Updated as at 19 Jan 2024

Healthcare Services (General) Regulations FAQ

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General

1. When did the new requirements under the General Regulations take effect?
• The new requirements under General Regulations took effect on 18 December 2023.
2. Are the requirements under HCSA and its subsidiary legislations applicable to local licensees who provide healthcare services overseas?
• HCSA applies to local or foreign entities providing licensable healthcare services in Singapore. HCSA does not have extra-territorial reach. Local entities providing licensable healthcare services overseas are reminded to comply with the legislations in the foreign country. • Similarly, the provision of licensable healthcare services by foreign entities to local patients who travel overseas will also be outside the jurisdiction of HCSA.

Part I Governance of Licensees

3. 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.
4. Under Section 3 of the Code of Practice, which tier do the following Accounting and Corporate Regulatory Authority (ACRA)-registered HCSA Licensees that are non-foreign companies fall under: **i. an exempt private company limited by shares;** **ii. a private company limited by shares;** **iii. a limited liability partnerships;** **iv. an exempt charity that is an Institution of Public Character ("IPC"); or** **v. a public company limited by guarantee**
For (i) An exempt private company limited by shares and (ii) a private company limited by shares: • HCSA Licensees which are registered as an exempt private company limited by shares or a private company limited by shares may still fall under the **Basic Tier**, if it is (a) a small company that is exempt from the audit requirements under Section 205C of the Companies Act 1967, or (b) a company which is

not a small company exempt from audit requirements under Section 205C of the Companies Act 1967, that has only one Board Director.

- However, such licensees will fall under the **Enhanced Tier** if they do not satisfy the requirements listed in (a) or (b) above.

For (iii) a limited liability partnership:

- A limited liability partnership is a form of partnership, hence HCSA licensees registered as a limited liability partnership falls under **the Basic Tier**. However, if there is one or more of the registered partners of the HCSA licensee is / are an entity that falls under the Enhanced Tier, the HCSA Licensee will fall under the **Enhanced Tier.**

For (iv) an exempt charity that is an Institution of Public Character (IPC):

- HCSA Licensees which are registered as an exempt charity that is an IPC falls under the **Basic Tier**, as it is a charity.

For (v) a public company limited by guarantee:

- HCSA Licensees which are registered as a public company limited by guarantee will fall under the **Basic Tier**, as a public company limited by guarantee is a type of company limited by guarantee.

5. 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 "clinic manager" under the PHMCA. The PO provides oversight to the 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.

6. What is considered a "suitable person" in terms of who can be a licensee, PO, CGO and key appointment holder?

- For the purposes of determining whether or not a person is a suitable person under HCSA, the following are considered:
  - Any evidence that the person is an undischarged bankrupt; Any prior conviction of offences under the HCSA, PHMCA or any applicable act, as well as offences involving fraud and dishonesty and offences specified in the Third Schedule of the Registration of Criminals Act 1949;
  - Any evidence of the cancellation, removal or suspension of the person's registration under any applicable act;
  - Any evidence of the revocation or suspension of any license granted to the person under HCSA or PHMCA.
- You may refer to further guidance on the suitability requirements for each of these roles in the Code of Practice found here.

7. Do KAHs have a duty to be involved in the 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.

8. 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.

9. 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.

- In the event of a breach, investigations will be conducted against the licensee. Depending on the facts of each case, KAHs may also be subjected to investigations.

10. 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 since 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.

11. Why are there no specific requirements for a Principal Officer to be a medical doctor? If the Principal Officer is not a medical doctor, who will be held responsible for medical decisions?

- The Principal Officer (PO) is an individual who is involved in the day-to-day management of the provision of the licensable healthcare service provided. The PO has to have the organisational position and influence to assist the licensee to ensure compliance to the Act e.g., a hospital CEO or COO or Chief Compliance Officer.
- For the intent and purposes of the Act, the PO is the authorised person to represent the licensee in the provision of the licensable healthcare service.
- There will be safeguards to ensure appropriate medical decision are made. For example, MOH will require that POs act on the medical opinions and recommendations surfaced to them by their CGOs, designated medical advisors or healthcare professionals in the area of patient safety, welfare and continuity of care.
- At the same time, licensees are expected to empower clinical staff to carry out their duties in accordance with safety standards and ethical codes they are required to abide.

12. Why are licensees required to seek approval from MOH for the appointment of a CGO, but not for a PO?

- Unlike the PO, the CGO needs to fulfil specific requirements for competencies and qualifications in order to be deemed as a suitable individual to discharge the CGO's roles and responsibilities. Hence, checking these requirements upfront provides greater assurance that the appointed individual is able to effectively perform the role of the CGO.

13. Can one person be appointed as the CGO for more than one licensee or licensable healthcare 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, licensees should take into consideration their bandwidth and capacity as part of assessing their suitability and ability for the role.

14. Can the licensee, PO and CGO be the same individual?

- Yes, as long as the individual can concurrently take on the role of the licensee, PO and CGO, and can fulfil all relevant prescribed requirements.
- The appointed individual also has to have the management bandwidth for these roles as he will be held accountable for these roles.

15. Why is there a need for a CGO in addition to a PO?

- A CGO is required to provide adequate clinical and technical oversight of services that are more complex and technical in nature.
- The CGO must possess the necessary specialised qualifications to carry out his or her role.

16. With the new requirements for CGO, what happens to licensees who do not have personnel that can fulfil the stipulated qualifications?

- The provider will have to engage a person who has the necessary skills and competency to act as the CGO. This can be done by either hiring a new CGO or entering into contractual arrangements with an independent contractor (e.g., one who belongs to another licensee).
- The requirements are essential to ensure competent, effective, and consistent clinical or technical governance over complex clinical services.
- Going forward, MOH will continue to engage the healthcare industry to ensure qualification requirements for CGOs are appropriate.

17. 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.

18. 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.

19. What should a licensee do in the event of an unexpected demise of a CGO?

- In the event of an unexpected demise of a CGO, a licensee must appoint the new CGO within 20 calendar days after the previous CGO has left. This period is inclusive of the application period to seek MOH's approval for the CGO appointment.

20. In the event of an unexpected demise or sudden departure of a CGO, can the licensee still operate while awaiting the appointment of the new CGO?

- Licensees must not operate their services without a suitable CGO actively employed by the licensee.
- In the event of an unexpected demise or sudden departure of a CGO, licensees must appoint a new CGO within 20 calendar days after the previous CGO has left.
- To avoid any situation where there is no CGO overseeing the clinical service, it is recommended for licensees to nominate another individual as a "back up" CGO who would take over the role of the CGO in the event of sudden death or departure. Licensees need not notify MOH of this "back up" CGO.

21. 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 its Regulations. The licensee will be investigated in the event of any non-compliance with HCSA.
- However, if MOH determines that key officeholders such as the PO and CGO are also responsible for the non-compliance, MOH may also hold these officeholders accountable. Their degree of culpability will depend on the specific facts borne out of investigations.

22. 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. The organisation can determine the reporting structure and arrangements that will allow this outcome to be best achieved.

23. Is there a reporting hierarchy for the various Key Office Holders (i.e., KAH, CGO and PO)?

- MOH does not stipulate the hierarchy of the various Key Office Holders. Each organisation can determine the reporting structure and arrangements.
- However, in practice, as the KAHs are usually the Board of Directors, they are usually on the same level of the licensee. The PO and CGO often tend to be the Chief Executive Officer or the Chief Medical Board of the licensee and therefore might need to report to the KAH or the licensee.

24. Can foreigners be a 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.

25. What will the degree of accountability be for licensee, PO and CGO in the event of a mishap?

- The degree of culpability of the licensee, PO and CGO would be assessed based on the specific facts borne out of investigations.
- If there is proof that the licensee had carried out his functions diligently and the non-compliance is traced to the PO or CGO, the PO or CGO will be taken to task.

26. Who will be held accountable if the licensee is a company?

- In the event of a non-compliance, actions may be taken against the licensee (natural person or company), depending on the specific facts borne out of investigations.
- Investigations will be conducted and if the contravention, be it connivance, negligence, or by conspiring with others, is traced back to a responsible party from the management, Board, PO or CGO, Chief Executive, manager, or similar officer or any person purported to act in such capacity, both the individual and the licensee can be prosecuted. This principle is no different from the PHMCA.

27. Does the HCSA allow MOH to take action against all key appointment holders in the event of a serious lapse of governance controls e.g., a Hepatitis C outbreak? Under the HCSA, what will be the added governance for action against personnel responsible to prevent the recurrence of serious incidents?

- The licensee is accountable and responsible for overall compliance to the HCSA. The licensee cannot delegate accountability and responsibility to the PO or CGO.
- In the event of a serious incident, investigations will be conducted to determine the facts and circumstances of the incident.
- Depending on the facts disclosed in the investigations, the Key Office holders (such as KAHs, PO or CGO) may be taken to task if there is sufficient evidence to support that the breach of the Act or Regulations is caused by their actions.
- MOH also has the power to require licensees to remove key office holders if they are found to be unsuitable persons or lack the necessary skills and competencies to perform their stipulated roles.

Part II Employees of licensees

28. What are the things a licensee should do to meet the requirements to ensure adequate supervision of employees?

- The licensee can have an organisation chart that clearly states the reporting line of every employee.
- The licensee can 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 did not meet the required standards due to the lack of supervision.

29. Are licensees required to retain employment records of their 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 is 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.

30. 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

31. Can licensees 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, the protection from personal liability offered under Section 55 of the HCSA is not applicable to such QACs, as the licensee is not legally required to set these up.

32. 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.

33. 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.

34. 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; and healthcare practices with proven benefits to patients are employed, as required.

35. Can licensees 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.

36. 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.

37. 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.

38. 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.

39. Can licensees 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.

40. 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.

41. 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.

42. 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.

43. 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.

44. 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 Section 25 of the HCSA.
- If each healthcare institution under the cluster holds its own licence (i.e., is a Section 25 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 Section 25 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 determining if the cluster should hold one licence for all its healthcare institutions.

45. As a licensee of an outpatient medical service which is not wholly owned or managed by the government or government holding company, or publicly funded, am I required to establish a Serious Reportable Events – Quality Assurance Committee (SRE QAC) and submit SRE reports to MOH?

- While OMS which are not wholly owned or managed by government or government holding company, or publicly funded, are not mandated to establish a SRE QAC, all licensees of OMS are strongly encouraged to set up processes/systems to identify, review and report SREs, and establish an SRE QAC. The processes/systems should aim to detect and collect information on SREs that occur within the licensed premises and the established SRE QACs should monitor, evaluate, and review the SREs for learning and improvement. References for the establishment of SRE QACs and related processes may be taken from the Licensing Conditions on Review of Serious Reportable Events.

46. What is the difference in function between QACs and SRCs? Can the same individuals be part of both a SRC and QAC?

- The function of a QAC is to monitor the quality of care of the service provided, while the function of a SRC is to monitor the provision of certain services to ensure that their utilisation is appropriate and to monitor patient outcomes in the utilisation of the new service.
- The same individuals can be part of both a SRC and QAC.

47. What is the criteria in deciding whether some programmes /services require SRC's review?

- Programmes/services that require SRC review are generally those that are deemed as higher-risk, more complex or of greater public interest to ensure appropriate usage and better safeguard patient welfare.
- The list of programmes/services that require SRC's review currently include:
  1) Proton Beam Therapy
  2) Collaborative Prescribing

48. What is the purpose of Clinical Ethics Committees (CECs)?

- CECs are established to assist licensees and the doctor to provide ethical care and treatment of patients for a list of prescribed medical treatments, in the Third Schedule of the Healthcare Services (General) Regulations 2021.
- These cases require CEC review due to the complex nature of the treatment/procedure and ethical concerns which may arise, as societal values may be undermined and/or the values of the medical practitioners may be challenged.
- These requirements are not entirely new as there was a prescribed list under the PHMCA, although the list has been expanded under the HCSA. The prescribed list was determined with inputs sought from ethics experts.
- Licensees or healthcare practitioners cannot proceed with any treatment or procedure if the CEC is of the view that a treatment or procedure is unethical. Penalties will be imposed for non-compliance.

49. What is the criteria in deciding whether some treatments require Clinical Ethics Committee (CEC)'s review?

- Treatments that involve controversial ethical issues would require ethics review by the CEC to ensure the treatment is ethically appropriate and the patient receives ethical care.
- The list of treatments that require CEC's review currently include:
  1) Surgical separation of conjoint twins
  2) Psychosurgery
  3) Treatment for sexual sterilisation on an unmarried person with mental capacity and below the age of 21.
  4) Reproductive organ transplant

5) Gender reassignment surgery

6) Deep brain stimulation for any indication other than Parkinson's disease, dystonia, essential tremor and epilepsy

7) Transcranial direct current stimulation

8) Preimplantation genetic diagnosis (PGD) with Human Leukocyte Antigen typing for the creation of saviour siblings

9) Testicular biopsy and testicular tissue freezing, if proposed to be performed on an individual who –

(a) has not experienced the onset of puberty and has been diagnosed with any medical condition that required gonadotoxic therapy; or

(b) who has Klinefelter syndrome

10) Transfer of an inter-generational gamete or embryo for assisted reproduction procedures

11) Any treatment for a medical condition that involves the use of a cell, tissue, gene therapy product –

(a) that is manufactured by a licensee; and

(b) in respect of such use has not been accepted by a respectable body of medical opinion as conventional treatment for the medical condition.

12) Pre-implantation genetic diagnosis with human leukocyte antigen typing for the creation of saviour siblings.

Part IV Licensed premises and licensed conveyances and equipment

50. Do licensees need to seek approval for co-located retail shops?

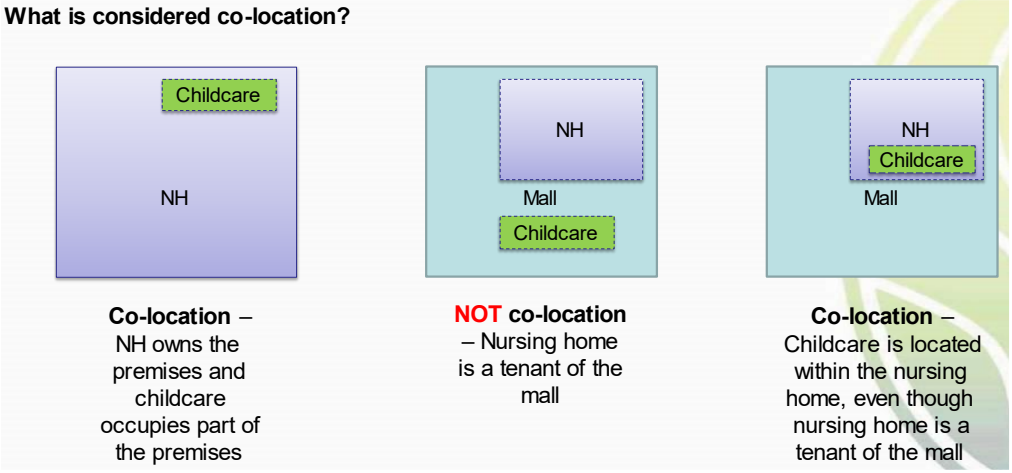
- Licensees are required to seek approval for any co-located non-licensable services not listed in the Fourth Schedule, including co-located retail shops. Licensees licensed to operate residential facilities, such as hospitals, nursing homes and hospices, would be given standing approvals to provide certain retail and F&B services (e.g., florist, food courts). 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.

51. Is sharing the same building, but operating in separate units from external vendors considered co-location? Would sharing the premises with another licensee be considered co-location?

- It is considered co-location if the external vendor is a non-licensable healthcare service (e.g., Childcare Centre) operating within the licensed premises of a licensable healthcare service (e.g., Nursing Home). The

licensed premises is the address stated on the licence of the licensable healthcare service.

- If the services are sharing a space that does not belong to any licensable healthcare service (e.g., licensee and external vendor are located in different units of the same building), it is not considered co-location.
- You may refer to the graphic below for further clarification on the co-location requirements:



- In the situation where the external vendor is a licensable healthcare service operating within the premises of another licensable healthcare service (e.g., a radiological service licensee operating in a Nursing Home (NH)), this is not considered co-location as this is simply two licensees sharing the same location.

52. 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.

53. Do advertisements for co-located services need to comply with the Healthcare Services (Advertisement) Regulations 2021?

- Where an advertisement covers both the licensable healthcare service and co-located non-licensable service, the licensee is responsible in ensuring compliance with the Healthcare Services (Advertisement) Regulations 2021 for the entire advertisement.
- If the advertisement only pertains to the co-located non-licensable service, it is not subject to these Regulations. However, the advertisement must state clearly that it is a non-licensable service co-located in a licensed premise.

54. Do licensees need to comply with co-location requirements for the services delivered through "Temporary Premises" or "Remote" MOSD?

- The concept of co-location only applies to Permanent Premises and Conveyance MOSDs. Hence, there is no need to comply with co-location requirements for services provided through Temporary or Remote MOSDs.

55. If the medical practitioner or dentist is also a licensed Traditional Chinese Medicine (TCM) practitioner, can TCM services be offered in the same medical/dental clinic?

- If the medical practitioner or dentist is also a licensed TCM practitioner, they are allowed to provide only acupuncture services (as defined in Section 2 of the Traditional Chinese Medicine Practitioners Act 2000) for their patients in the same medical/dental clinic without the need for specific approval from MOH. The non-licensable healthcare services that can be co-located with a licensed service are stipulated in the Fourth Schedule of the General Regulations. For all other services, MOH's prior approval is required before they can be co-located with a licensed service.

56. Are doctors allowed to provide mainstream medicine and complementary and alternative medicine (CAM) services in the same premises?

- The intent of the co-location requirement is to prevent the public from being misled that the unlicensed service is being regulated within a co-located space when it is not.
- While SMC's Ethical Code and Ethical Guidelines (ECEG) (section B6) requires doctors to treat patients only according to generally accepted methods, based on a balance of available evidence and accepted best practices, it does not restrict doctors from practising CAM, provided that it is

practised in an ethical manner and only those modalities specifically approved by SMC i.e., needle acupuncture (section B9 of ECEG).

- Doctors who wish to provide SMC-approved CAM modalities within the same licensed premises should write in to MOH for approval.
- In deciding whether to grant an approval for non-licensed services to be provided within the same licensed premises, factors that will be taken into consideration include whether the non-licensed service complements or supports the licensed healthcare service.
- Non-SMC approved CAM modalities or treatments/services where there is insufficient scientific evidence to support the use should not be provided as this could potentially mislead the public into believing that such therapies are part of mainstream healthcare services and are evidence-based or peer-accepted.

57. Why are certain registered healthcare professionals allowed to practise within the same premises as licensed service providers? Will the licensed service provider be liable for any adverse event caused by these healthcare professionals?

- The intent for disallowing co-location of unlicensed services is:
  - to prevent unlicensed services from being perceived by the public as "MOH-licensed healthcare services";
  - to prevent the public from being 'less vigilant' as they mistakenly believe they are consuming a regulated service;
  - to prevent licensees from "cross-selling" the services of the unlicensed entity thereby inducing unnecessary consumption by patients (e.g., clinic referring patients to the beauty clinic run by spouse).
- We have made an exception for certain registered healthcare professionals to co-locate with licensees, and this will be complementary for patients registered with the hospital/clinic e.g., physiotherapist co-located with an orthopaedic clinic or a speech therapist co-located with a neurology clinic. This is already the case in hospital services today.
- The provision of the licensee's licensable healthcare service is not adversely affected, and the privacy and safety of the licensee's patients is not compromised, by the provision of any specified healthcare service or co-located service.

58. The hospitals currently have various non-healthcare-related services such as retail shops and food courts within their premises. Will these establishments be required to write to MOH to seek approval to be located within the premises of the hospital?

- The hospital licensees will have to seek MOH's approval for the co-location of such non-healthcare related services (such as retail shops, convenience stores or food courts) and this will be given on a standing basis.

59. Hospitals and medical centres today have clinics within their premises run by allied health professionals that are not listed in the First Schedule of the Allied Health Professionals Act 2011. Does this mean that these allied health professionals are no longer allowed to operate their clinics in the same premises?
• Allied health professionals that are not listed in the First Schedule of the Allied Health Professionals Act 2011 are not on the exception list for co-location. • Therefore, licensees with clinics that co-locate with these professionals should write in to MOH to seek approval.
60. If MOH gives approval for a licensee (e.g., outpatient medical clinic) who applies to provide a non-healthcare-related service (e.g., café) within the same premises, will there be safeguards to ensure patients are not misled?
• The licensee is responsible for all services provided within the same premises. • The licensee should have overall control over the licensed premises to ensure compliance to this Act, particularly with regard to advertisements. • MOH has also imposed safeguards such as requiring the licensee to inform patients that certain parts of the services provided within the same premises are not licensed by MOH.

Part V Handling of medicinal products, health products and specimens

61. Whose responsibility is it if the specimen is compromised/destroyed during the transport? Is it the 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 accountable if it has not complied with HCSA's requirements.
62. Are medical practitioners required to record the specified dose prescribed to patients?
• As required by both the HCS (General) Regulations 2021 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 patient. 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).

63. 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 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

64. There are requirements for licensees to ensure patients are protected from abuse and negligence, 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 2014 (POHA), and there is also recourse available under the Penal Code 1871 against the abusive patients/family members.
- HCSA focuses on safeguarding the safety and welfare of patients, including protecting them from abuse and neglect.

65. 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).

66. 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 and/ or at the clinic, and/ 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 Step-in Orders

67. In what circumstances will MOH exercise step-in orders? What will MOH do once it has activated these powers? Why is there a need for these orders? Isn't it unfair that MOH can take control over the operations of private businesses? Do operators have no recourse?

- Step-in powers are meant to be **activated as a measure of last resort**. These powers are necessary to ensure patient safety, welfare and continuity of care. Failure of continued operations is detrimental to the interest of the patient.
- These powers are similar to other legislation involving critical services, such as the Banking Act 1970, Insurance Act 1966 and the Bus Services Industry Act 2015, which allow the Minister or a Public Authority to step-in and take over a licensee's operations.
- Whilst this power may appear intrusive, experience from other legislations shows that even though these powers exist, they are used very sparingly in very exceptional circumstances. For example, MAS has far-reaching powers to take over financial institutions under its purview, and 'step-in' will only be used in a very dire situation where it is necessary to prevent systemic risks to the financial markets.
- In Section 32 of the HCSA, step-in orders has been circumscribed to certain "designated" licensees. These are residential care licensees such as nursing homes and hospitals.
- MOH can only exercise these powers in certain circumstances (e.g., licence is revoked, suspended or surrendered or in cases of insolvency) and if it is necessary to take over the designated licensee to ensure the designated licensee's patients and customers receive safe, appropriate healthcare services or an adequate provision of healthcare services.
- Step-in measures are temporary, and used to ensure patient safety, welfare and continuity of care, and for the stabilisation of operations. Once continuity of care for patient is assured, MOH will 'step out'.
- To ensure fairness to businesses, Section 33(2) mandates that Minister must give the relevant designated licensee concerned a reasonable opportunity to make written representation in respect of the proposed step-in order.
- The exception to this is when step-in is urgent (such as in life and death situations) where an expedited step-in order is necessary because patient safety is jeopardised.

68. What controls are in place to ensure a step-in operator acts responsibly in running a licensee's operations and does not irresponsibly use or dispose of its financial assets?

- Under Section 33(4)(e), the step-in order contains ancillary directions as to how the costs of, and revenue generated from, running the healthcare service are to be dealt with.

- The responsibilities and liabilities of both the operator and designated licensee has also been spelt out clearly.

Part VIII Infection control, incident management and emergency preparedness

69. Why is vaccination against measles and diphtheria incorporated as a requirement under the HCSA?

- Measles and diphtheria are serious infectious diseases, and vaccinations against the two diseases are mandated under the Infectious Diseases Act 1976 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.

70. 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.

71. 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.

72. 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*.

73. 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.

74. 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.

75. How long does the measles vaccination last?

- The protection from measles due to a past infection / vaccination lasts for a lifetime. Therefore, any of the following scenarios can be taken as proof that an individual has immunity against measles:
- (a) documented proof of completion of a course of vaccination involving two doses of measles (or measles-containing) vaccine given at least four weeks apart;
- (b) serological evidence of immunity against measles; or
- (c) laboratory confirmation of past measles infection.

76. 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.

77. 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 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 (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.

78. 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.

79. 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.

80. We have outsourced partners and vendors 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 outsourced partners and vendors?

- Personnel from outsourced partners/vendors, 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.) regardless of frequency of such services, except where such partners and vendors provide services 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 have acquired 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.

81. If we engage an external vendor for a one-off event, but the vendor needs to make multiple trips to our institution or travel between multiple healthcare institutions under our cluster for this one-off event, is the vendor exempted from the immunity requirement?

- As it is a one-off event, the external vendor would meet the exemption criteria, regardless of the number of trips they make for the same one-off event.
- A vendor who visits multiple institutions under the same licensee on a one-off basis, regardless of whether the same staff is making the trip to each institution on the same day, would also meet the exemption criteria.

82. If we do not have a contract with the external vendor (e.g., food caterers where only purchase order and invoice are involved), how could we ensure that the external vendors comply with the immunity requirement? Do we need to obtain evidence of immunity from these external vendors?

- In the event where there is no contractual agreement between the licensee and the external vendor, the licensee should still inform the vendor of the need to comply with the immunity requirement and document such due diligence separately. This will help support the licensee's case should there be an audit by MOH on the licensee's compliance with the immunity requirement.

83. Do medical observers and visiting experts need to comply with the vaccination requirements?

- These groups of individuals will need to comply with the vaccination requirements, regardless of the duration of their stay, as they may attend

clinical procedures/clinical sessions within the licensable healthcare premises and thus may have physical contact with patients.

84. Are the vaccination requirements applicable to visitors such as patients' next-of-kin or friends?

- While it is not mandatory for next-of-kin and friends of the patients to comply with the immunity requirements, they are strongly encouraged to get themselves immunised as well, in order to better protect the health of their loved ones and other patients.

85. Are volunteers required to comply with the immunity requirement?

- Volunteers who are not registered healthcare professionals are exempted from the measles and diphtheria immunity requirements, and are instead strongly encouraged to meet these requirements as best practice.
- MOH recognises that the imposition of immunity requirements has deterred volunteerism, particularly in the Long-Term Care sector, where volunteers are crucial to augment the manpower capacity.
- Despite this stance for general volunteers, all healthcare institution licensees should continue to assess and determine if there are circumstances where diphtheria and measles immunity requirements may need to be imposed on volunteers.
- In addition, prevailing infection prevention and control measures would continue to apply. Examples of such measures include routine cleaning and disinfecting of premises especially following a large group-based activity or event, as well as general public exhortation such as keeping up-to-date with necessary vaccinations, hand hygiene, masking in patient-facing areas and avoid visiting the healthcare institutions if unwell. Licensee should reiterate these measures to the volunteers.

86. Are volunteers who are registered healthcare professionals and providing general volunteer activities (e.g., cutting hair, massages) exempted from the immunity requirement?

- Volunteers who are registered healthcare professionals are required to comply with the measles and diphtheria immunity requirements. This is because registered healthcare professionals have a professional duty to protect the health of their patients and the public, and thus should in principle be held to a higher standard compared to general volunteers.
- Such volunteers will be exempted from the requirements if:

  1. The volunteer's work does not involve direct interaction with a patient and they do not work within the premises or conveyance of a healthcare institution which is used to provide services that involve direct interaction with patients.

  2. Volunteers have documented proof that they are certified to be permanently medically unfit for vaccination (for measles and diphtheria); and

  3. Volunteers who are employed or engaged (by Licensees or otherwise) for volunteering on a one-off basis.

87. What measures can licensees put in place to lower the risk of transmission from volunteers to patients?

- Despite the exemption of measles and diphtheria immunity requirement for general volunteers, licensees should continue to put in place prevailing infection prevention and control measures to prevent the spread of such contagious diseases.
- In addition, licensees are encouraged to assess their own situation and take other risk-based measures, such as crowd management and cutting down non-essential interactions for highly immune compromised groups of patients. Licensees have the flexibility to tighten the measures as and when required, based on their own circumstances. For example, if there is an outbreak in the facility, the healthcare institution can impose stricter infection control measures, or stop the volunteer activities all together, or require that their volunteers be updated with measles and diphtheria vaccinations accordingly.

88. How can licensees decide whether to impose the immunity requirement on general volunteers?

- All healthcare institution licensees should continue to assess their own situation and determine if there are circumstances where diphtheria and measles immunity requirements may need to be imposed on general volunteers.
- This assessment should be risk calibrated, based on the potential exposure of general volunteers with no / unknown immunity to diphtheria and measles to vulnerable patients. In principle, this assessment should be conducted by undertaking a holistic review of the licensee's circumstances, rather than applying key considerations mechanistically. For instance, if a licensee assesses that having unvaccinated volunteers in close contact with highly vulnerable patients (e.g., transplant recipients) places excessive risk to the patients, the licensee should be allowed to exercise discretion in imposing the immunity requirements on the volunteers regardless of the length of contact time between the volunteers and patients.
- MOH may also reserve the right to impose immunity requirements on select licensees if there is an outbreak of diphtheria or measles or is a risk of an outbreak, to mitigate against future transmission.

89. If we have a contract with an outsourced agency to require the 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 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 external provider must ensure their staff meet the immunity requirements. I

90. 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.

91. After proof of immunity has been obtained, do we need to submit the supporting documents (e.g., vaccination records) to MOH?

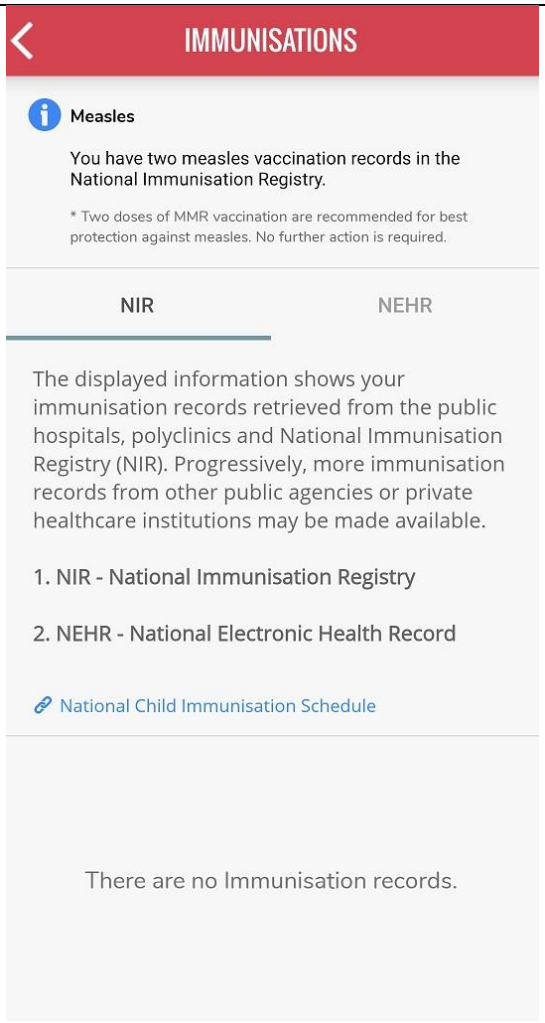
- Licensees are not required to submit the documents to MOH. However, licensees should keep such records minimally for the period specified in the licensing conditions. Such records may be subject to inspection and audit by MOH.
- For personnel who are not employed or engaged by the licensee or is a 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.

92. 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.

93. 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.

Part IX Power to Publish Information

94. What is the purpose of this power?
• Information can only be published for the purposes of public interest.

- The aim is to protect patient safety and welfare by improving public awareness and enabling patients to make better informed decisions.

95. Can MOH give some examples of what will be published?

- The HCSA allows the Director-General of Health (DGH) to publish information relating to —

(a) the lapsing, shortening, suspension or revocation of a licence or an exemption granted to any person;

(b) the making of a step-in order or an expedited step-in order against a designated licensee;

(c) the making of a direction under the Act against any person;

(d) the censure of any person;

(e) the removal of and replacement of any key appointment holder, Principal Officer or Clinical Governance Officer;

(f) the acceptance by any person of an offer to compound any offence under the Act; and

(g) the conviction of any person for any offence under the Act.

- MOH could also publish information on non-compliant providers and unlicensed providers, or information relating to the average patient bill sizes of different licensees.

96. If the licensee had corrected past non-compliance or paid criminal penalties etc., would the record still be published?

- The purpose of the watchlist is to help members of the public make better informed decisions.
- Informing the public about a history of previous egregious behaviour may still be relevant, even if the past non-compliance is corrected or if penalties have been paid.
- MOH will continuously review these watchlists and may consider removing entries, taking into account various factors (e.g., the licensee's continued compliance with the Act, whether the non-compliance has been rectified, etc.).

Part X Requirements on Delivery and Transportation of Medicinal Products and Health Products[1]

97. What are some measures that a licensee should take to ensure that the medicinal or health products are protected from any likelihood of contamination during delivery and transportation?

- A licensee should ensure that the medicinal or health products are packed and transported in a manner that is:
- protected from moisture or water;
- protected from attacks by microorganisms or pests; and
- not in contact with other materials (e.g., chemicals) or food.
- A licensee should also ensure that the storage facilities holding the products prior to delivery and the transportation vehicles are cleaned/ decontaminated on a routine basis using appropriate cleaning methods to minimise the risk of cross contamination.

98. What are some measures that a licensee should take to ensure that the medicinal or health products are kept under suitable conditions (such as temperature, humidity, length of time, lighting and position of the product) during delivery and transportation?

- The licensee should ensure that:
  a) the temperature of the medicinal or health products stored in the parcel is maintained and monitored using a temperature monitoring device such that the temperature of the products is maintained in accordance with the manufacturer's instructions. Such temperature records should also be maintained;
  b) for cold chain products, such products are packed in a configuration whereby they are not in direct contact with ice packs, and cold chain products are packed and stored separately from non-cold chain products;
  c) for products that are light sensitive, the products are packed in an opaque packaging to protect the items from light;
  d) for fragile products (e.g., medication glass bottles), the products are wrapped in a manner to secure against spillage/ breakage; and
  e) the parcel bears special handling instructions (e.g., cold chain, fragile, light-sensitive products) and such information should be clearly visible on the medication parcel so that the parcel can be handled appropriately.

99. What are some measures that a licensee should take to ensure that the medicinal or health products are delivered or transported directly to the intended destination without any diversion or deviation from the intended route?

- The licensee should ensure that the following measures are taken:
  a) the packed parcel bears the patient's name and the delivery details (e.g., address and date/time of delivery) and such information should be clearly visible on the parcel; and

b) the delivery address and the patient's identity are verified and acknowledged by the recipient before handing over the parcel to the recipient. For deliveries that are acknowledged remotely by the patient and requested to be left at the doorstep, the Licensee shall ensure that appropriate measures are taken to ensure that the products are not lost or stolen (i.e., there is a secure and private area at the doorstep to deposit the products). Otherwise, the Licensee should inform the patient to receive the parcel physically.

- To ensure traceability of supply and transportation of the medicinal and health products, the supply and transportation records should be maintained from the point where the products leave the packed/storage area to the point where the products are handed to the recipient.

100. I outsource the delivery and transportation of medicinal and/or health products to a third party logistic service provider (LSP). Will the LSP be accountable for issues arising from the delivery and transportation of the products to patients?

- Where the medicinal or health products are delivered and transported by an outsourced LSP, the licensee remains accountable for any issues arising from the delivery and transportation of the products to patients.
- As such, the licensee should: (a) ensure that the LSP conduct routine self-checks/audits; and (b) conduct internal checks/audits on the LSP to ensure that the processes and risk mitigation measures put in place to ensure that delivery and transportation process are carried out in accordance with Regulation 31 of the Healthcare Services (General) Regulations 2021 and with the service level agreement between the licensee and the LSP.

101. What is the expected protocol to handle a delivery failure?

- In the event of a delivery failure, the medicinal and health products should be returned to the Licensee and the delivery failure should be documented.
- The Licensee should notify the patient as soon as practicable on the subsequent arrangement to collect the products (i.e., redelivery or head down to the licensed premises to collect the products).

102. What is the expected protocol to handle a delivery error?

- In the event of a delivery error (i.e., wrong medication or wrong parcel is delivered to the wrong patient):

  a) the patient shall be informed of the error. If the licensee outsources the delivery to an LSP, the licensee shall also be informed of the error; and

  b) if the error requires a medication recall from the patient or any other person, the licensee shall ensure that the patient/person is informed not to take the wrong medicinal/ health products or to stop taking the products and advise on the appropriate actions thereafter (e.g., return, exchange or disposal of the products).

- To minimise the error from recurring, the licensee shall ensure that:

a) the occurrence of the incident is contemporaneously and accurately recorded;

b) the circumstances of the incident are reviewed to identify its causes;

c) appropriate steps are taken to prevent or reduce the likelihood of the recurrence of the incident; and

d) proper, complete and accurate records of the incident report is maintained.

103. I am using an electronic system to monitor the delivery status of patients' medicinal and/or health products. Are information in the electronic system considered patient health records?

- "Patient health record" means a record containing the personal data and medical information of a patient that is maintained by a licensee in relation to the provision of a licensable healthcare service to the patient.
- If the electronic system used to monitor the delivery status of the patients' medicinal and/or health products contains the personal data and medical information of patients, the licensee should ensure that the protection of patient health records are in accordance with Regulation 38 of the Healthcare Services (General) Regulations 2021.
- Where the electronic system is maintained by the outsourced LSP, the licensee remains responsible for ensuring that the LSP maintains the confidentiality, integrity and security of the Licensee's patient health record.

104. How should medicinal and/or health products be packed and labelled such that the parcel does not undermine the confidentiality of the patient's health record?

- The licensee should ensure that the medication name and medication instructions are not visible/ displayed on the outer parcel.

[1]The licensee may wish to refer to the prevailing Singapore Standard Guidelines for the Supply and Delivery of Medication (SS 644: 2019) for more details.

Part XI Miscellaneous

105. 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.

106. How detailed must the business continuity plans (BCP) be? Will there be a template or standard operating procedure provided by MOH to guide licensees on drafting the business continuity plan?

- 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.
- As such, MOH will not provide any templates or SOP, to allow licensees flexibility to decide what is appropriate for their needs. 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.

107. 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.

Annex A – Glossary of Acronyms

Acronym	Full Term
BCP	Business Continuity Plan
CAM	Complementary and Alternative Medicine
CEC	Clinical Ethics Committee
CGO	Clinical Governance Officer
HALP	Healthcare Application and Licensing Portal
HCSA	Healthcare Services Act
KAH	Key Appointment Holder
KOH	Key Office Holders
LHS	Licensable Healthcare Service
M&M	Mortality and Morbidity
MOSD	Mode of Service Delivery
PHMCA	Private Hospitals and Medical Clinics Act
PO	Principal Officer
QAC	Quality Assurance Committee
SS	Specified Service
SRC	Service Review Committee
SRE	Serious Reportable Events
TCM	Traditional Chinese Medicine