MINISTRY OF HEALTH
SINGAPORE

Stakeholder Consultation on the Healthcare Services (General) Regulations

Presented by Health Regulation Group
Ministry of Health
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HEALTHCARE SERVICES ACT (HCSA)

- ✓ To **safeguard patient safety and welfare**, while enabling the development of new and innovative healthcare services that benefit patients
  - ✓ To **enhance governance** of licensed entities
  - ✓ To **ensure continuity of care and accountability**
- ✓ To **strengthen regulatory clarity**

Phased Implementation for HCSA

Updated on 3 Sep 2021

Key target dates for HCSA implementation in phases

- **Phase 1: 3 January 2022**
- **Phase 2: June 2022***
- **Phase 3: March 2023***

Phases 2 and 3 will be deferred. We will share details at a later date.

HCSA passed on 6 Jan 2020

Jan 2020

Phase 1

1. General Regulations
2. Advertisement Regulations

Clinical Support Services Regulations

3. Clinical Laboratory Service
4. Radiological Service
5. Blood Banking Service
6. Tissue Banking Service (cord blood)

Special Services Regulations

7. Nuclear Medicine Imaging Service
8. Nuclear Medicine Assay Service

Non-premises Based Services Regulations

9. Emergency Ambulance Service
10. Medical Transport Service

Phase 2

Non-Premises Based Services Regulations

11. Telemedicine Service

Ambulatory Care Services Regulations

12. Medical Clinic Service
13. Dental Clinic Service
14. Health Screening Service
15. Ambulatory Surgical Centre Service
16. Renal Dialysis Centre Service

Special Services Regulations

17. Assisted Reproduction Service
18. Radiation Oncology (including Proton Beam Therapy) Service
19. Blood Transfusion Service
20. Nuclear Medicine Therapy Service

Clinical Support Services Regulations

21. Tissue Banking Service (human tissue, reproductive cell and/or embryo)

Phase 3

Hospital Services Regulations

22. Acute Hospital Service
23. Community Hospital Service

Long Term Care Services Regulations

24. Nursing Home Service
25. Inpatient Palliative Care Service

Special Services Regulations

26. Cell, Tissue and Gene Therapy Service
27. Clinical Genetic and Genomic Service
28. Organ Transplant Service
29. Specialised Interventional Procedures Service

Detailed working definitions of the services are in the Annex.

HCSA Regulations

- In developing HCSA requirements, MOH has reviewed the existing PHMC Regulations (PHMCR), licensing terms and conditions (LTCs), directives, circulars etc.
- Regulations structured into **General Regulations, Advertisement Regulations** and **Service-specific Regulations**
  - **General Regulations and Advertisement Regulations**: General requirements, usually applicable to **all licensees**
  - **Service-specific Regulations**: Unique requirements to each service or stipulates specific requirements articulated in the General Regulations
- Licensees must comply with the General Regulations **and** the Service-specific Regulation(s) of the licensed healthcare service(s) provided
- Regulations **will be complemented with:**
  - **LTCs** that set out specific technical requirements to be met
  - **Explanatory guidance documents** which will carry illustrations of good practices to help licensees interpret and meet the outcome-based approach
- Requirements that are “new” or “enhanced” compared to the PHMCR are highlighted as such in this deck

Major requirements under HCSA General Regulations

Updated on 22 Jan 2021

1. **Licensing Matters**
   - Licensable healthcare services underlying to special licensable healthcare service

2. **Governance**
   - Roles and responsibilities of licensee, Key Appointment Holders, Principal Officer, Clinical Governance Officer

3. **Committees appointed by licensees**
   - Quality Assurance Committee

4. **Licensed premises and licensed conveyances**
   - Use of licensed premises or licensed conveyance for other purposes

5. **Handling of medicinal products, health products and specimens**
   - Safe and proper handling specimens

6. **Service standards**
   - Requirements to protect patient safety and welfare
   - Communication with patients

7. **Price transparency**
   - Display of common charges, itemisation of bill, financial counselling

8. **Infection Control, Incident Management and Emergency Preparedness**
   - Measles and Diphtheria Vaccinations for Workers in Healthcare
   - Incident escalation
   - Business Continuity Plans

9. **Miscellaneous**
   - Restrictions on use of names
   - Outsourcing of licensable healthcare services
   - Penalties

Licensing Matters

Regulations 4-9: Timelines and Fees

- Certain timelines for the licensing process (licence applications, renewals) and other matters (amendment of licence, voluntary cessation / surrender of licence) will be set out in the Regulations.
  - Non-compliance with these timelines are a breach of the Regulations.
- Details on timelines and fees can be found in the “HCSA Administration and Transition” materials.

Updated on 3 Sep 2021

Regulation 6: Licensable healthcare services underlying to special licensable healthcare service

[NEW] A licensee that wishes to provide a special licensable healthcare service (in the first column) must also hold one of the corresponding underlying licences (in the second column)

Special licensable healthcare service	Underlying licence
Nuclear medicine assay service	(a) Clinical laboratory service (b) Acute hospital service
Nuclear medicine imaging service	(a) Radiological laboratory service
Assisted reproduction service	(a) Medical clinic service; or (b) Acute hospital service
Blood transfusion service	(a) Ambulatory surgical centre service; (b) Renal dialysis centre service; (c) Medical clinic service*; (d) Acute hospital service; (e) Community hospital service; or (f) Inpatient palliative care service **Only for medical clinics (e.g. oncology, haematology) that need blood transfusion service*
Nuclear medicine therapy service	(a) Medical clinic service; or (b) Acute hospital service
Radiation oncology service (including proton beam therapy)	(a) Medical clinic service; or (b) Acute hospital service
Cell, tissue and gene therapy service	(a) Medical clinic service; (b) Dental clinic service; or (c) Acute hospital service
Clinical genetic and genomic service (a) Clinical Genetic Testing (Ordering – Level 2) (b) Clinical Genetic Testing (Ordering – Level 3) (c) Clinical Genetics (Service) (d) Clinical Genetics (Laboratory Genetic Testing)	(a)-(c): Medical clinic service or Acute hospital service (d) Clinical laboratory service
Organ transplant service	(a) Acute hospital service (b) Medical clinic service
Specialised interventional procedural service	(a) Acute hospital service

Governance of Key Officeholders

Updated on 3 Sep 2021

Regulation 10: Roles and responsibilities of licensees

To ensure patient safety and welfare by putting in place governance frameworks staffed with the right people who have distinct roles

Personnel	Compared to PHMCA	Characteristics	Role	Responsibility
Licensee	No change	Licensee can be a corporation or an individual, e.g. the CEO. Not required to have clinical expertise.	The licensee is **responsible and accountable for overall compliance** with HCSA. Responsibility is **non-delegable** but KAHs, POs, CGOs assist the licensee to comply with HCSA requirements.	

- For smaller providers (e.g. solo-practitioner clinic), the same person can be the licensee, Principal Officer (PO) and Key Appointment Holder (KAH), as long as that person meets the requisite requirements of the various roles.

Enhanced governance

Updated on 3 Sep 2021

Roles and responsibilities of Key Appointment Holders (KAHs)

Personnel	Compared to PHMCA	Characteristics	Role	Responsibility
Key Appointment Holders	Not defined under the Private Hospitals and Medical Clinics Act (PHMCA). <u>Formalisation of the roles of KAHs that already exist today</u> (e.g. sole proprietor, partners, board of directors).	KAHs are the **governing body** and generally the controlling mind and will of the licensee. **At least 1 KAH is required to have clinical expertise* unless this can be fulfilled by the PO (or if a CGO is appointed).** Has the authority to <u>provide high-level management and clinical direction</u> but more limited direct influence over day-to-day operations on the ground as compared to the PO or CGO. *Only applicable for underlying licence, as the clinical requirement for special licensable services is fulfilled by CGO	To ensure the organisation is financially sustainable, and that organisational processes are robust and comply with all laws and regulations. Duties stipulated under the Code of Practice.	Responsible for the **strategic leadership and general management oversight** of the licensable service.

Enhanced governance

Regulation 14: Roles and responsibilities of Principal Officer (PO)

Personnel	Compared to PHMCA	Characteristics	Role	Responsibility
Principal Officer	Similar to the role of the manager under the PHMCA, except with no clinical expertise requirement[#], so as to allow businesses greater flexibility in appointing the PO ***# In effect, this clinical expertise requirement can be met either by the PO or the KAH under HCSA***	Required to have organisational authority. Generic role with no specific qualifications or requirements. PO has direct management authority over the day-to-day operations of the licensed service, e.g. the clinic manager.	**Oversees day-to-day management** of the licensee and ensures operational compliance with HCSA. Duties set out in the General Regulations.	To **ensure operational compliance** with HCSA and that services are provided in a manner that ensures patients' safety, welfare and continuity of care. **Oversees the implementation of policies and SOPs**, and reviews and manages any clinical or enterprise risk, to ensure that the healthcare service complies with HCSA.

Enhanced governance

Updated on 3 Sep 2021

Regulation 15: Roles and responsibilities of Clinical Governance Officer (CGO)

Personnel	Compared to PHMCA	Characteristics	Role	Responsibility
Clinical Governance Officer	New role, only required for certain prescribed services which require specialised technical expertise Formalisation of previous technical roles for certain services	The CGO is the technical expert, e.g. Clinical Laboratory Director, Director of AR Services. Will be required to possess specific qualifications.	**Oversees the day-to-day technical aspects** of the licensable service. Duties and qualifications will be set out in relevant service regulations.	**Responsible for technical oversight and implementation** of complex services that require specialised expertise.

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

Enhanced governance

Updated on 3 Sep 2021

Services that require CGO

Phase	Services that require CGO
Phase 1	Blood banking service
	Clinical laboratory service
	Nuclear medicine imaging service
	Nuclear medicine assay service
	Radiological service
	Tissue banking service (cord blood)
	Emergency ambulance service
	Medical transport service
Phase 2	Assisted reproduction service
	Blood transfusion service
	Nuclear medicine therapy service
	Radiation oncology service (including proton beam therapy)
	Tissue Banking Service (human tissue, reproductive cell and/or embryo)
Phase 3	Cell, tissue and gene therapy service
	Clinical genetic and genomic service
	Organ transplant service
	Specialised interventional procedural service

Roles and responsibilities of licensee, KAH, PO and CGO

Consideration factors in determining the roles and responsibilities of licensee, KAH, PO and CGO

1. The **licensee is responsible and accountable for overall compliance** with HCSA.

2. If there is non-compliance and the facts of the case suggest that KAH, PO, and/or CGO may also be culpable, action against these key officeholders along with the licensee may also be considered.

3. In assessing S/No. 2, MOH may have regard to the following:
   I. The nature of the breach; and
   II. The roles, responsibilities, and competencies of the KAH, PO and CGO vis-à-vis the nature of the breach; and
   III. Whether there is a wilful dereliction of duty by staff despite established processes and compliance checks by the KAH, PO and/or CGO.

Roles and responsibilities of licensee, KAH, PO and CGO

Consideration factors in determining the roles and responsibilities of licensee, KAH, PO and CGO

4. The overlaps among the roles of the licensee, KAH, PO and CGO provides some level of check and balance amongst the parties and means that multiple parties may be held responsible.

5. In assessing S/No. 4, **the degree of culpability for each party will be considered <u>based on the facts of the case</u>**, having regard to the following:

   I. Whether the KAH is suitable to act in its capacity

   II. Whether the PO had failed to perform its and qualified/competent function

      i. Key consideration: **is the breach something that the PO ought to have reasonably detected or flagged up**, taking into consideration whether he has clinical expertise

   III. Whether the CGO had failed to perform its function

      i. Key consideration: **is the breach something that the CGO ought to have reasonably detected or flagged up**, taking into consideration his technical expertise

Enhanced governance

Regulation 11-13: Appointment of and change in KAH, PO and CGO

Make sure that patients receive safe and good quality service

Requirement	Timeline
Appointment or change in appointment of PO or CGO	• Director must be notified **within 10 calendar days**
Appointment or change in appointment of KAH (e.g. board of directors, partner)	• Director must be notified **within 10 calendar days**
Change in majority of KAH (i.e. to remove or substitute *more than half* in number of the licensee's key appointment holders)	• Director must be notified within 1 month before the proposed removal or substitution takes effect
Remove unsuitable PO or CGO and appoint another suitable individual	• Unsuitable person must be removed and new appointment must be made **within 10 calendar days**
Submission of self-declarations of suitability to act	• Submission together with notification of appointment or change in appointment, i.e. **within 10 calendar days**

Committees appointed by Licensee

Enhanced governance

Regulations 17-20: Quality Assurance Committee (QAC)

To evaluate and monitor the quality and appropriateness of the healthcare service(s) provided by the QAC licensee (i.e. licensee that must appoint a QAC)

- **Requirements largely the same as under PHMCA**
  - E.g. appointment of QACs, reporting of prescribed serious reportable events (SREs)
  - QACs comprise qualified and appropriate individuals (LTCs will stipulate composition of QACs)
  - Up-to-date policies must be in place for suspension, limitation, reduction of clinical privileges or termination at the point when cases are being referred for disciplinary inquiry
  - QAC must institute root cause analysis and recommend appropriate corrective actions in a timely manner to prevent further recurrences
  - Recommendations of the QAC must be implemented in a timely manner

- **The scope of QAC licensees include nursing homes and special services (e.g. nuclear medicine, assisted reproduction, cell, tissue and gene therapy services)**
  - Other non-prescribed licensees must participate in QA activities when required by the Director

- **[NEW] Appointment of an individual to oversee and supervise QAC activities**

Enhanced governance

Updated on 3 Sep 2021

Regulation 17: Licensees required to appoint QAC

Prescribed licensee	*Quality assurance committee(s) required*
1. Every licensee authorised to provide an **acute hospital service**	(a)At least one Mortality and Morbidity Quality Assurance Committee (b)At least one Serious Reportable Event Quality Assurance Committee (c)At least one Peer Review Learning Quality Assurance Committee
2. Every licensee authorised to provide a **community hospital service**	(a)At least one Mortality and Morbidity Quality Assurance Committee (b)At least one Serious Reportable Event Quality Assurance Committee
3. Every licensee authorised to provide a **nursing home service**	At least one Serious Reportable Event Quality Assurance Committee
4. Every licensee authorised to provide an **ambulatory surgical centre service**	(a)At least one Mortality and Morbidity Quality Assurance Committee (b)At least one Serious Reportable Event Quality Assurance Committee
5. Every licensee authorised to provide an **nuclear medicine imaging service**	(a) At least one Quality Assurance Committee
6. Every licensee authorised to provide **blood banking service**	(a) At least one Serious Reportable Event Quality Assurance Committee
5. Every licensee authorised to provide: **(a) assisted reproduction service;** **(b) blood transfusion service;** **(c) nuclear medicine therapy service;** **(d) renal dialysis centre services;** **(e) radiation oncology service (including proton beam therapy) service** **(f) cell, tissue and gene therapy service;** **(g) clinical genetic and genomic service;** **(h) organ transplant service;** **(i) specialised interventional procedural service**	(a) At least one Mortality and Morbidity Quality Assurance Committee (b) At least one Serious Reportable Event Quality Assurance Committee
6. The following licensees: (a) Every licensee authorised to provide a medical clinic service that is operated as **a polyclinic** (b) Licensee of **National Skin Centre** (c) Licensee of **Student Health Centre**	(a) At least one Mortality and Morbidity Quality Assurance Committee for each medical clinic service (b) At least one Serious Reportable Event Quality Assurance Committee for each medical clinic service

Updated on
3 Sep 2021

Personnel

Updated on 3 Sep 2021

Regulation 16: Personnel

Personnel providing patient care are appropriate, qualified and adequate

- A licensee must employ or engage personnel of such number and suitability as is necessary to ensure the patient safety and quality of care
- Specific requirements will be stipulated in respective Service Regulations
- Licensee must establish and maintain proper systems to ensure adequate division of duties and clear reporting lines.

Licensed Premises and Conveyances

Regulation 21: Requirements on Licensees' Premises and Conveyances

Patients should receive care in a safe and suitable environment and using appropriate medical equipment

- **Premises/conveyances and facilities must be appropriate and adequate for delivery of healthcare services**
  - Premises/conveyances and facilities must be clean, adequate for current needs, safe and secure, suitable for the purposes, properly maintained, etc.
  - Measures to prevent unauthorised access to procedure / consultation rooms
  - Licensee's further obligations in relation to premises, facilities and equipment will be expanded in the relevant Service Regulations (e.g. Telemedicine).

- **Medical supplies and equipment must be safe, adequate and suitable / appropriate for the purposes(s) for which they are registered for**
  - Use of all equipment and apparatus comply with the relevant laws
  - Equipment and apparatus are appropriate for current and projected needs
  - Equipment and apparatus are regularly maintained, monitored and calibrated in accordance with manufacturers' recommendations

Regulations 22: Use of Licensed Premises or Conveyances for Other Purposes (Co-location)

[NEW] Clarity on requirements to distinguish licensable and non-licensable services provided within the same licensed premises or conveyance

Rationale: To prevent misperception that non-licensable services are regulated by MOH

- **Certain non-licensable healthcare services can be provided in a licensed premises or conveyance**
  - E.g. those provided by registered healthcare professionals (Allied Health Professionals)

- **MOH's approval required to provide other non-licensable services in a licensed premises or licensed conveyance***

- **Additional conditions will be imposed for such co-location of services, including but not limited to:**
  - Disclosure to patients that these services are not licensed by MOH
  - Patients must not be required or incentivised to patronise the licensable healthcare service in order to be able to use the non-licensable services (and vice versa)
  - Physical demarcation between licensable and non-licensable services, unless otherwise allowed by MOH

- **Licensees will be held accountable for all services provided (including the non-licensable services) within the licensed premises or conveyance, unless there is physical demarcation or clearly documented delineation of responsibilities (e.g. via means of a contract or written agreement)**

** Hospitals, nursing homes and hospices (i.e. residential facilities) to be given standing approvals to provide certain retail and F&B services (e.g. florist, foodcourts, etc.)*

Regulations 22: Use of Licensed Premises or Conveyances for Other Purposes (Co-location)

[NEW] Non-licensable healthcare services that can be provided in licensed premises or conveyances

(approval from MOH not required)

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** (limited to the provision of acupuncture service)
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**
Retail sale of medical devices, therapeutic products, oral dental gums and cosmetic products, as defined in the First Schedule of the Health Products Act

Handling of Medicinal Products, Health Products and Specimens

Updated on 3 Sep 2021

Regulation 22-26: Handling of medicinal products and health products

Medicinal and health products are used safely, appropriately and correctly

- **The requirements apply to health products (defined under Health Products Act) and medicinal products (defined under Medicines Act).**
- Licensee must ensure that the health and medicinal products from a person with a valid licence to supply or sell these products under relevant laws.
- **Licensee to be responsible for <u>preparation, administration, dispensing, storage, delivery and disposal</u> of medicinal and health products**
  - Ensuring that every medicinal product or health product is prepared in accordance with the manufacturer's instructions.
  - Ensuring that no product is administered, dispensed or provided or delivered to any patient after shelf life or expiry date of the product.
  - All products must be stored properly in appropriate facilities and in accordance with any code of practice providing for the quality and safety of such products.
  - Prompt disposal and recall of medicinal and health products where necessary.
  - During delivery or transportation, all products must be protected from contamination, kept under suitable conditions, delivered or transported directly to the intended destination without any diversion and in accordance with any code of practice relating to delivery or transportation of such products.

Regulation 23-26: Handling of medicinal products and health products

Medicinal and health products are used safely, appropriately and correctly

- **Licensee to be responsible for <u>prescription</u> of medicinal and health products**
  - Prescription is in accordance with the Health Products Act and any other relevant written law
  - Appropriate packing and labelling of medicinal and health products for each patient
  - Maintenance of appropriate medication records to prevent medication errors
  - Medicinal and health product errors to be identified, recorded and appropriate and timely measures taken to correct the error and prevent a recurrence
- **Controlled drugs to be handled in accordance with relevant regulatory requirements**
  - Requirements under Misuse of Drugs Act also apply to storage, sale and supply of controlled drugs

Updated on 3 Sep 2021

Regulation 27: Requirements for Specimens

[NEW] Specimens are packaged and transported in a safe manner

- Specimens are “biological material or matter derived or obtained from the body of an individual for use in or in connection with a healthcare service” (e.g. a piece of human tissue sample sent to a lab for testing)

- **No specimen mix-ups or contamination**
  - Positive identification of the patient
  - Proper collection and labelling
    - Correct specimen is obtained: (i) correct specimen type (e.g. blood, tissue), (ii) from the correct site, (iii) using the correct transport medium or anticoagulant, in the right proportion and in the right sequence (if it is required)
    - The primary container (i.e. the one containing the specimen) is clearly and accurately-labelled with the patient’s identifiers, minimally, his name and identity number, and any critical information on the nature of specimen.
  - Proper handling to ensure specimen is not contaminated, including with other patient’s specimens

- **Preservation of specimen integrity**
  - Protocols for the safe packaging, handling and transport of specimens
    - Basic dual packaging system for routine specimens
    - Triple packaging system for ‘high risk’ specimens
  - Timely transportation of patient samples under the appropriate conditions to the laboratory

- **Public safety is not compromised**
  - Labelling of transported specimens to indicate the general nature of the materials transported

Service Standards

Service standards

Patients are accorded privacy and treated with dignity and respect

- **Patients' privacy is respected**
  - Appropriate equipment and facilities (e.g. curtains, frosted window panes) to protect patients' privacy

- **[NEW] Patients are treated with dignity and respect**

Regulation 29: Safeguard against abuse and neglect

[ENHANCED] Patients are protected against abuse and neglect

- **Licensees to ensure that patients are protected from abuse or neglect**
- **A system in place to report any such abuse or neglect to an appropriate authority** so that appropriate action may be taken against the employee.

Definition of "abuse" and "neglect"

"Abuse" means:

(a) physical abuse;

(b) emotional or psychological abuse;

(c) conduct or behaviour by an individual that in any other way controls or dominates another individual and causes the other individual to fear for his or her safety or wellbeing; or

(d) conduct or behaviour by an individual that unreasonably deprives, or threatens to unreasonably deprive, another individual of that other individual's liberty of movement or wellbeing;

"Neglect" means the lack of provision to the individual of essential care (such as but not limited to food, clothing, medical aid, lodging and other necessities of life), to the extent of causing or being reasonably likely to cause personal injury or physical pain to, or injury to the mental or physical health of, the individual.

Updated on 3 Sep 2021

Regulation 30: Communication with patients

[NEW] Patients are well-informed of their conditions and options for treatment so that they are able to provide informed consent

- **Patients are duly informed about their conditions and care plans**
- **Patients are provided with sufficient and relevant clinical information to make an informed decision**
  - Appropriate systems must be in place for obtaining consent from patients and maintaining proper records of the consent obtained
  - Licensee must obtain consent from patients concerning the use of information of the patients.
- Where a test is conducted on a patient who is under direct care of the licensee, the licensee must ensure that the findings of the test are reviewed by a medical practitioner without undue delay, and the patient is informed of the findings, and the medical practitioner advises the patient, based on the test findings, on the patient's condition, prognosis and clinical management.

Updated on 3 Sep 2021

Regulation 31: Patients' health records

Patient health records are accurate, up-to-date and secured

- **Refers to physical (manual) and electronic (digital) records**
  - Record of all personal data and medical information of a patient obtained during the provision of a healthcare service, including both individual records and aggregate compilation/extracts of patient health records that contain patient identifiers and clinical information.
  - Includes medical, nursing and allied health care, medical investigations, all interventions and treatments provided by a licensed healthcare service provider to a patient

- **Appropriate, complete, up-to-date, and accurate health records are kept and maintained**
  - Protocols / processes to prevent against and manage unauthorised modification, copying and use of patient health records

- **Follow-ups must be recorded and acted upon**
  - E.g. incidental findings that require clinical intervention, including advice, must be highlighted and referred to the appropriate healthcare practitioner for follow-up

Updated on 3 Sep 2021

Regulation 31: Patients' health records

Patient health records are accurate, up-to-date and secured

- **Confidentiality, integrity and security of all health records is maintained**
  - Refers to physical (manual) and electronic (digital) records
  - Ensure that every staff handling any patient health record is aware of his role and responsibility in maintaining the confidentiality, integrity and security of the records.
  - Protocols and processes to prevent any unauthorised modification, copying or use of a patient health record, including cybersecurity measures, with periodical review of such protocols and processes to ensure that they are effective and being complied with by the staff involved in handling the patient health records.
  - Take reasonable care in the disposal or destruction of the patient health records so as to prevent unauthorized access.

- **Maintenance of continuity of care when service ceases or during patient transfer**
  - Informing patients in advance before the intended date of cessation
  - Consulting patients on the transfer or disposal of their health records
  - Transferring the licensee that is taking over the care of the patient, or the patient or his/her legal representative.

- For all other records in relation to the provision of a licensable healthcare service that do not contain patient info and may be organised/compiled at the provider-level, licensee must ensure and maintain accuracy, integrity and completeness of such service records.
  - e.g. data logs maintained by labs in relation to the lab tests performed, reagent inventory, SRE incident reports, linen and dietic services records, records on maintenance and pest control, certification of staff etc. maintained by clinics and hospitals.

Price Transparency

Updated on 3 Sep 2021

Regulation 32-34: Display of common charges, financial counselling and bill itemisation

[ENHANCED] Patients are provided with accurate information about charges for price transparency to make informed choices

- **Adequate information on fees and charges are provided through fee display**
  - Common charges must be prominently displayed on the premises/conveyance or website across all services

- **Financial counselling will be mandated for licensees providing selected licensable services**
  - These are services which are expected to generate significant bills, including cumulative over time
  - Financial counselling should provide fee information specific to the patient's treatment options and variability during the course of treatment

- **General Regulations will set out the minimum level of granularity in the form of generic categories for meaningful bill itemisation**
  - Service-specific Regulations may stipulate further categories for itemisation
  - If patients request more detailed bill itemisation, the licensee should facilitate where practicable

At the minimum, itemised billing must state the following categories of charges:

- Consultations
- Tests, procedures and investigations
- Medications
- Consumables
- Third party administrator services
- Other services and items
- Total fees payable (before Government subsidies, MediSave and MediShield Life)
- Total amount of Government subsidies, where relevant
- Net fees payable (after Government subsidies, MediSave and MediShield Life)

Infection Control, Incident Management and Emergency Preparedness

Updated on 3 Sep 2021

Regulation 35-37: Infection control and fire safety

[ENHANCED] Risk of infection transmission must be minimised

- **[ENHANCED] Licensees shall prevent, manage and control spread of infection suspected to be connected with the provision of the licensable healthcare service on its premises/conveyance**
  - Environment surrounding and within the licensed premises/conveyance is clean and safe
  - All the equipment and facilities at the licensed premises/conveyance are clean and safe
  - **[NEW]** Use of equipment, instruments, appliances and materials shall comply with established or recommended procedures for their maintenance and use (e.g. dental pouches must not be reused)
  - Implementation of appropriate infection control processes
  - Ensure a system or process in place to enable notification of a notifiable disease as required under the Infectious Diseases Act.

- **[NEW] Biohazardous materials are appropriately stored, used and disposed**
  - "Biohazardous material" includes any substance which contains toxins, any biological waste, any culture medium, any contaminated blood, urine or faeces, and any infected tissue or organ.

- Licensees must take adequate precautions against risk of fire in accordance with the Fire Safety Act

Updated on 3 Sep 2021

Requirement of Measles and Diphtheria Vaccinations for Workers in Healthcare

[NEW] To minimise the risk of disease outbreak in the healthcare settings, through ensuring that workers in healthcare are immune and not the conduits for the spread of diseases to patients they are in contact with

- **To regularize MOH Circular No. 41/2018 as regulatory requirement**
- **All licensees are required to meet the requirement by 3 January 2022.**
  - Phase 1 licensees under HCSA to meet the requirement by 3 January 2022.
  - PHMCA Licensing Terms and Conditions (LTCs) will be promulgated for all current PHMCA licensees.
- The **licensee must ensure that all staff (existing and new) of licensees meet the following vaccination requirements:**
  - Measles: Completion of two doses of measles vaccination (Singapore citizens and permanent residents born in Singapore before 1975 may be exempted)
  - Diphtheria: Completion of one dose of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap), followed by a booster dose of tetanus and diphtheria toxoids (Td) or Tdap every 10 years.
- **For staff who are not directly under the licensees' employment but working within licensees' premise,** licensees to put in place measures (e.g. entering into **contractual agreements**) to place the onus of ensuring vaccination on their outsourced partners or co-located non-licensable healthcare service providers.
- **Exemptions -** Licensees would need to self-assess the exemption, and any exemptions will have to be justified by the licensees
  - Staff 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;
  - Staff who are permanently unfit for vaccination
  - Staff who are employed or engaged (by Licensees or otherwise) for carrying out of work that is performed, or who volunteer, on a one-off basis.

Safeguarding patient safety and welfare

Requirement of Measles and Diphtheria Vaccinations for Workers in Healthcare

Qn 1: 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?

- Staff 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 terms and conditions, and do not have acceptable evidence of immunity.
- This applies to all staff of partners and vendors which provide services(e.g. maintenance of equipment, infrastructure, couriers etc.) as well as volunteers, save 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 staff of outsourced partners/vendors as well as volunteers have, or acquire the required immunity under the licensing terms and conditions. These may include, for example, stipulating the requirements for immunity and vaccination in their contractual agreements with such partners and vendors.

Please refer to the FAQs for further details.

Updated on 3 Sep 2021

Regulation 38: Incident escalation

[NEW] Incidents are escalated in a timely manner to prevent further harm to patients

- **There is an institutional risk management framework, a service-level incident risk management framework, and incident escalation framework**
  - Timely escalation of incidents to the relevant person(s) in a management capacity
  - Minimum incidents to be addressed:
    a) Clinical incidents impacting or endangering public health or patient safety
    b) Clinical incidents with institutional wide impact;
    c) Incidents of abuse or allegation of abuse or breach of privacy;
    d) Any compromise of the computer system that directly affects the safety or welfare of patients, or confidentiality or security of data;
    e) Incidents impacting the structural safety (includes fire safety) of the licensed premises or conveyances;

- **Further and future harm to patients and customers which may arise or have arisen as a result of the incident must be prevented**
  - Licensee to undertake appropriate and timely actions, including proper risk assessments to limit the harm to patients, minimise the risks and prevent the incidents from re-occurring

Updated on 3 Sep 2021

Regulation 39: Emergency Preparedness

Healthcare institutions are prepared to respond to national emergencies

- **Requirements largely the same as under PHMCA**
  - A licensee must establish an effective emergency response plan to deal with or respond to any national emergency
  - Participate in national emergency efforts
  - Participate in planning, design and conduct of national emergency preparedness exercises
  - Develop emergency infection control measures
  - Ensure every personnel whom the licensee involves in responding to national emergency is competent in responding to a national emergency, including but not limited to, the wearing of the Personal Protection Equipment safely and properly
  - Keep adequate stock of PPE
    - i.e. N95 facemask (or equivalent), isolation gowns (or equivalent) and examination gloves (or equivalent)
- **Requirement for operationally-ready emergency response team to be scoped to services with inpatients**

Updated on 3 Sep 2021

Regulation 40: Business Continuity Plans

[NEW] There are business continuity plans to ensure continuity of service

- A licensee must maintain a plan of action setting out the procedures, and establishing the systems, necessary to restore, in the event of any disruption to the operation of the licensee's business, the fair, orderly and transparent operations of the licensee's business.
- A licensee must review the procedures and systems on a regular basis.

Miscellaneous

Updated on 3 Sep 2021

Protected terms and names

Tightened requirements for naming of licensed healthcare services

Rationale: To prevent misperception about licensed healthcare services

- **[NEW] Protection of "National" and "Singapore"**
  - Licensees not allowed to use such terms, unless approved
  - Criteria to be considered for approval:
    a) Where the licensee is fulfilling or intending to fulfil a national role or its equivalent;
    b) If the licensee has an overseas presence. 'Singapore' can then be used (in parentheses) to denote a branch location

Safeguarding patient safety and welfare

Updated on 3 Sep 2021

Protected terms and names

[ENHANCED] Protected terms and names

1. Accident and emergency
2. Accident and Emergency Department
3. Acute hospital
4. Ambulatory surgical centre
5. Assisted reproduction
6. Blood bank
7. Blood transfusion
8. Cell, tissue and gene therapy
9. Clinical genetic and genomic service
10. Clinical laboratory
11. Community hospital
12. Dental clinic
13. Diagnostic imaging laboratory
14. Egg bank
15. Embryo bank
16. Emergency ambulance
17. Emergency department
18. General hospital
19. General practitioner clinic
20. Health screening
21. Hospice
22. Inpatient hospice
23. Inpatient palliative care
24. In-vitro fertilisation
25. Maternity home
26. Medical and surgery
27. Medical centre
28. Medical clinic
29. Medical clinic and surgery
30. Medical laboratory
31. Medical transport
32. Mobile medicine
33. National Centre
34. National Specialty Centre
35. Nuclear medicine assay
36. Nuclear medicine imaging
37. Nuclear medicine therapy
38. Nursing home
39. Oocyte bank
40. Organ transplant
41. Polyclinic
42. Proton beam therapy
43. Radiation oncology
44. Radiology laboratory
45. Renal dialysis centre
46. Specialised interventional procedure
47. Specialist centre
48. Specialist clinic
49. Sperm banking
50. Surgical centre
51. Telemedicine
52. Tissue banking
53. Urgent Care Centre
54. Urgent Care Clinic
55. X-ray laboratory

For some terms, they will be protected but, in the course of enforcement, we will consider the context of how the terms are used

Updated on 26 Jan 2021

Regulations 41: Restrictions on use of name

- **[ENHANCED] Names must be accurate and not misleading.** Names of licensable service(s) must:
  - **a) Reflect the service(s) that the licensee is licensed to provide**;
  - b) Not contain words that **do not reflect the licensee's capability**, or **purport to be a different licensable service**
    - i. e.g. GP clinic cannot call itself a "hospital", a 24-hour clinic cannot call itself an "A&E" if it does not meet the A&E requirements that will be contained in the Acute Hospital regulations

- Exemption: Current licensees that use HCSA-restricted terms can retain their name under HCSA
  - 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, or when there is a change in name

Regulation 42: Outsourcing of licensable healthcare service

[ENHANCED] Clarity on liability and accountability of outsourced services

- **Licensees are accountable and responsible for any outsourced services**
  - Licensees must exercise oversight for any outsourced service to ensure that the safety, quality and continuity of care required by the licensee is adhered to
  - In event of a breach, both the licensee and outsourced service provider will be investigated and may be held accountable

- **Outsourcing contracts must be clear**
  - Contracts must be written and clearly delineate the scope of service, authority and responsibility of the outsourced providers versus the contracting party (licensee)

- **Outsourced clinical services that require physical patient interaction shall be provided onsite (i.e. where the patient is)**

- **Outsourced service providers must be legitimate**
  - Local service providers must be licensed under the relevant Acts
  - Outsourced services shall not be contracted to foreign providers, unless expressly permitted under Service Regulations

Safeguarding patient safety and welfare

[ENHANCED] Updated penalties to align with other legislation such as Health Products Act, Human Biomedical Research Act

	PHMCR	HCSA General Regulations
Maximum fine	$2,000	$20,000
Maximum imprisonment term	12 months	12 months
Maximum composition sum	$2,000	Half of the amount of the maximum fine or $10,000, whichever is lower

Regulatory Actions in lieu of criminal offences

	PHMCR	HCSA General Regulations
Type of sanctions	a) Criminal sanctions; or b) Suspension or revocation of licence	a) Criminal sanctions; b) Revocation of licence or other regulatory action

✓ **The Director may take the following regulatory action(s):**

- Censure the licensee in writing
- Modify any condition of the licence
- Require the furnishing of additional performance bond, guarantee or other form of security etc.
- Forfeit the whole or part of any performance bond, guarantee or other form of security etc.
- Direct the licensee to do or refrain from doing things to rectify a contravention or non-compliance or prevent a recurrence of the contravention or non-compliance
- Shorten the term of the licence without compensation and without refund of any fee
- Suspend the licence for a period of time in respect of all or any of the licensed premises or licensed conveyances
- Direct the licensee to pay a financial penalty of a maximum of $10,000

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The End

Thank you

MINISTRY OF HEALTH
SINGAPORE

Annex

Comparison of PHMCR and HCSA General Regulations provisions

Provision	PHMCA	HCSA
Licensing Matters		
Application of licence	Clause 6 of PHMCA Application for issue and renewal of licences Clause 3 of PHMCR Application for licence	Clause 4 Application for licence
Licence fee	Clause 5 of PHMCR Licence Fee	Clause 5 Licence Fee Clause 9 Waiver or refund of fee
Licensable healthcare services underlying to special licensable healthcare service	-	Clause 6 Licensable healthcare services underlying to special licensable healthcare service
Amendment of licence	Clause 4 of PHMCR General duty of licensee Clause 5(5)-(7A) of PHMCR Licence fees pertaining to amendment of licence	Clause 7 Amendment of licence
Notice of voluntary cessation of licensable healthcare service or surrender of licence	Clause 9 of PHMCR Notification of cessation, etc., of private hospital, medical clinic, clinical laboratory or healthcare establishment	Clause 8 Voluntary cessation of licensable healthcare service or surrender of licence

Comparison of PHMCR and HCSA General Regulations provisions

Provision	PHMCA	HCSA
Governance of licensees		
Compliance with Act	Clause 4 of PHMCR General duty of licensee Clause 13 of PHMCR Private hospitals Licensee of private hospitals Clause 35 of PHMCR Medical Clinics Licensee of medical clinics Clause 47 of PHMCR Clinical Laboratories Person to whom licence for clinical laboratory may be issued Clause 48 of PHMCR Clinical Laboratories Responsibilities of licensee	Clause 10 Compliance with Act
Appointment of and change in Key Appointment Holders, Principal Officer, Clinical Governance Officer	Clause 10 of PHMCR Persons who may manage private hospital, etc. Clause 11 of PHMCR Duty of Manager of private hospital	Clause 11 Appointment of and change in key appointment holders, Principal Officer and Clinical Governance Officers Clause 12 Change in majority of key appointment holders Clause 15 Appointment of Clinical Governance Officers
Removal of PO or CGO and appointment of another	-	Clause 13 Removal of Principal Officer or Clinical Governance Officer and appointment of another
Functions and duties of PO, CGO	-	Clause 14 Functions and duties of Principal Officer

Comparison of PHMCR and HCSA General Regulations provisions

Provision	PHMCA	HCSA
Employees of licensees		
Requirements to ensure proper supervision of employees	Clause 24 of PHMCR Laboratory services Clause 25 of PHMCR Medical services Clause 26 of PHMCR Nursing services Clause 43 of PHMCR Medical Clinics Clinic practices Clause 50 of PHMCR Clinical Laboratories Personnel	Clause 16 Employment of registered healthcare professionals
Employment restrictions to protect vulnerable patients	-	Will be added in Phase 3
Committees appointed by licensees		
Quality Assurance Committee	Clause 11 of PHMCA Quality Assurance Committee Clause 12A of PHMCR Prescribed healthcare institutions and requirements for quality assurance committees Clause 12B of PHMCR Quality assurance activities	Clause 17 Licensees required to appoint QAC Clause 18 Functions and duties of QAC Clause 19 Duties of QAC licensee Clause 20 Appointment of supervisor of quality assurance activities Clause 21 Participation of non-QAC licensee in quality assurance activities
Service Review Committee	-	Will be added in Phase 3
Clinical Ethics Committee	PHMCA LTC on HEC	Will be added in Phase 3

Comparison of PHMCR and HCSA General Regulations provisions

Provision	PHMCA	HCSA
Premises, Conveyances, Equipment and Products		
Licensed premises and conveyances	Clause 32 of PHMCR Private Hospitals Equipment Clause 38, 39, 40 of PHMCR Medical Clinics Facilities for surgery, anaesthesia, Resuscitation facilities Clause 42 of PHMCR Medical Clinics Equipment Clause 51 of PHMCR Clinical Laboratories Facilities	Clause 22 Licensed premises and conveyances
Use of licensed premises or licensed conveyance for other purposes	Clause 5.(2) Licences for private hospitals, medical clinics, clinical laboratories and healthcare establishments Clause 30 of PHMCR Provision of other unrelated services Clause 45 of PHMCR Premises of medical clinic to be properly separated from premises used for other services	Clause 23 Use of licensed premises or licensed conveyance for other purposes
Handling of medicinal products, health products and specimens		
Safe and appropriate usage of medicinal and health products	Clause 27 of PHMCR Pharmaceutical services Clause 28 of PHMCR Drugs, etc.	Clause 24 Application of this Part Clause 25 Purchase of medicinal products and health products Clause 26 Dispensing, storage and disposal of medicinal products and health products Clause 27 Prescription of medicinal products and health products
Safe and proper handling specimens	-	Clause 28 Packaging and transport of specimens

Comparison of PHMCR and HCSA General Regulations provisions

Provision	PHMCA	HCSA
Service standards		
Requirements to protect the safety and welfare of patients	Clause 36 of PHMCR Patients under treatment	Clause 29 Privacy and dignity of care Clause 30 Safeguard against abuse and neglect
Informed consent	-	Clause 31 Communications with patients
Safe record-keeping of healthcare services	Clause 12 of PHMCR Records Clause 54 of PHMCR Clinical Laboratory Report on tests	Clause 32 Patients' health records
Price transparency		
Price transparency	Clause 11 of PHMCR Duty of manager of private hospital and LTCs on provision of information on charges and financial counselling	Clause 33 Display of common charges Clause 34 Itemisation of bill Clause 35 Financial counselling

Comparison of PHMCR and HCSA General Regulations provis

Updated on 25 Feb 2021

Provision	PHMCA	HCSA
Infection control, Incident Management, and Emergency Preparedness		
Infection control measures	Clause 33 of PHMCR Private Hospitals Infection control	Clause 36 Infection control Clause 37 Management of biohazardous materials
Measles and Diphtheria Vaccinations for Workers in Healthcare	Licensing Terms and Conditions on measles and diphtheria vaccinations to be issued on 1 June 2021	Requirement of Measles and Diphtheria Vaccinations for Workers in Healthcare
Incident management	-	Clause 39 Incident escalation
Emergency Preparedness	Clause 56A of PHMCR Emergency response plans and emergency response teams Clause 56B of PHMCR Participation in emergency preparedness exercises	Clause 40 Emergency preparedness
Business Continuity Plans	-	Clause 41 Business continuity planning
Step-in Arrangements	-	Will be included in Phase 3
Miscellaneous		
Restrictions on use of term or name	Clause 59 of PHMCR Use of title or name	Clause 42 Restrictions on use of name
Liability and accountability of outsourced services	Clause 55 of PHMCR Outsourcing of conduct of test and examination of samples	Clause 43 Outsourcing of licenseable healthcare service
Penalties	Clause 20 of PHMCA Composition of fines Clause 60 of PHMCR Penalty	Clause 44 Offence

HCSA service definitions (tentative)

Phase 1 Services	Definition
Licensable healthcare service	“licensable healthcare service” means any of the following healthcare services: (a) Clinical Support Services: (i) Clinical laboratory service; (ii) Tissue banking service; (iii) Blood banking service; (iv) Radiological laboratory service; (b) Specified Services: (i) Nuclear medicine imaging and assay service.
Blood banking service	“blood banking service” means a service relating to blood and blood products for therapeutic transfusion, comprising the following: (a) collection of blood and blood products; (b) testing, processing, distribution and storage of blood and blood products
Clinical laboratory service	“clinical laboratory service” means the examination or testing of any matter derived from the body of any individual for the purpose of — (a) assessing the health, condition or genetic predisposition of that individual or any other individual; (b) predicting or providing a prognosis of the health or medical condition of that individual or any other individual; (c) diagnosing a disease, disability or condition or an injury of the body or mind of that individual or any other individual; (d) determining the intervention to be taken, or the effect of any intervention taken, of a disease, disability or condition or an injury of the body or mind of an individual; (e) ascertaining the cause of death of that individual or any other individual, or the result of a medical or surgical treatment given to that individual or any other individual; or (f) assessing the health, condition or suitability of any human biological material that is used, or is intended to be used, in relation to any healthcare service;

HCSA service definitions (tentative)

Phase 1 Services	Definition
Nuclear medicine imaging and assay service	“nuclear medicine imaging and assay service” means a service comprising the following: (a) the use of radioactive substances (including radionuclides) for the purposes of medical diagnosis or monitoring the effects of therapy; (b) laboratory procedures that involve the use of radioactive substances, including radionuclides;
Radiological laboratory service	“radiological laboratory service” means the use of ionising or non-ionising radiation for any of the following purposes: (a) examination of the body, or any matter derived from the body, of an individual; (b) assessment of the health or condition of an individual; (c) observation, diagnosis and intervention of a disease, disability or condition or an injury of the body or mind of an individual; (d) provision of care for an individual; (e) determining, predicting or providing a prognosis of the health or condition of an individual;
Tissue banking service	“tissue banking service” means the acquisition, processing and storage of biological material derived or obtained from the body of an individual, which is distributed for subsequent use in the body of the same or another individual, and includes the screening of any donor, but does not include any blood banking service

HCSA service definitions (tentative)

Phase 1 Services	Definition
Emergency Ambulance Service	"Emergency ambulance service" – (a) means the provision of healthcare services to an individual using an emergency ambulance that is used or intended to be used for transporting, by land, any individual suffering, or believed to be suffering, from an injury or a condition that is a medical emergency or that has an acute onset; and (b) includes the clinical evaluation, diagnosis and provision of treatment to, care of or intervention with the individual while the individual is being transported by the emergency ambulance.
Medical Transport Service	"Medical transport service" – (a) means the provision of healthcare services to an individual using a medical transport that is used or intended to be used for transporting, by land, any individual suffering, or believed to be suffering, from an injury or a condition that is not a medical emergency or that does not have an acute onset; and (b) includes the provision of clinical care and monitoring while the individual is being transported by the medical transport.

HCSA service definitions (tentative)

Phase 2 Services	Definition
Medical Clinic Service	"Medical clinic service" – (a) means a service where a medical practitioner provides all or any of the following services to an individual: (i) the examination of the individual's body or mind; (ii) the [conduct/performance] of any point-of-care test on the individual; (iii) the assessment of the individual's health; (iv) the observation and diagnosis of, and intervention in, the individual's health condition; (v) the treatment of the individual for any disease, injury, disability or condition; (vi) the provision of [medical?] care to the individual; (vii) the performance of any clinical procedure that changes, or is intended to change, the individual's appearance or anatomy; but (a) excludes the following: (i) the provision, in relation to any service mentioned in sub-paragraph (a), of accommodation to the individual for a period exceeding 12 hours; (ii) the provision of any service mentioned in sub-paragraph (a), where general anaesthesia is used in the course or for the purpose of providing the service; (iii) the provision of a health screening service, independent of the provision of any service mentioned in sub-paragraph (a).

HCSA service definitions (tentative)

Phase 2 Services	Definition
Dental Clinic Service	““Dental clinic service” – (a) means a service where a dentist provides all or any of the following services to an individual: (i) the examination of the individual’s body; (ii) the [conduct/performance] of any point-of-care test on the individual; (iii) the assessment of the individual’s health; (iv) the observation and diagnosis of, and intervention in, the individual’s health condition; (v) the treatment of the individual for any disease, injury, disability or condition; (vi) the provision of dental care to the individual; (vii) the performance of any clinical procedure that changes, or is intended to change, the individual’s appearance or anatomy; but (b) excludes the following: (i) the provision, in relation to any service mentioned in sub-paragraph (a), of accommodation to the individual for a period exceeding 12 hours; (ii) the provision of any service mentioned in sub-paragraph (a), where general anaesthesia is used in the course or for the purpose of providing the service. (iii) the provision of a health screening service, independent of the provision of any service mentioned in sub-paragraph (a).

HCSA service definitions (tentative)

Phase 2 Services	Definition
Ambulatory Surgical Centre Service	"Ambulatory surgical centre service" – (a) means the provision of anaesthesia and surgical treatment to an individual in an operating theatre, and includes the following: (i) the examination of the individual's body or mind; (ii) the [conduct/performance] of any point-of-care test on the individual; (iii) the assessment of the individual's health; (iv) the observation and diagnosis of, and intervention in, the individual's health condition; (v) the treatment of the individual for any disease, injury, disability or condition; (vi) the provision of [medical?] care to the individual; (vii) the performance of any clinical procedure that changes, or is intended to change, the individual's appearance or anatomy; but (b) excludes the following: (i) the provision, in relation to any service mentioned in sub-paragraph (a), of accommodation to the individual for a period exceeding 24 hours; MOH: The use of the term "medical" is appropriate. However, we wish to highlight that there are ASCs which provide dental services as well. As such, we may have to include the term "dental" in the definition.
Renal Dialysis Service	"Renal dialysis service" means the provision of renal dialysis treatment and services related to that treatment to an individual, and includes the [conduct/performance] of any point-of-care test on the individual.
Health Screening Service	"Health screening service" means a service involving the examination or testing of an individual for all or any of the following purposes: (a) detecting the presence of any risks to the health of the individual; (b) assessing whether the individual has or is susceptible to any disease, injury, disability or condition of the body or mind, including where the individual is not known to have any symptoms of that disease, injury, disability or condition, as the case may be.

HCSA service definitions (tentative)

Phase 2 Services	Definition
Assisted Reproduction Service	"Assisted reproduction service" – (a) means the provision of treatment and related laboratory procedures in relation to the following: (i) the removal or attempted removal of oocytes from a woman for any purpose; (ii) the storage and handling of human gametes and embryos for the purpose of conception, but (b) excludes the provision of assisted conception procedures such as intrauterine insemination (IUI)
Radiation Oncology	"Radiation oncology" means a service for the treatment of any condition or disease using ionising radiation.
Blood Transfusion Service	"Blood transfusion service" means a service providing for the administration to an individual, by bolus injection or continuous infusion, of the following, whether obtained from that individual or one or more other individuals: (a) whole blood; (b) any blood component or product that is derived from plasma, red blood cells, white blood cells or platelets.
Nuclear Medicine Therapy Service	"Nuclear medicine therapy service" means a service involving the provision of therapy for any disease or condition using radioactive substances.

HCSA service definitions (tentative)

Phase 3 Services	Definition
Acute Hospital Service	"Acute hospital service" means a service comprising the following: (a) the provision of all or any the following to an individual: (i) the examination of the individual's body or mind; (ii) the assessment of the individual's health; (iii) the observation and diagnosis of, and intervention in, the individual's health condition; (iv) the care and treatment of the individual for any disease, injury, disability or condition; (v) the rehabilitation of the individual; (b) the performance of any clinical procedure that changes, or is intended to change, the individual's appearance or anatomy; (c) where the individual is a pregnant woman, the reception and medical care of the individual before, during and after giving birth, including antenatal and postnatal care and child delivery service; (d) the provision, in relation to any service mentioned in sub paragraph (a), (b) or (c), of accommodation to the individual for a period [, as estimated at the time of the individual's admission,] of not less than 24 hours.
Community Hospital Service	"Community hospital service" means: (i) the provision of care (other than care of the level and intensity provided by the licensee of an acute hospital service) to, and rehabilitation of, a relevant individual; and (ii) the provision, in relation to the service mentioned in sub-paragraph (i), of accommodation to the relevant individual for a period, as estimated at the time of the relevant individual's admission, of not less than 24 hours; and may include long-term residential care to an individual who, at the time of the individual's admission – (i) has any medical condition resulting in the individual's disability; (ii) has poor prognosis for recovery; and (iii) requires occasional medical support throughout the individual's admission. "Relevant individual" means an individual who requires either of the following: (a) continuing convalescent care, including following the individual's discharge from an acute hospital; (b) continuing medical and nursing care, and support from allied health professionals, for the individual's rehabilitation.

HCSA service definitions (tentative)

Phase 3 Services	Definition
Nursing Home Service	"Nursing home service" – (a) means a service for the provision of long-term residential care , for the nursing of persons suffering or convalescing from any sickness, injury or infirmity; and (b) may include the provision of long-term residential care, to an individual who, at the time of the individual's admission – (i) has any medical condition resulting in the individual's disability; (ii) has poor prognosis for recovery; and (iii) requires long-term maintenance nursing support and occasional medical support throughout the individual's admission, but (c) excludes a community hospital service or an inpatient palliative care service. For avoidance of doubt, a service provider that only provides services in limb (a) but not limb (b) is taken to provide a nursing home service as well.
Inpatient Palliative Care Service	"Inpatient palliative care service" means the provision of the following services to an individual with a life-limiting condition or illness : (a) the holistic assessment of the individual's physical, social, spiritual and cultural needs and preferences, and the planning of medical and nursing care required by the individual; (b) medical and nursing care to provide the individual with relief from pain and other distressing symptoms; (c) accommodation, in relation to the services mentioned in sub-paragraphs (a) and (b), of the individual for a period not less than 24 hours.
Telemedicine Service	"Telemedicine service" means a service involving the assessment of health, diagnosis, treatment, intervention or care where the service is provided exclusively through the use of info-communications technology by a medical practitioner or dentist.

HCSA service definitions (tentative)

Phase 3 Services	Definition
Organ Transplant Service	"Organ" – (a) means any organ and part of the human body that may be used for therapy or transplantation under any written law; and (b) includes tissues, bones and blood vessels of a human body. Organ transplant services means the provision of any of the following services: (a) the selection and evaluation for suitability, for the purposes of a proposed living donor organ transplant, of an individual as a living donor or recipient of a specified organ; (b) the medical screening, care and management, after a living donor organ transplant has been carried out, of a living donor of a specified organ; (c) the medical care and management of an individual who is to undergo, is undergoing or has undergone a transplant of any organ or part, including a living donor organ transplant of a specified organ.
Cell, Tissue and Gene Therapy	"Cell, tissue and gene therapy" – (a) means a service involving the processing, collection or use of any of the following: (i) autologous or allogeneic human cells or tissues; (ii) xenogeneic cells or tissues; (iii) recombinant nucleic acids, i.e. modified deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) as carriers of a therapeutic gene)., for administration to an individual for the diagnosis, treatment, or prevention of any disease or condition, or to change the appearance or anatomy of an individual; but (b) excludes the following: (i) an organ transplant service; (ii) the transplantation of haematopoietic stem cells; (iii) a blood transfusion service; (iv) an assisted reproduction service

HCSA service definitions (tentative)

Phase 3 Services	Definition
Clinical Genetic and Genomic Service	“Clinical genetic and genomic service” means a service for the diagnosis, management, risk assessment, education and provision of counselling services to an individual or the individual’s family members in relation to any condition that has a genetic basis.
Specialised Interventional Procedures Service	“Specialised interventional procedures service” means a service for the provision of endovascular procedures that are image guided, minimally invasive and used for diagnostic or therapeutic purposes.