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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;

"collaborative practice agreement", "collaborative prescribing practitioner" and "collaborative prescribing service" have the meanings given by regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023 (G.N. No. S 398/2023);

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"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;

"expiry date", in relation to any product or material, means —

(*a*) the date after which; or

(*b*) the month and year after the end of which,

as the case may be, the product or material should not be used;

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"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;

[*Deleted by S 414/2023 wef 26/06/2023*]

"simple in vitro diagnostic test" has the meaning given by paragraph 2 of the First Schedule to the Act;

[S 414/2023 wef 26/06/2023]

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

[S 414/2023 wef 26/06/2023]

Meaning of licensable healthcare services

2A. For the purposes of these Regulations, any reference to a licensable healthcare service is a reference to that licensable healthcare service within the meaning of paragraph 2 of the First Schedule to the Act.

[S 414/2023 wef 26/06/2023]

PART 1

ELECTRONIC LICENSING SYSTEM

Electronic licensing system

3.—(1) The Director-General may —

(*a*) require or permit any person to carry out any transaction with the Director-General 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.

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(2) Despite paragraph (1), the Director-General 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-General; or

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

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(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-General;

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"transaction" means —

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

[S 414/2023 wef 26/06/2023]

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

[S 414/2023 wef 26/06/2023]

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

[S 414/2023 wef 26/06/2023]

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

[S 414/2023 wef 26/06/2023]

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.

Application for approval under section 11A or 11C of Act

5.—(1) An applicant may apply for the grant of one or more of the following approvals in a single application, which must be accompanied by an application fee for the approval as determined in accordance with the Healthcare Services (Fees) Regulations 2021 (G.N. No. S 1032/2021), if prescribed:

(*a*) approval to provide a licensable healthcare service at any permanent premises;

(*b*) approval to provide a licensable healthcare service using a conveyance;

(*c*) approval to provide a licensable healthcare service by any other service delivery mode;

(*d*) approval to provide a specified service.

(2) An application for the grant of an approval must be made no later than —

(*a*) in relation to an approval mentioned in paragraph (1)(*a*), (*b*) or (*c*) — 2 months before the licensable healthcare service is provided at the permanent premises, using the conveyance or by the service delivery mode, or the expiry of any such approval, as the case may be; or

(*b*) in relation to an approval mentioned in paragraph (1)(*d*) — 2 months before the specified service is provided, or the expiry of any approval for the specified service, as the case may be.

[S 414/2023 wef 26/06/2023]

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.

(1A) For the purposes of section 15(3)(*b*)(i) of the Act, the prescribed time is 10 calendar days before the date the licensee intends to stop providing the licensable healthcare service at the approved permanent premises, using the approved conveyance or by the service delivery mode, as the case may be.

[S 414/2023 wef 26/06/2023]

(1B) For the purposes of section 15(3)(*b*)(ii) of the Act, the prescribed time is 10 calendar days before the date the licensee intends to stop providing the approved specified service.

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

[S 414/2023 wef 26/06/2023]

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-General to amend the name of the licensee in the licence no later than one month before the transfer or assignment is to take effect.

[S 414/2023 wef 26/06/2023]

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-General is one month.

[S 414/2023 wef 26/06/2023]

(2) Before a licensee wholly and permanently stops providing any 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 by another licensee;

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

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

[S 414/2023 wef 26/06/2023]

[S 414/2023 wef 26/06/2023]

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-General of the appointment of, or any change in, any key appointment holder or the Principal Officer of a licensee is 10 calendar days after the appointment or change, as the case may be.

[S 414/2023 wef 26/06/2023]

(1A) An application for the Director-General's approval for the appointment of an individual as a Clinical Governance Officer under section 24(2B) of the Act in relation to a licensable healthcare service or specified service must be made —

(*a*) at the same time that the application for the grant or renewal of the licence, or approval for the specified service, is made; or

(*b*) no later than 10 calendar days before the appointment.

[S 414/2023 wef 26/06/2023]

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

(*a*) in relation to the key appointment holder in respect of which the notice is given — about the matters mentioned in section 2(3)(*a*) to (*d*) of the Act; and

(*b*) in relation to the Principal Officer in respect of which the notice is given —

(i) that the person to be appointed as the Principal Officer is a suitable person to act as the licensee's Principal Officer; and

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

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(2A) An application under paragraph (1A) must include a declaration by the licensee in relation to the Clinical Governance Officer in respect of which the application is made —

(*a*) that the person to be appointed as the Clinical Governance Officer is a suitable person to act as the licensee's Clinical Governance Officer; and

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

[S 414/2023 wef 26/06/2023]

(3) Where any matter in a declaration made by a licensee under paragraph (2) or (2A) 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-General of the change.

[S 414/2023 wef 26/06/2023]

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-General of the proposed change one month before the removal or substitution takes effect.

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Period for appointment of replacement Principal Officer or Clinical Governance Officer

12.—(1) For the purposes of section 24(10)(*a*) of the Act —

(*a*) the prescribed period for the appointment of another Principal Officer is 10 calendar days after the removal of the previously appointed Principal Officer; and

(*b*) the prescribed period for the appointment of another Clinical Governance Officer is 20 calendar days (inclusive of the period for the application for the Director-General's approval of the Clinical Governance Officer) after the removal of the previously appointed Clinical Governance Officer.

(2) For the purposes of section 24(10)(*b*) of the Act —

(*a*) the prescribed period for the appointment of another Principal Officer is 10 calendar days after the previously appointed Principal Officer stops acting, or is unable to act, as Principal Officer; and

(*b*) the prescribed period for the appointment of another Clinical Governance Officer is —

(i) where the licensee had fewer than 10 calendar days' prior notice of the previously appointed Clinical Governance Officer's stopping, or inability, to act as Clinical Governance Officer, whether due to death or otherwise — 20 calendar days (inclusive of the period for the application for the Director-General's approval of the Clinical Governance Officer) after the previously appointed Clinical Governance Officer stops acting, or is unable to act, as Clinical Governance Officer; and

(ii) in any other case — one calendar day (inclusive of the period for the application for the Director-General's approval of the Clinical Governance Officer) after the previously appointed Clinical

Governance Officer stops acting, or is unable to act, as Clinical Governance Officer.

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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*) where the licensee is approved to provide the licensable healthcare service at any permanent premises, at any premises other than permanent premises (called in this sub-paragraph temporary premises) or using any conveyance — to ensure the safe operation of every approved permanent premises, temporary premises and approved conveyance, and the safety of persons at every approved permanent premises, temporary premises and approved conveyance;

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(*ca*) where the licensee is approved to provide the licensable healthcare service by remote provision and a patient is required to use any structure, facility, equipment or device provided by the licensee to receive the licensable healthcare service — to ensure the safe operation of the structure, facility, equipment or device and the safety of persons in the vicinity of the structure, facility, equipment or device;

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(*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 to handle the matter; or

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

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(*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 or specified services for which a licensee must appoint one or more Clinical Governance Officers are specified in the Second Schedule.

[S 414/2023 wef 26/06/2023]

(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 licensee's Clinical Governance Officer appointed for a licensable healthcare service or specified service (as the case may be) are as follows:

(*a*) to provide clinical governance and technical oversight over the licensable healthcare service or specified service, as the case may be;

(*b*) to assist the licensee in the day-to-day management of the clinical and technical aspects of the licensable healthcare service or specified service, as the case may be;

(*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 for the licensable healthcare service or specified service (as the case may be), 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 or specified service (as the case may be) 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 aspects of the licensable healthcare service or specified service (as the case may be) 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 aspects of the licensable healthcare service or specified service (as the case may be), 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 with any licence condition applicable to the licensable healthcare service or specified service, as the case may be.

(2) For the purposes of paragraph (1)(*b*), the Clinical Governance Officer's duty in relation to the day-to-day management of the clinical and technical aspects of the licensable healthcare service includes the following:

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

(i) the Clinical Governance Officer must be available to handle the matter; or

(ii) if the Clinical Governance Officer cannot be so available, the Clinical Governance Officer must appoint a suitably qualified and competent personnel of the licensee to handle the matter on the Clinical Governance Officer's behalf;

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

(3) 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 or specified service.

[S 414/2023 wef 26/06/2023]

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.

Step-in arrangements

16A. For the purposes of section 32 of the Act, Part 4 of the Act applies to the following licensees:

(*a*) a licensee authorised to provide an acute hospital service;

(*b*) a licensee authorised to provide a community hospital service;

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[S 848/2023 wef 18/12/2023]

(*c*) a licensee authorised to provide a nursing home service.

[S 848/2023 wef 18/12/2023]

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

Division 1 — Definitions

[S 414/2023 wef 26/06/2023]

Definitions for this Part

19. In this Part —

"CEC licensee" means a licensee who is required to appoint a clinical ethics committee under regulation 23C;

[S 414/2023 wef 26/06/2023]

"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;

"clinical ethics committee" or "CEC" means a clinical ethics committee appointed pursuant to regulation 23C;

[S 414/2023 wef 26/06/2023]

"mortality and morbidity review" or "MMR" means a review of the circumstances surrounding either of the following:

(*a*) the death of a patient, except where the event that caused the patient's death is a serious reportable event;

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

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"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;

"prescribed programme or activity" means any programme or activity set out in Part 2 of the Third Schedule;

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"QAC licensee" means a licensee who belongs to any of the categories of licensees specified in the first column of Part 1 of the Third Schedule that is required to appoint a quality assurance committee;

[S 414/2023 wef 26/06/2023]

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

"referring licensee", in relation to a CEC, means a licensee who is not a section 25 licensee and who refers or causes to be referred any proposed prescribed medical treatment to the CEC for an ethics review under section 26(2)(*b*) of the Act;

[S 414/2023 wef 26/06/2023]

"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;

"service review committee" or "SRC" means a service review committee appointed pursuant to regulation 23A;

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"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;

[S 414/2023 wef 26/06/2023]

"SRC licensee" means a licensee who is required to appoint a service review committee under regulation 23A.

[S 414/2023 wef 26/06/2023]

Division 2 — Quality assurance committees

[S 414/2023 wef 26/06/2023]

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 Part 1 of the Third Schedule must appoint one or more quality assurance committees specified in the second column of Part 1 of that Schedule opposite that category of licensees.

[S 414/2023 wef 26/06/2023]

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-General to the QAC licensee are complied with;

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

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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-General —

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

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

[S 414/2023 wef 26/06/2023]

Division 3 — Service review committees

Licensees required to appoint SRC

23A. For the purposes of section 25 of the Act, the following licensees must appoint a service review committee in relation to each prescribed programme or activity that is undertaken or to be undertaken in the provision of the licensable healthcare service by the licensee:

(*a*) a licensee approved under section 11D of the Act to provide a collaborative prescribing service;

(*b*) a licensee approved under section 11D of the Act to provide proton beam therapy.

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Service review

23B. The functions and duties of an SRC licensee's service review committee are as follows:

(*a*) to identify any trend or pattern of events in connection with the SRC licensee's undertaking of a prescribed programme or activity that does not comply with any requirements under the Act or code of practice applicable to that prescribed programme or activity;

(*b*) to identify the benefits and risks to patients in connection with the SRC licensee's undertaking of a prescribed programme or activity;

(*c*) to review —

(i) the trend or pattern of events referred to in paragraph (*a*) and make recommendations to the SRC licensee in relation to compliance with the requirements under the Act or code of practice mentioned in that paragraph; and

(ii) the benefits and risks mentioned in paragraph (*b*);

(*d*) to monitor the implementation by the SRC licensee of the recommendations made under paragraph (*c*)(i) and assess the effectiveness of the implemented recommendations;

(*e*) if patient safety and outcomes are jeopardised, to recommend to the licensee to stop the prescribed programme or activity.

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Division 4 — Clinical ethics committees

Licensees required to appoint CEC

23C.—(1) For the purposes of section 25 of the Act, every licensee authorised to provide an acute hospital service must, in accordance with paragraph (2), appoint one or more clinical ethics committees.

(2) A CEC appointed to conduct an ethics review must comprise —

(*a*) at least 6 members who are healthcare professionals each with at least 10 years of practice experience and who are in active practice, of whom at least 3 must each be an independent member; and

(*b*) at least 3 other members who are not healthcare professionals.

(3) In this regulation, "independent member", in relation to a licensee appointing a CEC to conduct an ethics review, means a member of the CEC —

(*a*) who is not employed by the licensee; and

(*b*) who does not have any interest (whether personal, professional or otherwise) in the outcome of the ethics review.

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Prescribed medical treatments for ethics review

23D. For the purposes of section 26 of the Act, the treatments specified in Part 3 of the Third Schedule are prescribed medical treatments.

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Ethics review

23E. The functions and duties of a CEC licensee's clinical ethics committee are as follows:

(*a*) to conduct an ethics review of —

(i) every prescribed medical treatment relating to the care and treatment of a patient of the CEC licensee; and

(ii) every prescribed medical treatment relating to a patient of a referring licensee;

(*b*) to conduct an ethics review of any case (other than a case mentioned in paragraph (*a*)) referred to it by the CEC licensee or any other licensee;

(*c*) to advise the CEC licensee on the formulation of clinical ethics policies and guidelines;

(*d*) to recommend appropriate education and training for healthcare professionals providing any healthcare service at any of the CEC licensee's approved permanent premises on the provision of the healthcare service in an ethical manner;

(*e*) to assist the CEC licensee in ensuring that ethical misdemeanours are reviewed and addressed promptly and appropriately;

(*f*) to document every discussion and decision by the CEC;

(*g*) to establish criteria for an ethics review conducted for a prescribed medical treatment;

(*h*) within 10 calendar days after a CEC completes the review of any case mentioned in paragraph (*a*) — inform the Director-General whether the CEC is of the opinion that it is ethically appropriate to administer the prescribed medical treatment as proposed by the CEC licensee or referring licensee.

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Duties of CEC licensee

23F. A CEC licensee must —

(*a*) deploy appropriate and adequate personnel to provide secretariat support to each CEC that the licensee appoints;

(*b*) provide adequate training and educational resources to the members of each CEC that the licensee appoints to enable the members to carry out their functions and duties;

(*c*) establish a system to audit the procedures and decision-making of each CEC that the licensee appoints; and

(*d*) periodically review —

(i) the system for referring licensees to refer cases to; and

(ii) the processes adopted by,

each CEC that the licensee appoints, and take appropriate measures to rectify any deficiencies detected.

[S 414/2023 wef 26/06/2023]

PART 6

PREMISES, CONVEYANCES AND EQUIPMENT, ETC.

[S 414/2023 wef 26/06/2023]

Premises, conveyances and equipment, etc.

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

(*a*) every premises or conveyance used in the provision of the licensable healthcare service is safe, sanitary, accessible and appropriately equipped;

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(*b*) where the licensee provides the licensable healthcare service by remote provision — every structure, facility, equipment or device provided by the licensee for a patient's use is sanitary and safe for the patient's use;

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(*c*) all medical and surgical equipment, instruments, appliances, materials and facilities —

(i) are installed, and used or operated, in accordance with the instructions of the manufacturer; and

(ii) are checked regularly, maintained and repaired properly and according to the specifications of the manufacturer,

so as to ensure that they are adequate, functional and effective and the licensable healthcare service is provided safely; and

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(*d*) any medical or surgical equipment, instrument, appliance, material or facility which is not functioning properly or effectively is replaced in a timely manner.

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[S 414/2023 wef 26/06/2023]

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 approved permanent premises or approved 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 approved permanent premises or approved conveyance to provide a non-licensable healthcare service specified in the first column of the Fourth Schedule (called in this regulation a specified healthcare service), subject to the condition specified opposite in the second column of that Schedule.

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(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 approved permanent premises or approved 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-General to do so.

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(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 approved permanent premises or in the approved conveyance where the licensee's licensable healthcare service is also provided;

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(*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-General, stating that the specified healthcare service or co-located service is not licensed under the Act; and

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(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 approved permanent premises or approved conveyance.

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(4) In paragraph (3)(*a*), 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.

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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;

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(*aa*) the label on the medicinal product or health product includes the expiry date of the product; and

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(*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 and administration 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 expiry date of the product.

[S 414/2023 wef 26/06/2023]

(2) A licensee must establish and implement processes to ensure —

(*a*) that every medicinal product or health product is accurately prepared, dispensed and administered in accordance with a prescription that is issued by —

(i) a dentist;

(ii) a medical practitioner; or

(iii) a collaborative prescribing practitioner in accordance with a collaborative practice agreement; and

(*b*) the keeping and maintenance of proper and accurate records of each medicinal product or health product prepared, dispensed or administered under sub-paragraph (*a*).

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(3) A licensee must establish and implement measures to ensure that each of the licensee's personnel undertaking any activity related to the preparation, dispensation and administration of medicinal products or health products complies with the processes mentioned in paragraph (2).

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(4) Where a licensee knows that there is a deviation between the amount or type of medicinal product or health product dispensed or administered to a patient and the amount or type of medicinal product or health product prescribed, the licensee must —

(*a*) immediately inform the patient of the deviation and the steps or measures to be taken to avoid or minimise patient harm; and

(*b*) keep and maintain proper and accurate records of the deviation and when the patient was informed of the deviation under sub-paragraph (*a*).

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[S 414/2023 wef 26/06/2023]

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 by the licensee at any place used for the provision of the licensable healthcare service 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 the manufacturer's specifications.

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(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; and

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

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(*d*) [*Deleted by S 414/2023 wef 26/06/2023*]

PART 8

SPECIMENS

Collection of specimens

32.—(1) 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 requestor to be carried out for the patient; and

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(*c*) the container containing the specimen is labelled accurately and clearly with —

(i) a name and reference number unique to the patient;

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

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

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(2) A licensee must —

(*a*) implement a system where all relevant specimen collection information may be traced from an identifier on the container containing the specimen; or

(*b*) include all relevant specimen collection information on the label on the container containing the specimen.

[S 414/2023 wef 26/06/2023]

(3) In this regulation —

"relevant specimen collection information", in relation to a specimen, means the following information:

(*a*) the date and time of the collection of the specimen;

(*b*) the type of specimen;

"requestor", in relation to a patient, means the medical practitioner, dentist or collaborative prescribing practitioner who ordered a test for the patient.

[S 414/2023 wef 26/06/2023]

Testing of specimens

32A.—(1) Subject to paragraph (2), a licensee who, in the provision of a licensable healthcare service, collects any specimen from an individual for the specimen to be tested must ensure that the specimen is tested by —

(*a*) a licensee authorised to provide a clinical laboratory service; or

(*b*) where the sample is intended to be sent for testing outside Singapore — a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director-General.

(2) Paragraph (1) does not apply in relation to a licensee who tests any specimen with the use of a simple in vitro diagnostic test for a purpose that is incidental to the licensee's provision of a licensable healthcare service.

[S 414/2023 wef 26/06/2023]

Tests must have clinical utility

32B. A licensee must ensure that every test that is carried out on a specimen from a patient provides information that is relevant for the clinical management of the patient's health or medical condition.

[S 414/2023 wef 26/06/2023]

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, complete and timely information about the patient's care and treatment.

[S 414/2023 wef 26/06/2023]

(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, in the provision of the licensable healthcare service, and maintaining a proper record of the consent obtained.

[S 414/2023 wef 26/06/2023]

(3) Where, in the provision of a licensable healthcare service by a licensee, a test is conducted (whether or not by the licensee) 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 the requestor without undue delay;

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(*b*) the requestor reviews the findings in a timely manner;

[S 414/2023 wef 26/06/2023]

(*c*) the patient is informed, without undue delay, of the findings that, in the professional opinion of the requestor, are clinically significant;

[S 414/2023 wef 26/06/2023]

(*d*) the requestor advises the patient, based on the findings and without undue delay, on the patient's condition, prognosis and clinical management.

[S 414/2023 wef 26/06/2023]

[S 414/2023 wef 26/06/2023]

(4) In this regulation, "requestor", in relation to a test conducted on a patient, means —

(*a*) the medical practitioner, dentist or collaborative prescribing practitioner who ordered the test for the patient; and

(*b*) any medical practitioner, dentist or collaborative prescribing practitioner designated by the person mentioned in sub-paragraph (*a*) to carry out any duty mentioned in paragraph (3)(*a*), (*b*), (*c*) or (*d*).

[S 414/2023 wef 26/06/2023]

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-General may specify, an accurate, complete and up-to-date patient health record of every patient in accordance with this regulation.

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(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 and patient registration number for the visit, consultation or admission;

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(*e*) medical history, referral documents and declaration forms relating to the patient's health or medical history;

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(*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;

(*ga*) the name of each medical practitioner or dentist (as the case may be) who has provided care or treatment to the patient;

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(*gb*) the date of and reason for each medical certificate issued to the patient;

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(*gc*) any consent or acknowledgment forms;

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(*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;

(*ma*) health declaration forms;

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(*mb*) financial counselling forms;

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(*mc*) records of any adverse event that occurred in the provision of the licensable healthcare service and the actions taken by the licensee's personnel in response to the adverse event;

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(*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, clinical laboratory service, cord blood banking service, human tissue banking service, nuclear medicine service or radiological service.

[S 414/2023 wef 26/06/2023]

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

Issuance of bill

40.—(1) Subject to paragraphs (2) and (3), 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.

[S 414/2023 wef 26/06/2023]

(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 is an adult who lacks capacity within the meaning of section 4 of the Mental Capacity Act 2008 — any of the following persons:

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

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

(iii) in any other case — any of the patient's next of kin;

[S 848/2023 wef 18/12/2023]

(*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) Paragraph (1) does not apply where the patient or other person mentioned in paragraph (2) requests the licensee not to issue a bill.

[S 414/2023 wef 26/06/2023]

(4) [*Deleted by S 414/2023 wef 26/06/2023*]

(5) [*Deleted by S 414/2023 wef 26/06/2023*]

(6) [*Deleted by S 414/2023 wef 26/06/2023*]

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 by ensuring that —

(*a*) where the licensable healthcare service is provided at approved permanent premises or using an approved conveyance — the environment surrounding and within the approved permanent premises or approved conveyance is clean and safe;

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(*b*) all the equipment and facilities used for the provision of the licensable healthcare service are clean and safe;

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(*c*) the use of all the appliances, equipment, instruments and materials for the provision of the licensable healthcare service is in compliance with the established or

recommended procedures for their maintenance and use; and

[S 414/2023 wef 26/06/2023]

(*d*) appropriate infection control processes are implemented at any premises or in any conveyance used for the provision of the licensable healthcare service.

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[S 414/2023 wef 26/06/2023]

Notification of infectious diseases

42. For the purposes of the requirement in the Infectious Diseases Act 1976 to notify the Director-General 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.

[S 414/2023 wef 26/06/2023]

43. [*Deleted by S 414/2023 wef 26/06/2023*]

Management of biohazardous materials and sharps

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 or the use of sharps, the licensee must —

(*a*) take effective measures to ensure the safe and proper use, storage and disposal of the biohazardous material or sharps;

(*b*) establish policies and procedures to prevent any patient or personnel from contracting an infection resulting from exposure to biohazards or any sharps injury; and

(*c*) ensure that each policy and procedure mentioned in sub-paragraph (*b*) is implemented.

[S 414/2023 wef 26/06/2023]

(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.

[S 414/2023 wef 26/06/2023]

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 approved permanent premises or approved conveyance or any structure, facility, equipment or device used for the provision of the licensable healthcare service which requires an individual to enter the structure, facility, equipment or device.

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(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.—(1) 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;

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(*f*) in relation to each premises or conveyance that the licensee uses for the provision of a licensable healthcare service —

(i) ensure that there is at all times, at least one week's supply of Personal Protective Equipment (PPE) available at the premises or conveyance for each personnel deployed at the premises or conveyance; or

(ii) implement processes to ensure that the licensee may, at any time, obtain at least one week's supply of Personal Protective Equipment (PPE) for each

personnel deployed at the premises or conveyance; and

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(*g*) ensure that each item of Personal Protective Equipment (PPE) given to the licensee's personnel is fit for use and has not passed its expiry date, if any.

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(2) In this regulation, "Personal Protective Equipment (PPE)" includes 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.

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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) Subject to paragraph (2A), 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.

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(2A) Where a licensee is an individual —

(*a*) the business continuity plan must also establish the systems and set out the procedures necessary (including the measures specified in regulation 39(1)) for the transfer of the care of the licensee's patients to another licensee in the event of the licensee's death; and

(*b*) the licensee must nominate a person to carry out the procedures mentioned in sub-paragraph (*a*) in the event of the licensee's death.

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(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, 30(1), (2) or (3), 31, 32, 33(1), 35, 36, 38, 39(1), 41, 44(1), 45 or 47(1) shall be guilty of an offence.

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(1A) Where —

(*a*) a licensee contravenes regulation 29(2)(*a*) or (3) in relation to any medicinal product or health product dispensed or administered to a patient; and

(*b*) the contravention results in the patient suffering any harm,

the licensee shall be guilty of an offence.

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(2) A person who is guilty of an offence under paragraph (1) or (1A) 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.

[S 414/2023 wef 26/06/2023]

FIRST SCHEDULE

[*Deleted by S 414/2023 wef 26/06/2023*]

SECOND SCHEDULE

Regulation 14(1)

LICENSABLE HEALTHCARE SERVICES AND SPECIFIED SERVICES REQUIRING APPOINTMENT OF CLINICAL GOVERNANCE OFFICERS

1. Blood banking service
2. Clinical laboratory service
3. Nuclear medicine service

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4. [*Deleted by S 414/2023 wef 26/06/2023*]
5. Radiological service
6. Cord blood banking service
7. Emergency ambulance service
8. Medical transport service

SECOND SCHEDULE — *continued*

9. Ambulatory surgical centre service

[S 414/2023 wef 26/06/2023]

10. Assisted reproduction service

[S 414/2023 wef 26/06/2023]

11. Contingency care service

[S 414/2023 wef 26/06/2023]

12. Human tissue banking service

[S 414/2023 wef 26/06/2023]

13. Outpatient dental service

[S 414/2023 wef 26/06/2023]

14. Outpatient medical service

[S 414/2023 wef 26/06/2023]

15. Outpatient renal dialysis service

[S 414/2023 wef 26/06/2023]

[S 414/2023 wef 26/06/2023]

16. Nursing home service

[S 848/2023 wef 18/12/2023]

THIRD SCHEDULE

Regulations 19, 20 and 23D

COMMITTEES APPOINTED BY LICENSEES

PART 1

QUALITY ASSURANCE COMMITTEES (QAC)

First column	*Second column*
Licensees or category of licensees	*Quality assurance committees required to be appointed by licensees*
1. Every licensee authorised to provide any of the following licensable healthcare services: (*a*) a blood banking service (*b*) a nuclear medicine service	At least one Serious Reportable Event QAC
1. Every licensee authorised to provide any of the following licensable healthcare services:	At least one Serious Reportable Event QAC

THIRD SCHEDULE — *continued*

(*a*) a blood banking service (*b*) a nuclear medicine service (*c*) a nursing home service	
2. Every licensee authorised to provide a nuclear medicine service, in relation to the provision of the service for a therapy purpose	At least one Mortality and Morbidity QAC
3. Every licensee authorised to provide an acute hospital service	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC (iii) At least one Peer Review Learning QAC
4. Every licensee authorised to provide any of the following licensable healthcare services: (*a*) ambulatory surgical centre service (*b*) assisted reproduction service (*c*) community hospital service (*d*) outpatient renal dialysis service	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC
5. Every licensee authorised to provide an outpatient medical service and approved to provide any of the following specified services: (*a*) blood transfusion service (*b*) proton beam therapy (*c*) radiation oncology and radiation therapy	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC
6. Every licensee authorised to provide an outpatient medical service and who provides the service only to students enrolled in a primary school or secondary school	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC

THIRD SCHEDULE — *continued*

7. Every licensee authorised to provide an outpatient medical service and who provides the service at a polyclinic	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC
8. Every licensee authorised to provide an outpatient medical service and who provides the service at a specialist outpatient clinic, where the licensee is a cluster HQ or its subsidiary	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC
9. Every licensee authorised to provide a contingency care service	(i) At least one Mortality and Morbidity QAC (ii) At least one Serious Reportable Event QAC

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In Part 1 of this Schedule —

"cluster HQ" means any of the following:

(*a*) National Healthcare Group Pte Ltd;

(*b*) National University Health System Pte Ltd;

(*c*) Singapore Health Services Pte Ltd;

"Mortality and Morbidity QAC" means a QAC established by a licensee to identify and evaluate any case for mortality and morbidity review, and take any steps that are necessary or appropriate, in accordance with the Act and these Regulations;

"Peer Review Learning QAC" means a QAC established by a licensee to review and evaluate clinical quality, safety and appropriateness of care provided by specialists employed or engaged by the licensee, and take any steps that are necessary or appropriate, in accordance with the Act and these Regulations;

"Serious Reportable Event QAC" means a QAC established by a licensee to identify and evaluate any serious reportable event that occurs in the course of providing a licensable healthcare service, and take any steps that are necessary or appropriate, in accordance with the Act and these Regulations.

THIRD SCHEDULE — *continued*

PART 2

PRESCRIBED PROGRAMMES AND ACTIVITIES IN RESPECT OF WHICH A SERVICE REVIEW COMMITTEE MUST BE APPOINTED

1. Proton beam therapy.

2. Collaborative prescribing service.

PART 3

PRESCRIBED MEDICAL TREATMENTS TO BE REVIEWED BY A CLINICAL ETHICS COMMITTEE

1. Surgical separation of conjoint twins.

2. Psychosurgery.

3. Treatment for sexual sterilisation on an unmarried person with mental capacity and below 21 years of age.

4. Reproductive organ transplant.

5. Gender reassignment surgery.

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

7. Transcranial direct current stimulation.

8. Testicular biopsy, if proposed to be performed on an individual who —

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

(*b*) has Klinefelter syndrome.

9. Testicular tissue freezing, if proposed to be performed on an individual who —

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

(*b*) has Klinefelter syndrome.

10. The transfer of an intergenerational gamete or embryo for an assisted reproduction procedure.

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

(*a*) that is manufactured by a licensee; and

THIRD SCHEDULE — *continued*

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

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

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FOURTH SCHEDULE

Regulation 26(1)

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

First column	*Second column*
Specified healthcare service	*Prescribed condition*
1. Any activity or service within the description of a prescribed allied health profession set out in the third column of the Second Schedule to the Allied Health Professions Act 2011 that is a healthcare service	Must be provided by an allied health professional who is registered under the Allied Health Professions Act 2011 for the prescribed allied health profession and holds a valid practising certificate under that Act
2. Any act of nursing that is a healthcare service	Must be provided by a registered nurse or an enrolled nurse under the Nurses and Midwives Act 1999 who holds a valid practising certificate under that Act
3. Any activity or service involved in attending a woman at childbirth that is a healthcare service	Must be provided by a registered midwife under the Nurses and Midwives Act 1999 who holds a valid practising certificate under that Act
4. Any act or activity specified in Part 1 of the Schedule to the Optometrists and Opticians Act 2007 that is a healthcare service	Must be provided by an optician who is registered under the Optometrists and Opticians Act 2007 and holds a valid practising certificate under that Act
5. Any act or activity specified in Part 2 of the Schedule to the Optometrists and Opticians	Must be provided by an optometrist who is registered under the Optometrists and Opticians Act 2007

FOURTH SCHEDULE — *continued*

Act 2007 that is a healthcare service	and holds a valid practising certificate under that Act
6. Any act or activity specified in the Schedule to the Pharmacists Registration Act 2007 that is a healthcare service	Must be provided by a pharmacist who is registered under the Pharmacists Registration Act 2007 and holds a valid practising certificate under that Act
7. Acupuncture	Must be provided by 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

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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

FIFTH SCHEDULE — *continued*

15. Embryo bank
16. Emergency ambulance
17. Emergency department
18. General hospital
19. General practitioner clinic
20. Health screening
21. Hospice
22. Inpatient hospice
23. Inpatient palliative care
24. In-vitro fertilisation
25. Maternity home
26. Medical and surgery
27. Medical centre
28. Medical clinic
29. Medical clinic and surgery
30. Medical laboratory
31. Medical transport
32. Mobile medicine
33. National Centre
34. National Specialty Centre
35. Nuclear medicine assay
36. Nuclear medicine imaging
37. Nuclear medicine therapy
38. Nursing home
39. Oocyte bank
40. Organ transplant
41. Polyclinic
42. Proton beam therapy
43. Radiation oncology

FIFTH SCHEDULE — *continued*

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
56. Family physician

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

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