licensee's patients, there is no need for physical separation, as the licensee is by default responsible for the safety of his patients in the provision of the non-licensable services that are co-located with the licensable healthcare service. If the co-located non-licensable services also serve their own walk-in patients or customers (i.e. not the licensee's patients and without going through the licensee), there is a need for:

(a) a clear physical separation (e.g. separate entrances and walls in between) of the non-licensable services from the licensable healthcare service, or

(b) a conspicuously displayed signage, or other means of communication to patients as agreed by the Director, stating that the co-located service is not licensed by MOH and a clearly documented delineation of responsibilities between the licensee and the party providing the non-licensable services (e.g. via means of a contract or written agreement).

(ii) For certain non-licensable services that are not complementary to holistic healthcare delivery e.g. chiropractic services, MOH will impose clear physical separation (same as stated in (i)(a) above) as an additional condition for co-location, to minimise the risk of patient misperception that the service is regulated by MOH. This applies regardless of whether these non-licensable services serve only the licensee's patients or not.

34. [Updated on 7 Jan 2022] Do advertisements for co-located services need to comply with HCS Advertisement Regulations?

Where an advertisement covers both the licensable healthcare service and co-located non-licensable service, the licensee is responsible in ensuring compliance with the HCS Advertisement Regulations for the entire advertisement.

If the advertisement only pertains to the co-located non-licensable service, it is not subject to the HCS Advertisement Regulations. However, the advertisement must state clearly that this is a non-licensable service co-located in a licensed premises.

Part V Handling of medicinal products, health products and specimens

35. 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.

36. [Updated on 7 Jan 2022] Are medical practitioners required to record the specified dose prescribed to patients?

As required by both the HCSA General Regulations and the Health Products Regulations 2016, medical practitioners should record details including the product name, amount supplied and dose instructions to patients to ensure that the appropriate dose has been prescribed and dispensed or administered to the correct individual. Patient's medication records should contain adequate, accurate and relevant information to ensure clear documentation, and safe and appropriate use of the product by the patient.

Any pertinent information in relation to the supply of medications to patients should be recorded accordingly (e.g. drug allergies, G6PD deficiency, medication history, dietary information).

37. [Updated on 7 Jan 2022] What should a licensee do if he/she intends to provide medication delivery services to patients?

Licensees who provide medication delivery services to patients should ensure their compliance with legal and professional requirements, as well as refer to the Singapore Standards on Supply and Delivery of Medication (SS 664) to ensure the proper storage, security and traceability of medication during the delivery process.

Part VI Service standards

38. 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.

39. 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).

40. [Updated on 7 Jan 2022] What "reasonable measures" should be taken to ensure continuity of care of affected patients in the event of cessation of service / transfer of care?

Some examples of "reasonable measures" could include contacting every affected patient within a reasonable period prior to cessation of service, putting up a notice on the website or at the clinic, or arranging transfer of care to another appropriate licensee (in such cases, the patient's acknowledgement should be obtained).

Licensees may wish to seek legal advice pertaining to the handling of patient health records (e.g. if patient is uncontactable).

Part VII Price transparency

41. [Updated on 7 Jan 2022] 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.

As a good practice, licensees that have the system capabilities to provide summary bills upon request are encouraged to retain these capabilities to address any concerns of patient confidentiality (e.g. where bills are used for reimbursement claims from employers).

Part VIII Infection control, incident management and emergency preparedness

42. [Updated on 7 Jan 2022] Why is vaccination against measles and diphtheria incorporated as a requirement under the Private Hospitals and Medical Clinics Act (PHMCA) and Healthcare Services Act (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 highlight 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 up-to-date vaccinations.

43. [Updated on 7 Jan 2022] 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 is: (i) documented proof of completion of a course of vaccination involving 2 doses of a measles (or measles-containing) vaccine given at least 4 weeks apart; (ii) serological evidence of immunity; or (iii) laboratory confirmation of past infection.

For diphtheria, acceptable evidence of immunity is documented proof of vaccination with tetanus toxoid, reduced diphtheria toxoid and acellular pertussis ("Tdap") or tetanus and diphtheria toxoids ("Td") which (1) reflects vaccination on or after 3 January 2012, and (2) is not Expired. Documented proof of vaccination is regarded as Expired after 10 years from the date of vaccination with a dose of Tdap or Td.

44. [Updated on 7 Jan 2022] We understand that there are exemptions whereby certain age groups need not be vaccinated. Who is exempted/not exempted? Why are there such age-group exemptions?

Healthcare workers who do not have evidence of immunity against measles will have to be vaccinated against measles. The only exception is if they are Singaporeans or Permanent Residents (PRs) born in Singapore before 1 January 1975. Serological studies have shown that there is a high level of immunity against measles (~100%) in these cohorts.

There is no age-group exemption for the diphtheria vaccination requirement. All workers in healthcare who do not have evidence of immunity against diphtheria will have to be vaccinated against diphtheria.

45. [Updated on 7 Jan 2022] Why is the age-group exemption (Singaporeans or PRs born before 1975 are exempted) not extended to foreigners or Singaporeans or PRs not born in Singapore?

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

46. [Updated on 7 Jan 2022] I am an SC/PR born in Singapore before 1975 and should be exempted from the measles immunity requirement. However, my institution/clinic insists that I should be vaccinated against measles or provide documentary proof that I am immune. Why is this so?

While SC/PR born in Singapore before 1975 are exempted from the measles immunity requirement, licensees may put in place additional appropriate measures based on their risk assessment to ensure that there is no risk of spreading the disease.

47. [Updated on 7 Jan 2022] On measles vaccination, for personnel 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 at least 4 weeks. Personnel who have taken one dose should take the second dose 4 weeks after the first dose.

In the event that they fail to take a second dose, they will not fulfil the immunity requirement. Licensees should therefore ensure that personnel who have taken one dose take the next dose as soon as possible, once the minimum dose interval of 4 weeks has elapsed.

48. [Updated on 7 Jan 2022] How can the licensees assess whether the exemption criteria are met?

As a first step, licensees should review the records of personnel who are employed or engaged by them, or volunteer with them, to ascertain if they fall within the scope of any of the exemptions in the licensing conditions.

In respect of other personnel that are not employed or engaged by them, or who do not volunteer with them (such as external vendors), licensees should take appropriate steps to satisfy themselves that the exemption criteria are met. For example, one possibility would be for the licensees to include the immunity requirements and requirements for proof in relation to exemptions in their contracts with vendors. Licensees may also wish to establish an agreement with the vendors to allow licensees to access relevant records of immunity of such personnel upon request.

The intent behind the immunity requirements is to ensure that personnel are not a conduit of spread of diseases to patients (and healthcare workers) in the healthcare setting. Personnel whose work does not involve direct interaction with patients **and** who do not work within any premises of a healthcare institution which provides services that involve direct interaction with patients do not have to meet the immunity requirement. To illustrate, personnel who work in a testing laboratory would not have to meet the immunity requirements, if the laboratory is not located within the physical site of a healthcare institution which provides services involving direct interaction with patients (such as hospitals and clinics). If, however, the laboratory is located within the physical site of such a healthcare institution, it would be considered to be within its premises, and the immunity requirement would apply for the laboratory's personnel.

In addition, personnel who are clinically not suitable for the vaccination (i.e. they have been certified permanently medically unfit for vaccination) also do not have to meet the immunity requirement.

49. [Updated on 7 Jan 2022] How should persons who refuse the vaccinations be managed?

Licensees should implement appropriate measures to ensure that high vaccination coverage is maintained, in keeping with the intent of the requirements. For example, licensees may require new hires to comply with immunity requirements imposed by these licensing conditions as part of their employment contracts.

Licensees should also proactively encourage existing personnel who do not have acceptable evidence of immunity to be vaccinated. For example, for older personnel who may be concerned about vaccine side-effects, a vaccinated individual of around the same profile could be asked to provide reassurance. For personnel who decline vaccination, the licensee may consider redeploying such personnel to settings which do not involve direct interaction with patients (in the

interests of patient safety), while continuing to engage such personnel on their concerns and encouraging them to be vaccinated.

50. [Updated on 7 Jan 2022] Will this vaccination requirement among healthcare workers be extended to COVID-19 vaccination?

COVID-19 vaccination is currently voluntary for healthcare workers. However, healthcare workers are at high risk of exposure to the disease in their workplaces. 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.

51. [Updated on 7 Jan 2022] 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 on 3 January 2022. Licensees will be required to ensure their staff have undergone the measles and diphtheria vaccinations by 3 January 2022 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.

52. [Updated on 7 Jan 2022] We have outsourced partners and vendors, volunteers, who provide services in our premises at various frequencies. For example, air conditioner servicing is done quarterly, while couriers enter our premises either daily or weekly. Are the vaccination requirements applicable to such volunteers, outsourced partners and vendors?

Personnel from outsourced partners/vendors, and volunteers will need to be vaccinated if they do not fall within the scope of the exemptions in the licensing conditions, and do not have acceptable evidence of immunity.

This applies to all personnel of partners and vendors which provide services (e.g. maintenance of equipment, infrastructure, couriers etc.) as well as volunteers, regardless of frequency of such services, except where such partners, vendors and volunteers provide services or volunteer on **only a one-off basis** (for example, providing catering services for, or organising a one-off event).

Licensees should ensure that they put in place measures to ensure that they comply with their obligations to ensure that personnel of outsourced partners/vendors as well as volunteers have, or acquire the required immunity under the licensing conditions. These may include, for example, stipulating the requirements for immunity and vaccination in their contractual agreements with such partners and vendors.

53. [Updated on 7 Jan 2022] If we have a contract with an outsourced agency/volunteering agency to require agency to ensure immunity of personnel employed/engaged by it and maintain up-to-date records, but the agency does not do so, who is responsible?

For personnel who are employed/engaged by external providers, the licensee is only required to maintain records of the arrangement made between licensee and the external provider to ensure that the staff of the external provider meet the immunity requirements (for example, records of the contracts with the external provider which stipulate the immunity requirements). The onus is on the external provider to ensure their staff meet the immunity requirements.

54. [Updated on 7 Jan 2022] If vaccination is needed, are the vaccinations subsidised by MOH? If not, will the personnel be eligible for the National Adult Immunisation Schedule (NAIS) subsidy for the measles and diphtheria vaccination?

All Singapore Citizens (SCs) and Permanent Residents (PRs) for whom vaccination is recommended under the NAIS are eligible for subsidies for the relevant vaccinations. Under the NAIS, measles vaccination (as part of the Measles Mumps and Rubella vaccine) 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. Licensees may also further subsidise the remaining cost of vaccinations for personnel, at their discretion.

55. [Updated on 7 Jan 2022] After proof of immunity has been obtained, do we need to submit the supporting documents (e.g. vaccination records) to MOH?

Licensees are not required to submit the documents to MOH. However, licensees should keep such records minimally for the period specified in the licensing conditions. Such records may be subject to inspection and audit by MOH.

For personnel who are not employed or engaged by the licensee or volunteer with the licensee, licensees may consider establishing an agreement with the vendors to ensure that licensees are able to access such records upon request. Examples of such personnel include personnel employed or engaged by outsourced vendors and partners or vendors co-located with the licensee.

56. [Updated on 7 Jan 2022] I am a doctor. Can I vaccinate myself, or certify myself as being medically unfit for vaccination?

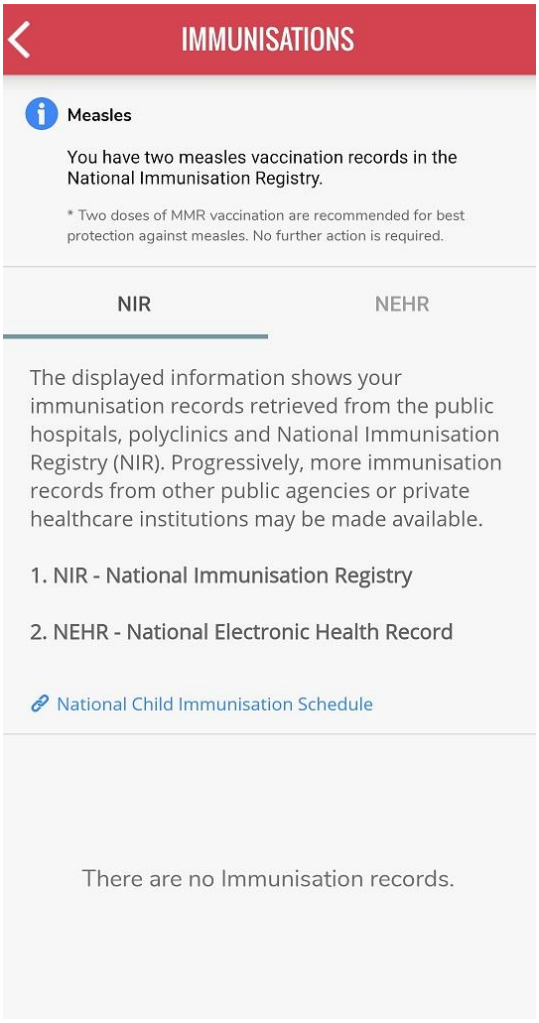
It is not recommended that doctors vaccinate themselves, or certify themselves as medically unfit for vaccination. For the purposes of proper and objective verification, and to avoid conflicts of interest, an appropriately trained third party should perform and document the vaccination, or certify medical unfitness for vaccination.

57. [Updated on 7 Jan 2022] Where can I retrieve past vaccination records, if available?

Singaporeans who are born in 1996 and after can access their past vaccination records via HealthHub with their SingPass.

Singaporeans born before 1996 will be able to access their vaccination records via HealthHub for vaccinations under the National Adult Immunisation Schedule, taken on or after 1 Nov 2017.

Some Singaporeans born before 1996 may also have records of the measles vaccination administered before 1 Nov 2017 shown in HealthHub. An example of such a record, which will be acceptable as proof of vaccination, is shown in the screenshot attached.



Persons whose records are not available in HealthHub may request for the proof of immunity from the healthcare providers where they had received the vaccination or, in the case of measles only, where they were diagnosed.

For measles, persons may as an alternative undergo a serology test to check for immunity, or obtain laboratory confirmation of past measles infection. If the result of their serology test is negative and/or they are unable to obtain laboratory

confirmation of past measles infection, they will need to receive the necessary vaccination. For diphtheria, as serology testing is not readily available, the only acceptable evidence of immunity is vaccination with Tdap or Td which (1) reflects vaccination on or after 3 January 2022, and (2) is not Expired. Documented proof of vaccination is regarded as Expired after 10 years from the date of vaccination with a dose of Tdap or Td.

58. [Updated on 7 Jan 2022] How long is the validity period of serological test for measles?

There is no upper time limit to the validity of positive measles serology test. Immunity following vaccination persists for decades and the protection is thought to be life-long. The same applies to immunity against measles following natural infection.

Part IX Miscellaneous

59. 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.

60. [Updated on 9 Jun 2021] Is the term “aesthetic” allowed for use in a clinic name?

The business name for the licensed service should accurately reflect the services it is licensed to provide as well as its capabilities, and not be misleading. As such, the term “aesthetic” is allowed where it accurately reflects the services provided at the clinic.

Additionally, a recognised specialty may only be reflected in the business name if there is at least one specialist for that specialty registered by SMC or SDC. This specialist must be actively practising in the clinic.

61. 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.

62. [Updated on 9 Jun 2021] Do we have to change our clinic names which may be deemed inappropriate under the new HCSA?

Existing licensees are grandfathered and may continue to use their present names until there is a change in their licence, such as where there is a transfer of ownership, a substantial change in the governing body (e.g. ≥ 50% of the Board of Directors) of the licensee, or the name of the business or institution.

63. [Updated on 7 Jan 2022] If we provide multiple services under HCSA, am I required to use different business names to reflect the respective services?

HCSA does not stipulate that licensees must use different business names for different licensed services (i.e. one business name can be used for multiple services if the licensee so wishes), as long as the business name used for the service accurately reflects the licensed service and is in compliance with HCSA section 29.

64. [Updated on 7 Jan 2022] What does a licensee need to do to comply with business continuity requirements?

A licensee must maintain business continuity at all times, on top of having business continuity plans (BCPs).

During service disruption, the actual actions that the licensee needs to take to maintain business continuity will depend on the situation. As the situation may or may not have been planned for in the BCP, or the interventions planned for such a scenario may not be completely suited for the actual situation, our intent is not to bind the licensees to strictly or only implementing what was covered in the BCP.

Should a licensee fail to maintain business continuity in practice, and this presents potential or actual harm to patient safety or welfare, the licensee would be liable for the non-compliance, even if the licensee had developed a BCP.

65. [Updated on 9 Jun 2021] How detailed must the business continuity plans (BCP) be?

Given that the risk and impact of disruptions, and the corresponding need for business continuity plans vary based on the business structure, size and services involved, the regulations are not intended to prescribe exactly what licensees should do in developing such plans.

Rather, they are intended as a general obligation for licensees to think about the actions to be taken in case of service disruption, which may again vary depending on the services involved. For instance, in dealing with a power failure, clinics may decide to stop operating, whereas acute hospitals may require the procurement and activation of back-up power sources.

Generally, where the licensee decides to continue with the service, the licensee should consider what needs to be in place for the service to continue despite the disruptions in question.

Compliance with the BCP requirements will be checked as part of the inspection process. While large and complex set-ups (e.g. acute and community hospitals, nursing homes, clinic chains, laboratories) should have documented BCPs, smaller set-ups (e.g. those involving solo practitioners) may not need to do so. Regardless of the need for documentation, licensees must be clear on the actions to be taken in case of service disruption, to ensure continuity of care for the patients.

66. [Updated on 7 Jan 2022] What does a licensee need to include in the plan of action as part of Business Continuity Planning (BCP)?

As guidance, a licensee can consider including the following plans as part of the plan of action:

a. A service continuity plan;

b. A plan to transfer the patient health records of the licensee's patients to another licensee;

c. A plan for alternative manpower arrangements in the event that the licensee's employees who are involved in delivering clinical services are unable to continue doing so;

A licensee should also develop a risk management plan identifying the risks specific to the licensable healthcare service that the licensee is authorised to provide, and set out the risk mitigation processes and requisite audits.

67. 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 clearly states the obligations of the outsourced service provider. Licensees may also wish to consider random audits and checks 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.

For completeness, outsourced services cannot be contracted to foreign providers unless expressly permitted under the Service Regulations.

68. [Updated on 9 Jun 2021] Is sending genetic testing panels to an overseas accredited laboratory considered outsourcing?

Yes, that is considered outsourcing. There will be provisions stipulated in the service regulations to allow outsourcing to overseas labs. The overseas labs must be accredited by the list of accreditation authorities that MOH accepts.