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HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES (GENERAL) REGULATIONS 2021

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In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Healthcare Services (General) Regulations 2021 and come into operation on 3 January 2022.

Definitions

2. In these Regulations, unless the context otherwise requires —

"abuse", "emotional or psychological abuse", "neglect", "physical abuse" and "wellbeing" have the meanings given by section 2(1) of the Vulnerable Adults Act 2018;

"calendar day" includes Saturday, Sunday and every public holiday;

"clinical incident" means an event or a circumstance that has resulted, or is likely to result, in harm to a patient;

"clinical risk" means the impact of a clinically unsafe environment or situation on the safety and wellbeing of patients and persons who perform or are engaged in any work relating to the provision of a licensable healthcare service;

"electronic licensing system" means the electronic licensing system established and maintained by the Ministry of Health for the purposes of the Act, that is accessible on the Ministry's website;

"enterprise risk", in relation to a licensee's business of providing a licensable healthcare service, means the risk to service delivery and continuity;

"health product" has the meaning given by section 2 of the Health Products Act 2007;

"healthcare professional" means —

(*a*) an allied health professional who is registered under the Allied Health Professions Act 2011 and holds a valid practising certificate under that Act;

(*b*) a dentist or an oral health therapist who is registered under the Dental Registration Act 1999 and holds a valid practising certificate under that Act;

(*c*) a medical practitioner who is registered under the Medical Registration Act 1997 and holds a valid practising certificate under that Act;

(*d*) a nurse or midwife who is registered, or an enrolled nurse who is enrolled, under the Nurses and Midwives Act 1999 and holds a valid practising certificate under that Act;

(*e*) an optometrist or optician who is registered under the Optometrists and Opticians Act 2007 and holds a valid practising certificate under that Act;

(*f*) a pharmacist who is registered under the Pharmacists Registration Act 2007 and holds a valid practising certificate under that Act; or

(*g*) a traditional Chinese medicine practitioner who is registered under the Traditional Chinese Medicine Practitioners Act 2000 and holds a valid practising certificate under that Act;

"infectious disease" has the meaning given by section 2 of the Infectious Diseases Act 1976;

"licence", in relation to a licensee, means a licence granted under the Act and that is in force, authorising the licensee to provide the licensable healthcare service specified in the licence;

"licensable healthcare service", in relation to an applicant or a licensee, means a licensable healthcare service that the applicant intends to provide under a licence or the licensee is authorised by a licence to provide, as the case may be;

"licensee", in relation to a licensable healthcare service, means the person who is authorised by a licence to provide that licensable healthcare service;

"medicinal product" has the meaning given by section 3 of the Medicines Act 1975;

"medisave account" means a medisave account maintained under section 13 of the Central Provident Fund Act 1953;

"MediShield Life Scheme" means the MediShield Life Scheme established by section 3 of the MediShield Life Scheme Act 2015;

"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;

"personnel", in relation to a licensee, means any individual employed or engaged by the licensee to assist the licensee in providing the licensable healthcare service;

"specimen" means any biological material or matter derived or obtained from the body of an individual for use in, or in connection with, the provision of a licensable healthcare service.

PART 1

ELECTRONIC LICENSING SYSTEM

Electronic licensing system

3.—(1) The Director may —

(*a*) require or permit any person to carry out any transaction with the Director under the Act or these Regulations; and

(*b*) issue any approval, licence, notice, determination or other document pursuant to or connected with a transaction mentioned in sub-paragraph (*a*),

using the electronic licensing system.

(2) Despite paragraph (1), the Director may, in any particular case —

(*a*) require or permit a person to carry out any transaction mentioned in paragraph (1)(*a*) in any other manner specified by the Director; or

(*b*) issue any document mentioned in paragraph (1)(*b*) in any other manner that the Director thinks fit.

(3) In this regulation —

"document" includes any application, form, report, certification, notice, declaration, return or other document (whether in electronic form or otherwise) filed with or submitted to the Director;

"transaction" means —

(*a*) the filing of any document with the Director, or the submission, production, delivery, providing or sending of any document to the Director;

(*b*) the making of any application, submission or request to the Director;

(*c*) the provision of any declaration or undertaking to the Director; or

(*d*) the extraction, retrieval or accessing of any document, record or information maintained by the Director.

PART 2

LICENSING MATTERS

Application for licence

4.—(1) An applicant may apply for the grant or renewal of one or more licences in a single application, which must be accompanied by an application fee for each licence as determined in accordance with the Healthcare Services (Fees) Regulations 2021 (G.N. No. S 1032/2021).

(2) An application for the grant of one or more licences must be made no later than 2 months before the licensable healthcare service to which the licence or each of the licences (as the case may be) relates is provided to the public.

(3) An application to renew any licence must be made no later than 2 months before the date the licence expires (called in this regulation the renewal deadline).

(4) Where an application to renew a licence is made after the renewal deadline, the applicant must, at the time of making the application for renewal, pay a late renewal application fee of an amount specified in the Healthcare Services (Fees) Regulations 2021.

Special licensable healthcare services and underlying licensable healthcare services

5.—(1) For the purposes of the definition of "special licensable healthcare service" in section 2(1) of the Act, the licensable healthcare services set out in Part 1 of the First Schedule are special licensable healthcare services.

(2) For the purposes of sections 11(3)(*c*) and 13(3) of the Act, each licensable healthcare service specified in the second column of Part 2 of the First Schedule is prescribed as an underlying licensable healthcare service to the special licensable healthcare service set out in the first column of that Schedule corresponding thereto.

Amendment of licence

6.—(1) An application to amend the name of a licensee must be made by the licensee concerned no later than one month before the amendment is to take effect.

(2) An application to amend the particulars of a licence, other than the licence conditions and the particulars mentioned in paragraph (1), must be made by the licensee concerned no later than 10 calendar days before the amendment is to take effect.

Transfer of licence

7. Where there is a change of the licensee because of a transfer or an assignment of a licence, or of any rights, benefits or privileges under a

licence, under section 16(1) of the Act, the original licensee must apply to the Director to amend the name of the licensee in the licence no later than one month before the transfer or assignment is to take effect.

Voluntary cessation of licensable healthcare service or surrender of licence

8.—(1) For the purposes of section 17(2) of the Act, the prescribed time for giving of the notice to the Director is one month.

(2) Before a licensee wholly and permanently stops providing any licensable healthcare service, or stops using any licensed premises or licensed conveyance specified in the licence, or surrenders the licence, the licensee must do all the following:

(*a*) ensure that every patient of the licensee continues to receive adequate and proper care or accommodation, whether by the licensee in another licensed premises or conveyance, or by another licensee;

(*b*) ensure that the measures in regulation 39(1)(*a*), (*b*) and (*c*) are taken;

(*c*) comply with every direction given by the Director in relation to the accommodation, care and medical information of the patients until the cessation of the licensable healthcare service, licensed premises or licensed conveyance, or surrender of the licence, as the case may be.

PART 3

GOVERNANCE OF LICENSEES

Compliance with Act, etc.

9.—(1) The licensee is responsible for complying with —

(*a*) the provisions of the Act and these Regulations, the licence conditions and all directions and codes of practice given or issued under the Act that are applicable to the licensee; and

(*b*) the provisions of any other written law regulating or relating to the provision of any licensable healthcare

service in a safe and proper manner, that are applicable to the licensee.

(2) For the purposes of compliance under paragraph (1) —

(*a*) the licensee must ensure that the Principal Officer and every Clinical Governance Officer appointed by the licensee have the necessary authority and are adequately empowered to carry out their duties under the Act and these Regulations; and

(*b*) the licensee must not obstruct the licensee's Principal Officer or any of the licensee's Clinical Governance Officers from carrying out his or her duties in compliance with the Act and these Regulations.

Appointment of and change in key appointment holders, Principal Officer and Clinical Governance Officers

10.—(1) For the purposes of sections 23(3) and 24(5) of the Act, the prescribed period for notifying the Director of the appointment of, or any change in, any key appointment holder, the Principal Officer or any Clinical Governance Officer of a licensee is 10 calendar days after the appointment or change, as the case may be.

(2) A notice under paragraph (1) must include a declaration by the licensee —

(*a*) in relation to every key appointment holder appointed by the licensee, about the matters mentioned in section 2(3)(*a*) to (*d*) of the Act; or

(*b*) in relation to the Principal Officer and every Clinical Governance Officer appointed by the licensee —

(i) that they are suitable persons to act as the licensee's Principal Officer or Clinical Governance Officer, as the case may be; and

(ii) about the matters mentioned in section 2(3)(*a*) to (*d*) of the Act,

as the case may be.

(3) Where any matter in a declaration made by a licensee under paragraph (2) in relation to any key appointment holder, Principal Officer or Clinical Governance Officer is no longer accurate due to a change of circumstances of the key appointment holder, Principal Officer or Clinical Governance Officer (as the case may be), the licensee must notify the Director of the change.

Change in majority of key appointment holders

11. Without affecting regulation 10(1), if at any time a licensee intends to remove or substitute more than half in number of the licensee's key appointment holders, the licensee must notify the Director of the proposed change one month before the removal or substitution takes effect.

Removal of Principal Officer or Clinical Governance Officer and appointment of another

12. For the purposes of section 24(10)(*a*) and (*b*) of the Act, the prescribed period for the appointment of another Principal Officer or Clinical Governance Officer is 10 calendar days after the removal of the previously appointed Principal Officer or Clinical Governance Officer, as the case may be.

Functions and duties of Principal Officer

13.—(1) The functions and duties of the Principal Officer of a licensee are as follows:

(*a*) to exercise oversight over the day-to-day provision of the licensable healthcare service by the licensee;

(*b*) to ensure that the licensable healthcare service is, at all times, provided in a manner that ensures the safety, welfare and continuity of care of the licensee's patients and customers;

(*c*) to ensure the safe operation of every licensed premises and licensed conveyance, and the safety of persons at every licensed premises and licensed conveyance;

(*d*) to oversee the implementation of processes to review and manage any clinical risk and enterprise risk that may arise

in the provision of the licensable healthcare service, and ensure that the licensee and every personnel comply with the processes.

(2) For the purposes of paragraph (1)(*a*), the Principal Officer's duty in relation to the day-to-day provision of the licensable healthcare service includes the following:

(*a*) where a matter requires the Principal Officer's attention —

(i) the Principal Officer must be available at the licensed premises or licensed conveyance to handle the matter; or

(ii) if the Principal Officer cannot be so available, the Principal Officer must appoint a suitably qualified and competent employee of the licensee to be present at the licensed premises or licensed conveyance to handle the matter on the Principal Officer's behalf;

(*b*) the Principal Officer must at all times be contactable by any personnel.

(3) Despite paragraph (1) and subject to paragraph (4), the Principal Officer must, before making any decision on a clinical matter, consult —

(*a*) if one or more Clinical Governance Officers are appointed — the Clinical Governance Officer who oversees the subject that the clinical matter relates; and

(*b*) in any other case — any key appointment holder of the licensee who is a healthcare professional with clinical experience that is relevant to the licensable healthcare service.

(4) The Principal Officer is not required to consult any key appointment holder under paragraph (3)(*b*) if the Principal Officer is also a healthcare professional with clinical experience that is relevant to the licensable healthcare service.

Appointment of Clinical Governance Officers

14.—(1) For the purposes of section 24(2) of the Act, the prescribed licensable healthcare services for which a licensee must appoint one or more Clinical Governance Officers are specified in the Second Schedule.

(2) If a licensee appoints more than one Clinical Governance Officer for a prescribed licensable healthcare service, the licensee must ensure that the responsibilities of each Clinical Governance Officer are clearly delineated and all the Clinical Governance Officers are informed of their respective responsibilities.

Functions and duties of Clinical Governance Officer

15.—(1) The principal functions and duties of a Clinical Governance Officer of a licensee are as follows:

(*a*) to provide clinical governance and technical oversight over the licensable healthcare service;

(*b*) to assist the licensee in the day-to-day management of the clinical and technical aspects of the licensable healthcare service;

(*c*) to ensure the implementation and regular review of policies and systems for clinical governance, clinical risk management, effective quality management systems and any other clinical and technical related matters, so as to detect and address in a timely manner any risks affecting the safety and welfare of, or the continuity of care provided to, patients;

(*d*) to ensure that any weakness or inadequacy related to any clinical or technical aspect of the licensable healthcare service is promptly identified and remedied, including informing the licensee of the weakness or inadequacy, and proposing and implementing measures to prevent the recurrence of the weakness or inadequacy;

(*e*) to ensure that the licensee's personnel involved in the clinical or technical aspect of the licensable healthcare

service comply with the appropriate policies and processes concerning clinical and technical standards;

(*f*) to ensure that there is close supervision, adequate training and regular competency assessments of the licensee's personnel involved in the clinical or technical aspect of the licensable healthcare service, to enable them to perform their work effectively and safely;

(*g*) to immediately notify the licensee of any matter within the Clinical Governance Officer's purview that may affect compliance of any licence condition applicable to the licensable healthcare service.

(2) To avoid doubt, paragraph (1) does not restrict any other regulations made under the Act from prescribing additional functions and duties of a Clinical Governance Officer in respect of a licensable healthcare service.

Licensee's duty to ensure continued suitability of Principal Officer and Clinical Governance Officers

16. For the purposes of section 24(7) of the Act, a licensee must ensure that the individual appointed to act as the Principal Officer and every individual appointed to act as Clinical Governance Officer are, during the term of the respective individuals' appointments, resident in Singapore so as to be able to effectively carry out the functions and duties of a Principal Officer or Clinical Governance Officer, as the case may be.

PART 4

PERSONNEL

Employment or engagement of suitable personnel

17.—(1) A licensee must employ or engage such number of suitable personnel as is necessary to ensure the safety of the licensee's patients and the quality of care that the licensee is reasonably expected to provide to the patients.

(2) For the purposes of determining the suitability of a person to be employed or engaged as personnel under paragraph (1), the matters that the licensee must have regard include (but are not limited to) the professional qualifications, skills and competencies that the person possesses.

(3) For the purposes of ensuring proper accountability and supervision of every personnel, the licensee must establish and maintain proper systems to ensure adequate division of duties and clear reporting lines.

Healthcare professionals

18. A licensee must establish and implement a policy, and establish and maintain the appropriate processes, for the suspension, termination, limitation or reduction of the clinical privileges to which the healthcare professionals employed or engaged by the licensee are entitled, in the event that any such healthcare professional is found guilty of professional misconduct in any disciplinary proceedings or is subject to disciplinary proceedings.

PART 5

COMMITTEES APPOINTED BY LICENSEES

Definitions for this Part

19. In this Part —

"clinical appropriateness", in relation to a licensable healthcare service provided by a QAC licensee to a patient, means the appropriateness of the clinical care that is provided to the patient, as determined by —

(*a*) the extent to which the relevant clinical care plans and clinical procedures are properly executed by the QAC licensee in relation to the patient; and

(*b*) whether there is evidence that those clinical procedures are beneficial to the patient;

"mortality and morbidity review" or "MMR" means a review of the circumstances surrounding the death of a patient, or of

any clinical incident with other adverse consequences (but is not death or a serious reportable event);

"peer review learning" or "PRL" means the encouragement of learning and improvement of quality of care through a documented review and evaluation of a specialist's competencies and performance by one or more other specialists in the same branch of medicine, including identifying the areas for improvement;

"QAC licensee" means a licensee who belongs to any of the categories of licensees specified in the first column of the Third Schedule that is required to appoint a quality assurance committee;

"quality assurance committee" or "QAC" means a quality assurance committee appointed pursuant to regulation 20;

"serious reportable event" means an adverse event occurring, or that has occurred, during the care or treatment of a patient that —

(*a*) has caused, or is likely to cause, death, serious injury or other harm to the patient; and

(*b*) is not an intended or expected outcome of any examination, procedure or treatment provided to the patient;

"specialist" means a person who is registered as a specialist in the Register of Specialists under section 22 of the Medical Registration Act 1997 or section 14C of the Dental Registration Act 1999.

Licensees required to appoint QAC

20. For the purposes of section 25 of the Act, the category of licensees specified in the first column of the Third Schedule must appoint one or more quality assurance committees specified in the second column of that Schedule opposite that category of licensees.

Quality assurance

21.—(1) A QAC licensee must ensure that the quality, safety standards and clinical appropriateness of the licensable healthcare service that the QAC licensee provides are monitored and evaluated regularly by one or more QACs, and the timely implementation of the recommendations by the QACs to improve the quality and safety standards of the licensable healthcare service.

(2) The functions and duties of a QAC are as follows:

(*a*) to devise and maintain a quality assurance programme for the purposes of evaluating and monitoring —

(i) the quality and clinical appropriateness of the licensable healthcare service provided by the QAC licensee to patients; and

(ii) the procedures and practices of the QAC licensee in relation to the provision of the licensable healthcare service;

(*b*) to identify —

(i) any serious reportable event; or

(ii) any case for peer review learning or mortality and morbidity review (called in this Part a PRL case or an MMR case, respectively),

as the case may be, that has occurred or may occur in the course of providing, or in relation to the provision of, the licensable healthcare service by the QAC licensee;

(*c*) to evaluate any serious reportable event, PRL case or MMR case (as the case may be) mentioned in sub-paragraph (*b*), so as to assess whether the quality of the licensable healthcare service provided by the QAC licensee is, in the opinion of the QAC, acceptable;

(*d*) to identify and develop solutions for any problem that has arisen or may arise in connection with any serious reportable event, PRL case or MMR case (as the case may be) mentioned in sub-paragraph (*b*);

(*e*) to make recommendations to the QAC licensee to improve the quality of the licensable healthcare service provided by the QAC licensee and to prevent the occurrence or recurrence of any serious reportable event, PRL case or MMR case (as the case may be) mentioned in sub-paragraph (*b*), that was identified previously;

(*f*) to monitor the implementation by the QAC licensee of the recommendations mentioned in sub-paragraph (*e*);

(*g*) to ensure that the requirements relating to QAC in these Regulations and any directive issued by the Director to the QAC licensee are complied with;

(*h*) to conduct such other quality assurance activity or programme as the Director requires.

Appointment of supervisor of quality assurance activities

22.—(1) Every QAC licensee must appoint, for each QAC appointed by the QAC licensee, a suitably qualified and competent individual (called in this regulation the QAC supervisor), who may or may not be a member of the QAC, to oversee and supervise the quality assurance activities of the QAC.

(2) In overseeing and supervising the quality assurance activities of the QAC, the QAC supervisor must —

(*a*) maintain an ongoing quality assurance programme in accordance with the licence conditions applicable to the QAC licensee;

(*b*) ensure the timely identification and reporting of such cases for peer review learning and mortality and morbidity review and such serious reportable events as may be specified in the licence conditions; and

(*c*) in the case of a QAC for MMR cases or serious reportable events, ensure that the QAC institutes an effective system for a root cause analysis of every MMR case or serious reportable event (as the case may be), and recommends appropriate solutions in a timely manner to prevent a further recurrence.

Participation of non-QAC licensee in quality assurance activities

23. A licensee that is not a QAC licensee must, if directed by the Director —

(*a*) participate in such quality assurance activities as the Director may specify; and

(*b*) provide to the Director such information as the Director may require in relation to any quality assurance activity that the licensee has participated.

PART 6

LICENSED PREMISES, LICENSED CONVEYANCES AND EQUIPMENT, ETC.

Licensed premises, licensed conveyances and equipment, etc.

24. In the provision of a licensable healthcare service, a licensee must ensure that —

(*a*) every licensed premises and licensed conveyance are safe, sanitary, accessible and appropriately equipped; and

(*b*) all medical and surgical equipment, instruments, appliances, materials and facilities necessary for patient care are checked regularly, and maintained properly and according to the manufacturer's specifications, so as to ensure that they are adequate, functional and effective and the licensable healthcare service is provided safely.

Security of equipment data

25. A licensee must, in respect of every equipment used for the provision of a licensable healthcare service that holds data, ensure that —

(*a*) the equipment is secured against unauthorised access, interference and tampering;

(*b*) the data held in the equipment is protected from unauthorised local or remote electronic access by implementing appropriate security measures;

(*c*) the security measures mentioned in paragraph (*b*) are reviewed regularly; and

(*d*) the transmission of the data held in the equipment to any person authorised by the licensee to receive such data is done so securely.

Use of licensed premises or licensed conveyance for other purposes

26.—(1) For the purposes of section 30(1)(*c*) of the Act and subject to paragraph (3), a licensee may use, or allow any other person to use, the whole or any part of any licensed premises or licensed conveyance to provide a non-licensable healthcare service specified in the Fourth Schedule (called in this regulation a specified healthcare service).

(2) For the purposes of section 30(2) of the Act and subject to paragraph (3), a licensee may use, or allow any other person to use, any part (but not the whole) of any licensed premises or licensed conveyance to provide a service (called in this regulation a co-located service) that is not mentioned in section 30(1) of the Act if the licensee has obtained the prior permission of the Director to do so.

(3) A licensee mentioned in paragraph (1) or (2) must ensure that —

(*a*) every patient of the licensee who enters into a transaction for the provision of a specified healthcare service or co-located service makes an independent decision in relation to the transaction;

(*b*) every advertisement relating to the licensee's licensable service that also advertises a specified healthcare service or co-located service is in compliance with the requirements in the Healthcare Services (Advertisement) Regulations 2021 (G.N. No. S 1033/2021) that apply to, or in relation to, an advertisement of a licensable healthcare service;

(*c*) every advertisement that advertises a specified healthcare service or co-located service but not the licensee's licensable healthcare service must state that the service advertised —

(i) is not licensed under the Act; but

(ii) is permitted under the Act to be provided at the licensed premises or in the licensed conveyance where the licensee's licensable healthcare service is also provided;

(*d*) 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; and

(*e*) if the provision of a specified healthcare service or co-located service is also for individuals other than the licensee's patients —

(i) there is a clear demarcation of the space used to provide the specified healthcare service or co-located service; or

(ii) where the space cannot be so demarcated —

(A) there is a conspicuously displayed signage, or such other means of communication to the licensee's patients as specified by the Director, stating that the specified healthcare service or co-located service is not licensed under the Act; and

(B) there is a written agreement between the licensee and the provider of the specified healthcare service or co-located service (as the case may be) which stipulates clearly the respective responsibilities of the licensee and the provider in relation to the use of the licensed premises or licensed conveyance.

(4) In paragraph (3)(*b*), a patient makes an independent decision in relation to a transaction for the provision of a specified healthcare service or co-located service if —

(*a*) the licensee does not make such transaction a condition for the provision to the patient of a licensable healthcare service, unless otherwise allowed by any written law or the applicable professional ethical guidelines or standards;

(*b*) the licensee does not give the patient any incentive for such transaction that is connected to the provision of a licensable healthcare service; and

(*c*) the licensee does not give the patient any incentive for the provision of a licensable healthcare service that is connected to such transaction.

PART 7

MEDICINAL PRODUCTS AND HEALTH PRODUCTS

Purchase of medicinal products and health products

27. A licensee must ensure that the purchase by or on behalf of the licensee of any medicinal product or health product in connection with the provision of a licensable healthcare service is —

(*a*) from a person who holds a valid licence authorising that person to supply or sell the product; or

(*b*) otherwise expressly permitted under any written law.

Prescription of medicinal products and health products

28.—(1) A licensee must ensure that the prescription of any medicinal product or health product to a patient in connection with the provision of a licensable healthcare service is in accordance with the provisions of the Health Products Act 2007 and any other written law that applies to the prescription.

(2) For every patient who is prescribed a medicinal product or health product in connection with the provision of a licensable healthcare service by a licensee, the licensee must ensure that —

(*a*) the medicinal product or health product is packed and labelled appropriately; and

(*b*) the patient's medication record contains adequate, accurate and relevant information to ensure that there is no error or confusion as to the medicinal product or health product prescribed, dispensed, administered or otherwise provided (as the case may be), and to ensure the proper and safe use of the medicinal product or health product by the patient.

(3) If there is a prescription of a medicinal product or health product in error, a licensee must —

(*a*) ensure that the erroneous prescription is properly identified and recorded; and

(*b*) take appropriate and timely measures to correct the error and prevent a recurrence.

Preparation of medicinal products and health products, and dispensing before expiry date

29.—(1) A licensee must ensure that no medicinal product or health product is administered, dispensed or provided to any patient after the shelf life or expiry date of the product.

(2) A licensee must ensure that every medicinal product or health product is prepared in accordance with the manufacturer's instructions before it is administered, dispensed or provided to any patient.

Storage and disposal of medicinal products and health products

30.—(1) A licensee must ensure that every medicinal product or health product in the licensee's possession or kept at any licensed premises or in any licensed conveyance is stored —

(*a*) in such a way that —

(i) it is protected from the likelihood of contamination; and

(ii) the environmental conditions under which it is stored will not adversely affect its efficacy, quality and safety; and

(*b*) in accordance with any code of practice relating to the quality and safety of medicinal products or health products.

(2) Subject to paragraphs (3) and (4), a licensee must ensure that a medicinal product or health product is properly disposed —

(*a*) if the expiry date is known — as soon as practicable after the expiry date of the product; and

(*b*) in any other case — when the product shows its first sign of deterioration.

(3) Subject to paragraph (4), if the manufacturer has given instructions as to the date of disposal after opening the packaging of a medicinal product or health product or removing the product from its packaging, a licensee must ensure that the product is properly disposed of on that date even if that date is earlier than the expiry date of the product.

(4) Paragraphs (2) and (3) do not apply if the licensee is given notice that the medicinal product or health product may be required as evidence in any coroner's inquiry, and for so long as the product is so required.

Delivery and transportation of medicinal products and health products

31. A licensee must ensure that during the delivery or transportation of a medicinal product or health product, the product is —

(*a*) protected from any likelihood of contamination;

(*b*) kept under suitable conditions (such as temperature, humidity, length of time, lighting and position of the product), so as not to affect its efficacy, quality and safety;

(*c*) delivered or transported directly to the intended destination without any diversion or deviation from the intended route; and

(*d*) delivered or transported in accordance with any code of practice relating to the delivery or transportation of medicinal products or health products.

PART 8

SPECIMENS

Collection of specimens

32. For the purposes of the traceability of a specimen that is collected from a patient, a licensee must ensure that —

(*a*) the personnel who is responsible for collecting the specimen checks and verifies the identity of the patient prior to the collection;

(*b*) the specimen collected is the correct specimen for the type of test that is ordered by a medical practitioner to be carried out for the patient; and

(*c*) the container containing the specimen is labelled accurately and clearly with all of the following information:

(i) the patient's name and identification number or passport number;

(ii) the date and time of the collection;

(iii) the type of specimen;

(iv) the site from which the specimen is collected, where relevant;

(v) where the test ordered by a medical practitioner to be carried out for the patient requires the collection of more than one specimen, the sequence in which the specimen is collected.

Packaging and transportation of specimens

33.—(1) For the purposes of transporting a specimen to another location, a licensee must ensure that —

(*a*) the container containing the specimen is kept safely in packaging that is appropriate for transportation; and

(*b*) the specimen is transported in a manner that —

(i) does not cause any confusion in the identification of the specimen;

(ii) preserves the integrity of the specimen; and

(iii) does not endanger public safety.

(2) For the purposes of paragraph (1)(*b*)(ii), the integrity of a specimen is preserved if the composition or structure of the specimen is not damaged or in any other way affected during the transportation.

PART 9

SERVICE STANDARDS

Privacy and dignity of care

34. A licensee must ensure that every patient's privacy is respected and every patient is treated with dignity and respect.

Safeguard against abuse and neglect

35. A licensee must ensure that —

(*a*) every patient is protected from abuse or neglect by any personnel in the course of receiving care and treatment; and

(*b*) there is in place a proper system to report any such abuse or neglect to an appropriate authority so that appropriate action may be taken against the personnel.

Communications with patients

36.—(1) A licensee must implement effective measures to ensure that every patient receives accurate and timely information about the patient's care and treatment.

(2) A licensee must establish and implement an appropriate system for obtaining the consent of a patient for any medical procedure that is carried out, or to be carried out, at any licensed premises or in any

licensed conveyance, and maintaining a proper record of the consent obtained.

(3) Where, in the provision of a licensable healthcare service by a licensee, a test is conducted on a patient who is under the direct care of the licensee, the licensee must ensure all of the following:

(*a*) the findings of the test are brought to the attention of a medical practitioner practising in the licensable healthcare service without undue delay;

(*b*) the medical practitioner mentioned in sub-paragraph (*a*) reviews the findings in a timely manner;

(*c*) the patient is informed, without undue delay, of the findings that, in the professional opinion of the medical practitioner mentioned in sub-paragraph (*a*), are clinically significant;

(*d*) the medical practitioner mentioned in sub-paragraph (*a*) advises the patient, based on the findings and without undue delay, on the patient's condition, prognosis and clinical management.

Information to be contained in patient health records

37.—(1) A licensee must keep and maintain, for such period and in such manner as the Director may specify, an accurate, complete and up-to-date patient health record of every patient in accordance with this regulation.

(2) A patient health record must contain all of the following information relating to the patient:

(*a*) name;

(*b*) identification number or passport number;

(*c*) gender;

(*d*) date of birth.

(3) In addition, a patient health record must contain all of the following information in relation to the patient, if the information is available to the licensee:

(*a*) residential address;

(*b*) ethnic group;

(*c*) date and time of every consultation, referral, admission, investigation and discharge;

(*d*) admission forms;

(*e*) medical history and referral documents;

(*f*) clinical findings and progress notes;

(*g*) clinical management and care plan containing details such as medication, nursing care, treatment, diet and allied health care;

(*h*) allergies and other factors requiring special consideration;

(*i*) results of laboratory tests;

(*j*) reports of X-rays and other investigations;

(*k*) vaccinations;

(*l*) consent forms;

(*m*) discharge summary containing details such as significant findings and events of the patient's stay, the patient's condition on discharge and recommendations and arrangements for future care;

(*n*) date and time of death (if the patient is deceased).

(4) A licensee must ensure that every patient health record —

(*a*) accurately and clearly sets out any follow-up action identified by the licensee or any personnel as being appropriate and necessary for the patient; and

(*b*) subject to paragraph (5), contains accurate information about whether that follow-up action is taken, and if no follow-up action is taken, the reason for the failure to take that follow-up action.

(5) Paragraph (4)(*b*) does not apply to a licensee who provides a blood banking service, cord blood banking service, clinical

laboratory service, radiological service, nuclear medicine assay service or nuclear medicine imaging service.

Protection of patient health records

38.—(1) A licensee must keep every patient health record confidential and ensure that —

(*a*) the confidentiality, integrity and security of every patient health record is maintained at all times; and

(*b*) every personnel handling any patient health record is aware of his or her role and responsibility in maintaining the confidentiality, integrity and security of the records.

(2) In addition, where any information in patient health records is in the form of an extract or aggregated compilation, the licensee must ensure that the confidentiality, integrity and security of the information in the extract or aggregated compilation is maintained at all times.

(3) A licensee must —

(*a*) implement adequate safeguards and appropriate protocols and processes to protect the patient health records against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification;

(*b*) periodically monitor and evaluate the safeguards, protocols and processes mentioned in sub-paragraph (*a*) to ensure that they are effective and being complied with by the staff involved in handling the patient health records; and

(*c*) take reasonable care in the disposal or destruction of the patient health records so as to prevent unauthorised access to the records.

Continuity of care where licensee intends to cease provision of licensable healthcare service or transfer care of patient to another licensee

39.—(1) Where a licensee intends to cease the provision of any licensable healthcare service or transfer the care of a patient to another licensee, the firstmentioned licensee must, prior to such cessation or transfer, ensure that all reasonable measures are taken to ensure the continuity of care of every affected patient, such as but not limited to the following:

(*a*) inform the patient of the cessation or transfer of care (as the case may be) within a reasonable period before the cessation or transfer of care, as the case may be;

(*b*) consult the patient about the transfer or disposal of his or her patient health record;

(*c*) transfer the patient health record or give a detailed medical report of the patient to —

(i) the licensee that is taking over the care of the patient; or

(ii) the patient or his or her authorised representative, upon request by the patient or authorised representative, as the case may be.

(2) In this regulation, a patient's authorised representative means any of the following persons:

(*a*) if the patient is a child — the patient's parent, adoptive parent, step-parent or guardian;

(*b*) if the patient lacks capacity within the meaning of section 4 of the Mental Capacity Act 2008 —

(i) a deputy appointed or deemed to be appointed for the person by the court under that Act with power in relation to the person for the purposes of these Regulations; or

(ii) a donee under a lasting power of attorney registered under that Act with power in relation to the patient for the purposes of these Regulations;

(*c*) if the patient is an adult who has capacity — a person whom the patient has authorised to act on the patient's behalf for any matter (including legal proceedings) that requires information in his or her patient health record.

PART 10

PRICE TRANSPARENCY

Itemisation of bill

40.—(1) Subject to paragraph (2), a licensee must ensure that every patient is given a bill of the fees charged by the licensee for every licensable healthcare service provided to the patient.

(2) A bill mentioned in paragraph (1) may be given to the following persons, instead of the patient, in the following circumstances:

(*a*) if the patient is a child — the patient's parent, adoptive parent, step-parent or guardian;

(*b*) if the patient lacks capacity within the meaning of section 4 of the Mental Capacity Act 2008 —

(i) a deputy appointed or deemed to be appointed for the person by the court under that Act with power in relation to the person for the purposes of these Regulations; or

(ii) a donee under a lasting power of attorney registered under that Act with power in relation to the patient for the purposes of these Regulations;

(*c*) if the patient is an adult who has capacity — a person whom the patient has authorised to receive the bill on the patient's behalf;

(*d*) if the patient has died — any of the patient's next of kin.

(3) Subject to paragraph (5), a bill mentioned in paragraph (1) must contain the fee for each of the following components of the licensable healthcare service that is provided to the patient:

(*a*) consultations;

(*b*) tests, procedures and investigations;

(*c*) medications;

(*d*) consumables;

(*e*) third party administrator services;

(*f*) any item or service not mentioned in sub-paragraphs (*a*) to (*e*) that is provided to or used by the patient.

(4) Subject to paragraph (5), a bill must, in addition to the components mentioned in paragraph (3), contain all of the following:

(*a*) the total amount of the fees payable, before deducting all of the following:

(i) the amount mentioned in sub-paragraph (*b*);

(ii) any deduction from any medisave account;

(iii) any reimbursement under the MediShield Life Scheme;

(*b*) the total amount of the Government subsidy or subsidies, if applicable to the patient and relevant for the purposes of the bill;

(*c*) the net amount of the fees payable by the patient, after deducting all of the following:

(i) the amount mentioned in sub-paragraph (*b*), if applicable;

(ii) the deduction from one or more medisave accounts allowed by regulations made under the Central Provident Fund Act 1953;

(iii) the reimbursement under the MediShield Life Scheme.

(5) Paragraphs (3) and (4) do not apply in relation to a bill where the fees charged by the licensee are based on a package rate.

(6) Where a licensee charges fees based on a package rate, the licensee may, instead of giving a bill containing the fees for the components and matters mentioned in paragraphs (3) and (4), give

the patient a document describing the components of the licensable healthcare service that are charged.

PART 11

INFECTION CONTROL, INCIDENT MANAGEMENT AND EMERGENCY PREPAREDNESS

Infection control

41. A licensee must prevent, manage, control and contain the spread of any infection that is, or is suspected to be, connected with the provision of a licensable healthcare service at any licensed premises or in any licensed conveyance by ensuring that —

(*a*) the environment surrounding and within the licensed premises or licensed conveyance is clean and safe;

(*b*) all the equipment and facilities at the licensed premises or in the licensed conveyance are clean and safe;

(*c*) the use of all the appliances, equipment, instruments and materials at the licensed premises or in the licensed conveyance is in compliance with the established or recommended procedures for their maintenance and use; and

(*d*) appropriate infection control processes are implemented at the licensed premises or in the licensed conveyance.

Notification of infectious diseases

42. For the purposes of the requirement in the Infectious Diseases Act 1976 to notify the Director of prescribed infectious diseases, a licensee must establish, implement and maintain an appropriate process or system to facilitate the notification under that Act of any such infectious disease that any of the following persons is suffering or suspected to suffer:

(*a*) a patient of the licensee;

(*b*) a person who is referred to the licensee by another licensee for care or treatment.

Immunity against measles and diphtheria

43.—(1) Subject to paragraph (2), a licensee must ensure that every personnel employed or engaged to work at any licensed premises or in any licensed conveyance has immunity against measles and diphtheria.

(2) Paragraph (1) does not apply in respect of —

(*a*) any personnel whose work does not involve direct interaction with patients and the place where the personnel works is not used to provide any service that requires direct interaction with patients;

(*b*) any personnel who is certified by a medical practitioner to be permanently unfit for vaccination against measles or diphtheria, as the case may be; and

(*c*) any of the following persons who enters the licensed premises or licensed conveyance on a single occasion and on an ad-hoc basis:

(i) a volunteer engaged by the licensee to assist in the provision of the licensable healthcare service;

(ii) an employee of a contractor engaged by the licensee to perform work at the licensed premises or licensed conveyance.

(3) A licensee must keep and maintain a record (including supporting documentation) of the immunity status of every personnel employed or engaged to work at any licensed premises or licensed conveyance for the duration of the personnel's employment or engagement by the licensee and until 30 calendar days after the cessation of such employment or engagement.

(4) To avoid doubt, paragraph (3) also applies in respect of any personnel mentioned in paragraph (2)(*a*) and (*b*).

Management of biohazardous materials

44.—(1) Where, in the provision of a licensable healthcare service. a licensee carries out any process, operation or work involving exposure to any biohazardous material, the licensee must take

effective measures to ensure the safe and proper use, storage and disposal of the biohazardous material.

(2) In this regulation, "biohazardous material" includes —

(*a*) any substance which contains toxins;

(*b*) any biological waste;

(*c*) any culture medium;

(*d*) any contaminated blood, urine or faeces; and

(*e*) any infected tissue or organ.

Incident escalation

45.—(1) A licensee must establish, implement and maintain an appropriate system to facilitate the expeditious escalation to a relevant person who is employed by the licensee in a management capacity of the following incidents that arise in the course of providing a licensable healthcare service:

(*a*) a clinical incident impacting or endangering public health or patient safety;

(*b*) a clinical incident indicating that there is a systemic or process failure;

(*c*) an incident of abuse or allegation of abuse, or of a breach of privacy, of any patient;

(*d*) any compromise of data kept by the licensee, whether in electronic form or otherwise, that directly affects the safety or welfare of patients, or the confidentiality or security of data;

(*e*) an incident impacting the structural safety (including fire safety) of any licensed premises or licensed conveyance.

(2) A licensee must take appropriate and timely action, including a proper risk assessment —

(*a*) to prevent or limit the occurrence of any incident mentioned in paragraph (1);

(*b*) to minimise the harm to patients that may arise or has arisen as a result of such an incident; and

(*c*) to prevent the recurrence of such an incident.

Emergency preparedness

46. A licensee must —

(*a*) establish an effective emergency response plan to deal with or respond to any national emergency;

(*b*) participate in national emergency efforts;

(*c*) participate in the planning, design and conduct of national emergency preparedness exercises;

(*d*) develop and implement emergency infection control measures (such as isolation facilities and infection control equipment) to control and prevent the spread of any infectious disease in an epidemic or a pandemic;

(*e*) ensure that every personnel, whose responsibility includes the handling of national emergencies, is competent in responding to any national emergency, including, but not limited to, the wearing of the Personal Protective Equipment (PPE) safely and properly; and

(*f*) keep adequate stock of the Personal Protective Equipment (PPE), including the following:

(i) N95 face masks or masks of the equivalent standard;

(ii) isolation gowns or gowns of the equivalent standard;

(iii) examination gloves or gloves of the equivalent standard.

Business continuity

47.—(1) If any contingency or disaster disrupts a licensee's business of providing a licensable healthcare service, the licensee must, as soon as practicable after the occurrence of the contingency or disaster, take action to restore the licensee's business.

(2) A licensee must maintain, at all times, a plan of action (called in this regulation a business continuity plan) that establishes the systems and sets out the procedures necessary to restore the licensee's business of providing a licensable healthcare service if any contingency or disaster disrupts that business.

(3) A licensee must —

(*a*) take reasonable steps to ensure that the business continuity plan can be effectively followed if any contingency or disaster disrupts the licensee's business of providing a licensable healthcare service;

(*b*) periodically review the business continuity plan; and

(*c*) implement changes, where necessary, to ensure the effectiveness of the business continuity plan.

PART 12

MISCELLANEOUS

Display of business name

48.—(1) A licensee must ensure that the licensee's business name as stated on the licence is displayed on every signage, website and stationery that makes reference to the licensable healthcare service that the licensee is authorised by the licence to provide.

(2) In this regulation, "business name", in relation to the provision of a licensable healthcare service by a licensee, means the name under which the licensee is authorised by a licence to carry on the business of providing the licensable healthcare service.

Restrictions on use of name

49. For the purposes of section 29(3) of the Act, the prescribed terms and names are as specified in the Fifth Schedule.

Offence

50.—(1) Any person who contravenes regulation 8(2), 24, 25, 26(3)(*b*), (*c*) or (*d*), 27, 28, 29, 30(1), (2) or (3), 31, 32, 33(1), 35, 36,

38, 39(1), 41, 43(1) or (3), 44(1), 45 or 47(1) shall be guilty of an offence.

(2) A person who is guilty of an offence under paragraph (1) shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding $1,000 for every day or part of a day during which the offence continues after conviction.

FIRST SCHEDULE

Regulation 5

PART 1

SPECIAL LICENSABLE HEALTHCARE SERVICES

1. Nuclear medicine assay service

PART 2

LICENSABLE HEALTHCARE SERVICE UNDERLYING TO SPECIAL LICENSABLE HEALTHCARE SERVICE

First column	*Second column*
Special licensable healthcare service	*Underlying licensable healthcare service*
Nuclear medicine assay service	Clinical laboratory service

SECOND SCHEDULE

Regulation 14(1)

LICENSABLE HEALTHCARE SERVICES REQUIRING APPOINTMENT OF CLINICAL GOVERNANCE OFFICERS

1. Blood banking service
2. Clinical laboratory service
3. Nuclear medicine imaging service
4. Nuclear medicine assay service
5. Radiological service
6. Cord blood banking service

SECOND SCHEDULE — *continued*

7. Emergency ambulance service
8. Medical transport service

THIRD SCHEDULE

Regulations 19 and 20

QUALITY ASSURANCE COMMITTEES (QAC)

First column	*Second column*
Category of licensees	*Quality assurance committees required to be appointed by licensees*
1. Every licensee authorised to provide blood banking service	At least one Serious Reportable Event QAC
2. Every licensee authorised to provide nuclear medicine imaging service	At least one Serious Reportable Event QAC

In this Schedule, "Serious Reportable Event QAC" means a QAC established by a licensee to monitor, evaluate and review any serious reportable event that occurs in the course of providing a licensable healthcare service, so that the licensee may take corrective action to prevent the occurrence or recurrence of the same or a similar serious reportable event and, if required by the Director under any licence condition, report every serious reportable event to the Director for the purposes of learning and improvement of the quality of the service.

FOURTH SCHEDULE

Regulation 26(1)

NON-LICENSABLE HEALTHCARE SERVICES THAT CAN BE PROVIDED IN LICENSED PREMISES OR LICENSED CONVEYANCES

1. Any healthcare service provided by a healthcare professional, other than a traditional Chinese medicine practitioner
2. Acupuncture provided by a traditional Chinese medicine practitioner mentioned in paragraph (*g*) of the definition of "healthcare professional" in regulation 2

FIFTH SCHEDULE

Regulation 49

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

FIFTH SCHEDULE — *continued*

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

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CHAN YENG KIT
Permanent Secretary,
Ministry of Health,
Singapore.

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