No. S 000

HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES (GENERAL) REGULATIONS 2021

ARRANGEMENT OF REGULATIONS

Regulation

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 2021.

Definitions

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

"abuse", "emotional or psychological abuse", "neglect", "physical abuse" and "wellbeing" have the meanings given in section 2 of the Vulnerable Adults Act 2018 (Act 34 of 2018);

"business day" means any day other than Saturday, Sunday or a public holiday;

"charity" means a registered charity or an exempt charity, that is established to assist vulnerable patients in their healthcare costs and expenses;

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

"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 at http://halp.moh.gov.sg;

"error", in relation to …, means the failure to carry out a planned action as intended or the application of an incorrect plan;

"exempt charity" has the meaning given by section 2(1) of the Charities Act (Cap. 37);

"governing body", in relation to a licensee that is a body corporate, means a member of the board of directors or committee or board of trustees;

"health product" has the meaning given in section 2 of the Health Products Act (Cap. 122D);

"healthcare professional" means —

(*a*) an allied health professional registered under the Allied Health Professionals Act (Cap. 6B);

(*b*) a dentist or an oral health therapist registered under the Dental Registration Act (Cap. 76) and holds a valid practising certificate under that Act;

(*c*) a medical practitioner registered under the Medical Registration Act (Cap. 174) and holds a valid practising certificate under that Act;

(*d*) a nurse or midwife registered, or an enrolled nurse enrolled, under the Nurses and Midwives Act (Cap. 209); or

(*e*) a pharmacist registered under the Pharmacists Registration Act (Cap. 230) and holds a valid practising certificate under that Act;

"infectious disease" has the meaning given in section 2 of the Infectious Diseases Act (Cap. 137);

"medicinal product" has the meaning given in section 3 of the Medicines Act (Cap. 176);

"medisave account" means a medisave account maintained under section 13 of the Central Provident Fund Act (Cap. 36);

"MediShield Life Scheme" means the MediShield Life Scheme established by section 3 of the MediShield Life Scheme Act 2015 (Act 4 of 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;

"registered charity" means a charity registered under section 5 of the Charities Act;

"specialist" means a person who is registered as a specialist in the Register of Specialists under section 22 of the Medical Registration Act (Cap. 174) or section 14C of the Dental Registration Act (Cap. 76);

"specialty" means the particular branch of medicine or dentistry for which a specialist is registered under section 22 of the

Medical Registration Act or section 14C of the Dental Registration Act, as the case may be;

"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;

"vulnerable patient" means a patient (whether an inpatient or outpatient) who, because of his or her physical or mental infirmity, disability or incapacity, has difficulty paying his or her healthcare costs and expenses.

PART I

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 and 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) 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, furnishing 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 II

LICENSING MATTERS

Application for licence

4.—(1) An application for a licence authorising the provision of one or more licensable healthcare services must be made no later than 2 months before the first of those services is provided to the public.

(2) An application to renew any licence must be made not later than 2 months before the date the licence expires (called in this regulation the renewal deadline).

(3) An application for or to renew a licence must be accompanied by an application fee that is determined in accordance with paragraph (4).

(4) Except where the applicant is a charity, the application fee mentioned in paragraph (3) is an amount calculated as follows:

$$(\$100 \times A) + (\$100 \times B)$$

where —

A is the number of licensable healthcare services that the application relates; and

B is the number of premises and conveyances that the application relates.

(5) Where the applicant is a charity, the application fee mentioned in paragraph (3) is an amount calculated as follows:

$$\$12 \times B$$

where B is the number of premises and conveyances that the application relates.

(6) 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 third column of the table under Part I or Part II (as the case may be) of the First Schedule that corresponds to the licensable healthcare service specified in the first column of that table to which the late renewal application relates.

Licence fee

5. For the purposes of section 11(1)(*a*) of the Act, the licence fee or renewal fee is of an amount specified in the second column of the table under Part I (if the applicant or licensee is not a charity) or Part II (if the applicant or licensee is a charity) of the First Schedule that corresponds to the licensable healthcare service specified in the first column of that table to which a licence is to be granted or renewed.

Licensable healthcare services underlying to special licensable healthcare service

6. For the purposes of section 11(3)(*c*) of the Act, the Director must have regard to whether an applicant for a licence to provide a special licensable healthcare service specified in the first column of the Second Schedule is granted a licence to provide the licensable healthcare service specified in the second column of that Schedule opposite the special licensable healthcare service, which is underlying to that special licensable healthcare service.

Amendment of licence

7.—(1) An application to amend any of the licensed premises or licensed conveyances specified in a licence must be accompanied by an application fee of an amount specified in Part III of the First Schedule and made by the licensee concerned —

(*a*) if the application is for the addition of one or more new licensed premises or licensed conveyances or both to the licence — no later than 2 months before the amendment is to take effect; or

(*b*) if the application is for the removal of any licensed premises or licensed conveyance from the licence — no later than one month before the amendment is to take effect.

(2) An application to amend the name of a licensee must be accompanied by an application fee of an amount specified in Part III of the First Schedule and made by the licensee concerned no later than one month before the amendment is to take effect.

(3) An application to amend the particulars of a licence, other than the licence conditions and the particulars mentioned in paragraphs (1) and (2), must be accompanied by an application fee of an amount specified in Part III of the First Schedule and made by the licensee concerned no later than 10 business days before the amendment 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 the licensable healthcare service to which the licence relates, or stops using any licensed premises or licensed conveyance specified in the licence for the provision of the licensable healthcare service, 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 32(8)(*a*), (*b*) and (*c*) relating to the health records of every patient of the licensee 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.

Waiver or refund of fee

9. Except as provided in the Act, the Director may waive or refund the whole or any part of any fee payable under these Regulations.

PART III

GOVERNANCE OF LICENSEES

Compliance with Act etc.

10.—(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

11.—(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 business 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

12. Without affecting the generality of regulation 11(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

13. 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 business 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

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

(*a*) to exercise adequate 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 oversee the implementation of processes to review and manage any clinical risk or enterprise risk that may arise in the provision of the licensable healthcare service, and ensure that the licensee complies with the processes.

(2) In this regulation —

"clinical risk" means the impact of a clinically unsafe environment or situation on the safety and wellbeing of patients and healthcare workers;

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

Appointment of Clinical Governance Officers

15. 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 Third Schedule.

PART IV

EMPLOYEES OF LICENSEES

Employment of healthcare professionals

16.—(1) A licensee must employ such number of competent and qualified healthcare professionals 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 ensuring proper accountability and supervision of every healthcare professional employed by a licensee, the licensee must establish and maintain proper systems to ensure adequate division of duties and clear reporting lines.

(3) To avoid any imminent danger to the health or safety of patients, 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 that the healthcare professionals employed 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 V

COMMITTEES APPOINTED BY LICENSEES

Licensees required to appoint QAC

17. For the purposes of section 25 of the Act, the category of licensees specified in the first column of the Fourth Schedule (called in these Regulations the QAC licensees) must appoint the quality assurance committees (called in these Regulations the QAC) specified in the second column of that Schedule opposite that category of licensees.

Functions and duties of QAC

18.—(1) A QAC is responsible for evaluating and monitoring the quality, safety and clinical appropriateness of, and improving the quality and safety standards of, the licensable healthcare service provided by the QAC licensee.

(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 the cases for peer review learning and mortality and morbidity review (called in this Part the PRL and MMR cases), and any serious reportable event 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 the PRL and MMR cases and serious reportable events 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 PRL or MMR case or serious reportable event 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 PRL or MMR case or serious reportable event 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.

(3) In this regulation, "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.

Appointment of supervisor of quality assurance activities

19.—(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*) ensure that the QAC institutes an effective system for a root cause analysis of all MMR cases and serious reportable events, and recommends appropriate solutions in a timely manner to prevent a further recurrence.

Participation of non-QAC licensee in quality assurance activities

20. 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 VI

LICENSED PREMISES AND LICENSED CONVEYANCES

Licensed premises and conveyances

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

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

(*b*) all the facilities and equipment in every licensed premises and every licensed conveyance are regularly checked and properly maintained so to ensure that the facilities and equipment give accurate results and the licensable healthcare service is provided safely.

Use of licensed premises or licensed conveyance for other purposes

22.—(1) For the purposes of section 30(1)(*c*) of the Act and subject to paragraph (3), a licensee may use, or allow to be used, the whole or any part of any licensed premises or licensed conveyance to provide a non-licensable healthcare services specified in the Fifth 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 any part (but not the whole) of any licensed premises or licensed conveyance for a purpose that is not mentioned in section 30(1) of the Act (called in this regulation an external service) if the licensee has obtained the prior approval of the Director to do so.

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

(*a*) the licensee's patients are informed that the use of the licensed premises or licensed conveyance for a specified healthcare service or an external service is not authorised by a licence under the Act;

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

(*c*) every advertisement relating to a specified healthcare service or an external service is in compliance with the requirements in the Healthcare Services (Advertisement) Regulations 2021 that apply to, or in relation to, an advertisement of a licensable healthcare service;

(*d*) the provision of the licensable healthcare service is not adversely affected by the provision of the specified healthcare service or external service; and

(*e*) for a licensee mentioned in paragraph (2), the conditions that the Director may impose for the approval mentioned in that paragraph (2) are complied with.

(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 an external service if —

(*a*) the licensee does not make such transaction a condition for the provision to the patient of a licensable healthcare service;

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

PART VII

HANDLING OF MEDICINAL PRODUCTS, HEALTH PRODUCTS AND SPECIMENS

Purchase of medicinal products and health products

23. 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 from a distributor, wholesaler or pharmacy that holds a valid licence under [*to specify the relevant Acts*], except where such purchase is expressly permitted under the Medicines Act or Health Products Act.

Dispensing, storage and disposal of medicinal products and health products

24.—(1) A licensee must ensure that no medicinal product or health product is 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 and 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 quality and safety; and

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

(3) Subject to paragraphs (4) and (5), 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;

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

(4) Subject to paragraph (5), if the manufacturer has given instructions as to the date of disposal after opening the packaging of a medicinal product 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.

(5) Paragraphs (3) and (4) 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.

Prescription of medicinal products and health products

25.—(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 by the licensee is in accordance with the provisions of the Health Products Act and any other written law that applies to the prescription.

(2) For every patient who is prescribed a medicinal product or health product, a licensee must ensure that —

(*a*) the medicinal product or health product (as the case may be) 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 (as the case may be), and to ensure the proper and safe use of the medicinal product or health product (as the case may be) 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.

Delivery and transportation of medicinal products and health products

26. 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 a suitable temperature so as not to affect its quality and safety; and

(*c*) in accordance with any code of practice relating to delivery or transportation of medicinal products or health products.

Packaging and transportation of specimens

27.—(1) A licensee must ensure that every specimen taken from a patient is —

(*a*) kept in appropriate packaging; and

(*b*) if it has to be transported to another place — 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 VIII

SERVICE STANDARDS

Privacy and dignity of care

28. 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

29. A licensee must ensure that —

(*a*) every patient is protected from abuse or neglect by any of the licensee's employees 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 employee.

Communications with patients

30.—(1) A licensee must implement effective measures to ensure that every patient receives accurate and timely information about the patient's care and treatment from the licensee or a healthcare professional employed by the licensee.

(2) A licensee must establish 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 licensed conveyance, and maintaining a proper record of the consent obtained.

Patients' health records

31.—(1) A licensee must keep and maintain an accurate, complete and up-to-date patient health record of every patient containing all of the following information relating to the patient:

(*a*) Name;

(*b*) Identification number or passport number;

(*c*) Gender;

(*d*) Date of birth;

(*e*) Ethnic group;

(*f*) Residential address;

(*g*) Date and time of every consultation, referral, admission, investigation and discharge;

(*h*) Date and time of death (if the patient is deceased).

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

(*a*) Admission forms;

(*b*) Medical history and referral documents;

(*c*) Clinical findings and progress notes;

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

(*e*) Allergies and other factors requiring special consideration;

(*f*) Results of laboratory tests;

(*g*) Reports of X-rays and other investigations;

(*h*) Vaccinations;

(*i*) Consent forms;

(*j*) 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.

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

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

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

(4) A licensee must —

(*a*) keep every patient health record confidential and secured safely in an appropriate physical storage area; and

(*b*) ensure that the confidentiality, integrity and security of every patient health record is maintained.

(5) If a licensee transfers any information contained in any patient health record to an electronic or any other medium, the licensee must take precautions to ensure that the confidentiality, integrity and security of the patient health record is maintained.

(6) A licensee must put in place appropriate protocols and processes to prevent any unauthorised modification, copying or use of a patient health record.

(7) A licensee must ensure that any incident involving the loss, unauthorised access or tampering of any patient health record is reported to a police officer immediately.

(8) Before a licensee ceases the provision of any licensable healthcare service or where the care of a patient is transferred to another licensee, the firstmentioned licensee must 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.

(9) 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 (Cap. 177A) — a deputy appointed or deemed to be appointed for the person by the court under the Mental Capacity Act with power in relation to the person for the purposes of these Regulations, or 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 IX

PRICE TRANSPARENCY

Display of common charges

32.—(1) A licensee must ensure that the common charges that are payable for the licensable healthcare service that the licensee provides are conspicuously displayed —

(*a*) at the licensed premises or in the licensed conveyance where the licensable healthcare service is provided; or

(*b*) on the licensee's Internet website,

in such format as the Director may specify.

(2) For the purposes of this regulation, the common charges for a licensable healthcare service are the fees chargeable by a licensee for such components of the licensable healthcare service as the Director may specify.

Itemisation of bill

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

(2) If a patient requests a detailed bill setting out the fee for every component of the licensable healthcare service that is provided by the licensee to the patient, the licensee must ensure that the patient is given the detailed bill.

(3) Subject to paragraph (3), a summary bill mentioned in paragraph (1) must contain the fees (including any zero charge) for each of the following components:

(*a*) consultations;

(*b*) tests, procedures and investigations;

(*c*) medications;

(*d*) consumables;

(*e*) third party administrator services;

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

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

(ii) any deduction from any medisave account;

(iii) any reimbursement under the MediShield Life Scheme;

(*g*) the total amount of the Government subsidy or subsidies applicable to the patient;

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

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

(ii) the deduction from one or more medisave accounts;

(iii) the reimbursement under the MediShield Life Scheme.

(4) If the Director directs a licensee not to disclose a Government subsidy, the licensee must not include the amount of that subsidy for the component in paragraph (3)(*g*) despite that the subsidy may be taken into account in the computation of the fees for any other component in paragraph (3).

Financial counselling

34.—(1) Before a licensee that is specified in the first column of the Sixth Schedule provides a licensable healthcare service to a patient, the licensee must, as far and as soon as reasonably practicable, conduct financial counselling to the patient or the patient's representative on every component of the fees chargeable for [a licensable healthcare service/treatment or procedure] that is specified in the second column of that Schedule if —

(*a*) the patient is a new patient of the licensee;

(*b*) the patient is advised by the licensee to undergo a new treatment or procedure; or

(*c*) there is a change in the licensee's fees for the treatment or procedure that the patient is advised by the licensee to continue to undergo.

(2) For the purposes of paragraph (1), financial counselling must include giving the patient or the patient's representative all of the following information:

(*a*) an estimated price range for the treatment of the patient's condition or the procedure that the patient intends to undergo or continue to undergo;

(*b*) the historical and national price ranges (if available) for the same or similar treatment or procedure and the benchmark used for such ranges;

(*c*) the status of the licensee's accreditation or participation in any public scheme specified in the Seventh Schedule, and if the licensee's accreditation or participation in any such public scheme has been revoked, cancelled or suspended, the date of and reason for such revocation, cancellation or suspension, as the case may be;

(*d*) if there is an investigation into the licensee's accreditation in any public scheme specified in the Seventh Schedule, the reason for such investigation.

(3) A licensee must record in writing every financial counselling that is conducted for any patient, and obtain the written acknowledgement of the patient or the patient's representative (as the case may be) upon the completion of the financial counselling.

(4) In this regulation, a patient's 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 (Cap. 177A) — a deputy appointed or deemed to be appointed for the person by the court under the Mental Capacity Act with power in relation to the person for the purposes of these Regulations, or 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.

PART X

INFECTION CONTROL, INCIDENT MANAGEMENT AND EMERGENCY PREPAREDNESS

Infection control

35.—(1) 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.

Management of biohazardous materials

36.—(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 —

(*a*) the proper use, storage and disposal of the biohazardous material; and

(*b*) that such use, storage and disposal is in accordance with any code of practice relating to biohazardous materials.

(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.

Fire safety

37. A licensee must take adequate precautions against the risk of fire in accordance with the Fire Safety Act (Cap. 109A).

Incident escalation

38.—(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 a computer system 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;

(f) an incident with national impact, as required by DMS to escalate.

(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

39.—(1) A licensee must establish an effective emergency response plan to deal with or respond to any national emergency.

(2) A licensee must participate in national emergency efforts.

(3) A licensee must participate in the planning, design and conduct of national emergency preparedness exercises.

(4) A licensee must develop and implement emergency infection control measures, including isolation strategies, isolation facilities and infection control equipment, to control and prevent the spread of any infectious disease in an epidemic or a pandemic.

(5) A licensee must ensure that every employee of the licensee is competent in responding to a national emergency including, but not limited to, the wearing of the Personal Protective Equipment (PPE) safely and properly.

(6) A licensee must keep adequate stock of the Personal Protective Equipment (PPE) including the following:

(*a*) N95 face masks or masks of the equivalent standard;

(*b*) isolation gowns or gowns of the equivalent standard;

(*c*) examination gloves or gloves of the equivalent standard.

Business continuity planning

40.—(1) 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.

(2) A licensee must review the procedures and systems mentioned in paragraph (1) on a regular basis as specified in the plan of action mentioned in that paragraph.

(3) A plan of action mentioned in paragraph (1) includes, but is not limited to, the following:

(*a*) a service continuity plan;

(*b*) contractual arrangements to support service continuity;

(*c*) a plan to transfer to another licensee the patient health records of the licensee's patients;

(*d*) a plan for alternative manpower arrangements in the event that the licensee's employees who are involved in delivering clinical services are unable to continue doing so;

(*e*) a risk management plan identifying the risks specific to the licensable healthcare service that the licensee is authorised to provide, and setting out the risk mitigation processes and requisite audits.

PART XI

MISCELLANEOUS

Restrictions on use of name

41.—(1) For the purposes of section 29(3) of the Act, the prescribed terms and names are as specified in the Eighth Schedule.

(2) A licensee must ensure that —

(*a*) the description or name of a licensable healthcare service, wherever displayed, consists of the name of the licensee as stated on the licence; and

(*b*) the description of the licensable healthcare service is not false or misleading as to the licensable healthcare service that the licence is authorised to provide.

Outsourcing of licensable healthcare service

42.—(1) Unless otherwise provided in any other regulations made under the Act, a licensee must not appoint any person to provide, on the licensee's behalf, a licensable healthcare service or any aspect of

a licensable healthcare service unless the person holds a valid licence under the Act.

(2) To avoid doubt, a licensee who appoints another person to provide, on the licensee's behalf, a licensable healthcare service or any aspect of a licensable healthcare service remains responsible to comply with the licence conditions and the duties of a licensee under the Act, these Regulations and any other regulations made under the Act.

Offence

43.—(1) Any person that contravenes regulation ….. shall be guilty of an offence.

(2) A person guilty of an offence under paragraph (1) shall be liable on conviction —

(*a*) in the case of an individual, 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; and

(*b*) in any other case, to a fine not exceeding [ ] and, in the case of a continuing offence, to a further fine not exceeding [ ] for every day or part of a day during which the offence continues after conviction.

FIRST SCHEDULE

Reg 5 and 7

FEES

PART I

LICENCE AND RENEWAL FEES PAYABLE BY APPLICANT OR LICENSEE THAT IS NOT A CHARITY

Licensable healthcare service to which licence relates	*Licence fee or renewal fee in respect of each premises or conveyance*	*Late renewal application fee*
Blood banking service	$1,950	$390
Clinical laboratory service	$1,760	$352
Nuclear medicine assay service	$1,900	$380
Nuclear medicine imaging service	$1,900	$380
Radiological laboratory service	$1,760	$352
Tissue banking service	$1,950	$390

PART II

LICENCE AND RENEWAL FEES PAYABLE BY APPLICANT OR LICENSEE THAT IS A CHARITY

Licensable healthcare service to which licence relates	*Licence fee or renewal fee in respect of each premises or conveyance*	*Late renewal application fee*
Blood banking service	$12	$390
Clinical laboratory service	$12	$352
Nuclear medicine assay service	$12	$380
Nuclear medicine imaging service	$12	$380
Radiological laboratory service	$12	$352
Tissue banking service	$12	$390

PART III

FEES FOR AMENDMENT OF LICENCE

1. For an amendment of a licence to add one or more new licensed premises or licensed conveyances or both to the licence, the application fee that is payable by the licensee for the amendment is as follows:

Licensable healthcare service to which licence relates	*Addition of each new licensed premises or licensed conveyance*	
	Licensee that is not a charity	*Licensee that is a charity*
Blood banking service	$1,950	$12
Clinical laboratory service	$1,760	$12
Nuclear medicine assay service	$1,900	$12
Nuclear medicine imaging service	$1,900	$12
Radiological laboratory service	$1,760	$12
Tissue banking service	$1,950	$12

2. For an amendment of a licence to remove one or more licensed premises or licensed conveyances or both from the licence, the application fee that is payable by the licensee for the amendment is as follows:

……

3. For any other amendment of a licence including, but not limited to, a change in the licensee's name and the particulars of any licensed premises or licensed conveyance:

Licensable healthcare service to which licence relates	*Licensee that is not a charity*	*Licensee that is a charity*
Blood banking service	$100	$12
Clinical laboratory service	$100	$12
Nuclear medicine assay service	$100	$12
Nuclear medicine imaging service	$100	$12
Radiological laboratory service	$100	$12
Tissue banking service	$100	$12

SECOND SCHEDULE

Reg 6

LICENSABLE HEALTHCARE SERVICES UNDERLYING TO SPECIAL LICENSABLE HEALTHCARE SERVICE

Special licensable healthcare service	*Underlying licensable healthcare services*
1. Nuclear medicine assay service	Clinical laboratory service
2. Nuclear medicine imaging service	Radiological laboratory service

THIRD SCHEDULE

Reg 15

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 laboratory service
6. Tissue banking service

FOURTH SCHEDULE

Reg 17

QUALITY ASSURANCE COMMITTEES (QAC)

Category of licensees	*Quality assurance committees required to be appointed by licensees*
1. Every licensee authorised to provide blood banking service	(a) At least one Mortality and Morbidity QAC; and (b) At least one Serious Reportable Event QAC
2. Every licensee authorised to provide nuclear medicine imaging service or nuclear medicine assay service	(a) At least one Mortality and Morbidity QAC; and (b) At least one Serious Reportable Event QAC

FIFTH SCHEDULE

Reg 22

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 an allied health professional)
2. Any healthcare service provided by an allied health professional set out in the second column of the Second Schedule to the Allied Health Professions Act

SIXTH SCHEDULE

Reg 35(1)

FINANCIAL COUNSELLING

LICENSEES REQUIRED TO CONDUCT FINANCIAL COUNSELLING	COMPONENTS OF FEES REQUIRING FINANCIAL COUNSELLING
3. Every licensee authorised to provide a [] service	(*a*) Consultations; (*b*) Tests, procedures and investigations; (*c*) Medications; (*d*) Consumables; (*e*) Third party administrator services; (*f*) Total amount of the fees payable, before deducting the amount mentioned in paragraph (*g*), any deduction from any medisave account and any reimbursement under the MediShield Life Scheme; (*g*) Total amount of the Government subsidy or subsidies applicable to the patient (except any subsidy that the Director has directed the licensee not to disclose); (*h*) Net amount of the fees payable by the patient, after deducting the amount mentioned in paragraph (*g*), deduction from one or more medisave accounts and reimbursement under the MediShield Life Scheme
4. Every licensee authorised to provide [] service	

SEVENTH SCHEDULE

Reg 35(2)

PUBLIC SCHEMES

1. Medisave Scheme
2. MediShield Life Scheme

EIGHTH SCHEDULE

Reg 42

PROTECTED TERMS AND NAMES

1. Accident and emergency
2. Acute hospital
3. Ambulatory surgical centre
4. Assisted reproduction
5. Blood bank
6. Blood transfusion
7. Cell, tissue and gene therapy
8. Clinical genetic and genomic service
9. Clinical laboratory
10. Community hospital
11. Dental clinic
12. Diagnostic imaging laboratory
13. Egg bank
14. Embryo bank
15. Emergency ambulance
16. Emergency department
17. General hospital
18. General practitioner clinic

19. Health screening
20. Hospice
21. Inpatient hospice
22. Inpatient palliative care
23. In-vitro fertilisation
24. Medical and surgery
25. Medical centre
26. Medical clinic
27. Medical clinic and surgery
28. Medical laboratory
29. Medical transport
30. Nuclear medicine assay
31. Nuclear medicine imaging
32. Nuclear medicine therapy
33. Nursing home
34. Oocyte bank
35. Organ transplant
36. Proton beam therapy
37. Radiation oncology
38. Radiology laboratory
39. Renal dialysis centre
40. Specialised interventional procedure
41. Specialist centre
42. Specialist clinic
43. Sperm bank
44. Surgical centre
45. Telemedicine
46. Tissue bank
47. X-ray laboratory

Made on 2021.

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

[Please insert your Ministry's file ref; AG/LEGIS/SL/122E/2020/1]

Note 1: Healthcare Services (General) Regs 2021 (v02.11) (29.12.20)