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No. S 414

HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (GENERAL) (AMENDMENT) REGULATIONS 2023

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) (Amendment) Regulations 2023 and come into operation on 26 June 2023.

Amendment of regulation 2

2. In the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021) (called in these Regulations the principal Regulations), in regulation 2 —

(*a*) after the definition of "clinical risk", insert —

> " "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);";

(*b*) after the definition of "enterprise risk", insert —

> " "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;"; and

(*c*) replace the definition of "specimen" with —

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

"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.".

New regulation 2A

3. In the principal Regulations, after regulation 2, insert —

"**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.".

Replacement of regulation 5

4. In the principal Regulations, replace regulation 5 with —

"**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.".

Amendment of regulation 6

5. In the principal Regulations, in regulation 6 —

(*a*) after paragraph (1), insert —

"(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.

(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."; and

(*b*) in paragraph (2), replace "the particulars mentioned in paragraph (1)" with "the matters mentioned in paragraph (1), (1A) or (1B)".

Amendment of regulation 8

6. In the principal Regulations, in regulation 8(2) —

(*a*) delete ", or stops using any licensed premises or licensed conveyance specified in the licence,";

(*b*) in sub-paragraph (*a*), delete ", whether by the licensee in another licensed premises or conveyance, or"; and

(*c*) in sub-paragraph (*c*), delete ", licensed premises or licensed conveyance,".

Amendment of regulation 10

7. In the principal Regulations, in regulation 10 —

(*a*) in paragraph (1), replace ", the Principal Officer or any Clinical Governance Officer" with "or the Principal Officer";

(*b*) after paragraph (1), insert —

"(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.";

(*c*) replace paragraph (2) with —

"(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.

(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."; and

(*d*) in paragraph (3), after "paragraph (2)", insert "or (2A)".

Replacement of regulation 12

8. In the principal Regulations, replace regulation 12 with —

"**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.".

Amendment of regulation 13

9. In the principal Regulations, in regulation 13 —

(*a*) in paragraph (1), replace sub-paragraph (*c*) with —

"(*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;

(*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;";

(*b*) in paragraph (2)(*a*)(i), delete "at the licensed premises or licensed conveyance"; and

(*c*) in paragraph (2)(*a*)(ii), delete "to be present at the licensed premises or licensed conveyance".

Amendment of regulation 14

10. In the principal Regulations, in regulation 14(1), after "services", insert "or specified services".

Replacement of regulation 15

11. In the principal Regulations, replace regulation 15 with —

"**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.".

New regulation 16A

12. In the principal Regulations, after regulation 16, insert —

"**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.".

New Division heading in Part 5

13. In the principal Regulations, in Part 5, after the Part heading, insert —

"*Division 1 — Definitions*".

Amendment of regulation 19

14. In the principal Regulations, in regulation 19 —

(*a*) before the definition of "clinical appropriateness", insert —

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

(*b*) after the definition of "clinical appropriateness", insert —

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

(*c*) replace the definition of "mortality and morbidity review" or "MMR" with —

" "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;";

(*d*) after the definition of "peer review learning" or "PRL", insert —

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

(*e*) in the definition of "QAC licensee", after "first column of", insert "Part 1 of";

(*f*) after the definition of "quality assurance committee" or "QAC", insert —

" "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;";

(*g*) after the definition of "serious reportable event", insert —

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

(*h*) in the definition of "specialist", replace the full-stop at the end with a semi-colon; and

(*i*) after the definition of "specialist", insert —

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

New Division heading in Part 5

15. In the principal Regulations, after regulation 19, insert —

"*Division 2 — Quality assurance committees*".

Amendment of regulation 20

16. In the principal Regulations, in regulation 20 —

(*a*) after "first column of", insert "Part 1 of"; and

(*b*) after "second column of", insert "Part 1 of".

New Divisions 3 and 4 of Part 5

17. In the principal Regulations, after regulation 23, insert —

"*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.

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.

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.

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.

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.

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.".

Amendment of Part 6 heading

18. In the principal Regulations, in Part 6, in the Part heading, replace "LICENSED PREMISES, LICENSED CONVEYANCES" with "PREMISES, CONVEYANCES".

Amendment of regulation 24

19. In the principal Regulations, in regulation 24 —

(*a*) in the regulation heading, replace "**Licensed premises, licensed conveyances**" with "**Premises, conveyances**";

(*b*) in paragraph (*a*), replace "every licensed premises and licensed conveyance are" with "every premises or conveyance used in the provision of the licensable healthcare service is";

(*c*) in paragraph (*a*), delete "and" at the end; and

(*d*) replace paragraph (*b*) with —

"(*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;

(*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

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

Amendment of regulation 26

20. In the principal Regulations, in regulation 26 —

(*a*) in the regulation heading, replace "**licensed premises or licensed conveyance**" with "**approved permanent premises or approved conveyance**";

(*b*) in paragraph (1), replace "licensed premises or licensed conveyance to provide a non-licensable healthcare service specified in the Fourth Schedule (called in this regulation a

specified healthcare service)" with "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";

(*c*) in paragraph (2), replace "licensed premises or licensed conveyance" with "approved permanent premises or approved conveyance";

(*d*) in paragraph (3)(*c*)(ii), replace "licensed premises or in the licensed conveyance" with "approved permanent premises or in the approved conveyance";

(*e*) in paragraph (3)(*e*)(ii)(B), replace "licensed premises or licensed conveyance" with "approved permanent premises or approved conveyance"; and

(*f*) in paragraph (4), replace "paragraph (3)(*b*)" with "paragraph (3)(*a*)".

Amendment of regulation 28

21. In the principal Regulations, in regulation 28(2) —

(*a*) in sub-paragraph (*a*), delete "and" at the end; and

(*b*) after sub-paragraph (*a*), insert —

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

Amendment of regulation 29

22. In the principal Regulations, in regulation 29 —

(*a*) in the regulation heading, after "**dispensing**", insert "**and administration**";

(*b*) in paragraph (1), delete "shelf life or"; and

(*c*) replace paragraph (2) with —

"(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*).

(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).

(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*).".

Amendment of regulation 30

23. In the principal Regulations, in regulation 30(1) —

(*a*) replace "at any licensed premises or in any licensed conveyance" with "by the licensee at any place used for the provision of the licensable healthcare service"; and

(*b*) in sub-paragraph (*b*), replace "any code of practice relating to the quality and safety of medicinal products or health products" with "the manufacturer's specifications".

Amendment of regulation 31

24. In the principal Regulations, in regulation 31 —

(*a*) in paragraph (*b*), insert "and" at the end;

(*b*) in paragraph (*c*), replace "; and" at the end with a full-stop; and

(*c*) delete paragraph (*d*).

Amendment of regulation 32

25. In the principal Regulations, in regulation 32 —

(*a*) renumber the regulation as paragraph (1) of that regulation;

(*b*) in paragraph (1)(*b*), replace "medical practitioner" with "requestor";

(*c*) in paragraph (1), replace sub-paragraph (*c*) with —

"(*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.”; and

(*d*) after paragraph (1), insert —

“(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.

(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.”.

New regulations 32A and 32B

26. In the principal Regulations, after regulation 32, insert —

"**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.

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.".

Amendment of regulation 36

27. In the principal Regulations, in regulation 36 —

(*a*) in paragraph (1), after "accurate", insert ", complete";

(*b*) in paragraph (2), replace "at any licensed premises or in any licensed conveyance" with "in the provision of the licensable healthcare service";

(*c*) in paragraph (3), after "conducted", insert "(whether or not by the licensee)";

(*d*) in paragraph (3)(*a*), replace "a medical practitioner practising in the licensable healthcare service" with "the requestor";

(*e*) in paragraph (3), in sub-paragraphs (*b*), (*c*) and (*d*), replace "medical practitioner mentioned in sub-paragraph (*a*)" with "requestor"; and

(*f*) after paragraph (3), insert —

"(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*).".

Amendment of regulation 37

28. In the principal Regulations, in regulation 37 —

(*a*) in paragraph (3)(*d*), after "forms", insert "and patient registration number for the visit, consultation or admission";

(*b*) in paragraph (3)(*e*), replace "and referral documents" with ", referral documents and declaration forms relating to the patient's health or medical history";

(*c*) in paragraph (3), after sub-paragraph (*g*), insert —

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

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

(*gc*) any consent or acknowledgment forms;";

(*d*) in paragraph (3), after sub-paragraph (*m*), insert —

"(*ma*) health declaration forms;

(*mb*) financial counselling forms;

(*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;"; and

(*e*) replace paragraph (5) with —

"(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.".

Amendment of regulation 40

29. In the principal Regulations, in regulation 40 —

(*a*) in the regulation heading, replace "**Itemisation**" with "**Issuance**";

(*b*) in paragraph (1), replace "paragraph (2)" with "paragraphs (2) and (3)"; and

(*c*) replace paragraphs (3) to (6) with —

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

Amendment of regulation 41

30. In the principal Regulations, in regulation 41 —

(*a*) delete "at any licensed premises or in any licensed conveyance";

(*b*) replace paragraph (*a*) with —

"(*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;";

(*c*) in paragraph (*b*), replace "at the licensed premises or in the licensed conveyance" with "used for the provision of the licensable healthcare service";

(*d*) in paragraph (*c*), replace "at the licensed premises or in the licensed conveyance" with "for the provision of the licensable healthcare service"; and

(*e*) in paragraph (*d*), replace "at the licensed premises or in the licensed conveyance" with "at any premises or in any conveyance used for the provision of the licensable healthcare service".

Deletion of regulation 43

31. In the principal Regulations, delete regulation 43.

Amendment of regulation 44

32. In the principal Regulations, in regulation 44 —

(*a*) in the regulation heading, after "**materials**", insert "**and sharps**"; and

(*b*) replace paragraph (1) with —

"(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.".

Amendment of regulation 45

33. In the principal Regulations, in regulation 45(1)(*e*), replace "licensed premises or licensed conveyance" with "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".

Amendment of regulation 46

34. In the principal Regulations, in regulation 46 —

(*a*) renumber the regulation as paragraph (1) of that regulation;

(*b*) in paragraph (1)(*e*), delete "and" at the end;

(*c*) in paragraph (1), replace sub-paragraph (*f*) with —

"(*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

(*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."; and

(*d*) after paragraph (1), insert —

"(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.".

Amendment of regulation 47

35. In the principal Regulations, in regulation 47 —

(*a*) in paragraph (2), replace "A licensee" with "Subject to paragraph (2A), a licensee"; and

(*b*) after paragraph (2), insert —

"(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.".

Amendment of regulation 50

36. In the principal Regulations, in regulation 50 —

(*a*) in paragraph (1), delete "29,";

(*b*) in paragraph (1), delete "43(1) or (3),";

(*c*) after paragraph (1), insert —

"(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."; and

(*d*) in paragraph (2), after "paragraph (1)", insert "or (1A)".

Deletion of First Schedule

37. In the principal Regulations, delete the First Schedule.

Amendment of Second Schedule

38. In the principal Regulations, in the Second Schedule —

(*a*) in the Schedule heading, after "SERVICES", insert "AND SPECIFIED SERVICES";

(*b*) replace items 3 and 4 with —

"3. Nuclear medicine service"; and

(*c*) after item 8, insert —

"9. Ambulatory surgical centre service

10. Assisted reproduction service

11. Contingency care service

12. Human tissue banking service

13. Outpatient dental service

14. Outpatient medical service

15. Outpatient renal dialysis service".

Replacement of Third and Fourth Schedules

39. In the principal Regulations, replace the Third and Fourth Schedules with —

"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
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
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

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.

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

(*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.

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 Act 2007 that is a healthcare service	Must be provided by an optometrist who is registered under the Optometrists and Opticians Act 2007 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

".

Amendment of Fifth Schedule

40. In the principal Regulations, in the Fifth Schedule, after item 55, insert —

"56. Family physician".

Miscellaneous amendments

41. In the principal Regulations, in the following provisions, replace "Director" wherever it appears with "Director-General":

Regulation 3

Regulation 7

Regulation 8(1) and (2)(*c*)

Regulation 10(1) and (3)

Regulation 11

Regulation 21(2)(*g*) and (*h*)

Regulation 23

Regulation 26(2) and (3)(*e*)(ii)(A)

Regulation 37(1)

Regulation 42.

Made on 19 June 2023.

CHAN YENG KIT
Permanent Secretary,
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Singapore.

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