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HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (OUTPATIENT MEDICAL SERVICE) REGULATIONS 2023

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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:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Healthcare Services (Outpatient Medical Service) Regulations 2023 and come into operation on 26 June 2023.

Definitions

2.—(1) In these Regulations —

“allied health professional” has the meaning given by section 2 of the Allied Health Professions Act 2011;

“blood transfusion service” means —

- (a) the collection of whole blood, or any blood component or product that is derived from plasma, red blood cells, white blood cells or platelets from an individual for the purpose of administering it to that individual (as a patient) or another patient;
- (b) the administration to a patient, by bolus injection or continuous infusion, of either or both of the following, whether obtained from the patient or one or more other individuals:
 - (i) whole blood;

(ii) any blood component or product that is derived from plasma, red blood cells, white blood cells or platelets; and

(c) the temporary storage of any whole blood or blood component or product that is derived from plasma, red blood cells, white blood cells or platelets for the purpose mentioned in paragraph (a) or (b);

“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);

“duly qualified allied health professional” has the meaning given by section 3 of the Allied Health Professions Act 2011;

“enrolled nurse” means a person who is an enrolled nurse within the meaning of the Nurses and Midwives Act 1999 and holds a valid practising certificate under that Act;

“essential life-saving measure” means any basic emergency procedure that may be carried out on a person for the purpose of resuscitating the person;

“expiry date” has the meaning given by regulation 2 of the General Regulations;

“General Regulations” means the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021);

“haematology service” means the diagnosis or treatment by a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in haematology, of a patient who has a disorder of the blood or bone marrow;

“healthcare professional” has the meaning given by regulation 2 of the General Regulations;

“health product” has the meaning given by section 2(1) of the Health Products Act 2007;

“licensee” means a person who holds a licence to provide an outpatient medical service;

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- “medicinal product” has the meaning given by section 3 of the Medicines Act 1975;
- “MediShield Life Scheme” means the MediShield Life Scheme established by section 3 of the MediShield Life Scheme Act 2015;
- “minor surgical procedure” has the meaning given by paragraph 2 of the First Schedule to the Act;
- “nurse” means a registered nurse or an enrolled nurse;
- “oncology service” means the diagnosis and treatment by a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in oncology, of a person who has cancer;
- “outpatient medical service” has the meaning given by paragraph 2 of the First Schedule to the Act;
- “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 an outpatient medical 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 an outpatient medical service;
- “pharmacist” means a person who is registered under the Pharmacists Registration Act 2007 and holds a valid practising certificate under that Act;
- “registered nurse” means a person who is a registered nurse within the meaning of the Nurses and Midwives Act 1999 and holds a valid practising certificate under that Act;
- “remote service kiosk”, in relation to the provision of an outpatient medical service by a licensee by remote provision, means an equipment or facility that —
- (a) is provided by the licensee for any patient to receive the outpatient medical service by remote provision;
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(b) may include a booth or a vending machine or any similar equipment which dispenses any medicinal product or health product that is prescribed for the patient, or both;

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

“software application” means a software application that operates on any computer or mobile device such as a smartphone;

“specimen” has the meaning given by regulation 2 of the General Regulations;

“temporary premises” means any premises other than permanent premises;

“testing material” means any test kit, material, device, equipment, instrument or other article that is used to conduct a simple in vitro diagnostic test.

(2) For the purposes of these Regulations, a licensee is not to be treated as providing any outpatient medical service by remote provision to a patient, merely because —

(a) the licensee provides any information and communication technology to the patient to enable the transmission of data related to the patient’s health status between the patient and the licensee and the monitoring of the patient’s health by the licensee; or

(b) the licensee communicates with the patient remotely for administrative matters, including (but not limited to) the arrangement of the date of the patient’s next medical appointment.

Application of Regulations

3. Unless otherwise expressly provided in these Regulations, the provisions of these Regulations —

(a) apply in addition to the provisions of the General Regulations; and

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- (b) prevail if, and to the extent that, there is any inconsistency between these Regulations and the General Regulations insofar as the matter relates to a licensee.

PART 2

LICENSING MATTERS

Specified services

4. For the purposes of section 9A(1) of the Act, the services set out in paragraph 1 of the First Schedule are specified services for an outpatient medical service.

Prohibited service delivery modes

5.—(1) A licensee must not provide an outpatient medical service using a conveyance that is not a vehicle.

(2) A licensee must not provide a specified service set out in the first column of the Second Schedule by the service delivery mode or modes set out in the second column of that Schedule that corresponds with that specified service.

Prerequisites for application for approval of specified service

6. A licensee may apply for approval to provide a blood transfusion service as a specified service for an outpatient medical service only if, in the course of providing the outpatient medical service, the licensee also provides, or intends to also provide, an oncology service or haematology service.

PART 3

REQUIREMENTS RELATING TO PERSONNEL

Qualifications, skills and competencies of Clinical Governance Officer

7. For the purposes of section 24(3)(b) of the Act, an individual is suitably qualified to be appointed as a Clinical Governance Officer for an outpatient medical service or a specified service for an outpatient medical service if the individual —

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- (a) is registered under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner and holds a valid practising certificate under that Act;
- (b) has one of the following:
- (i) registration under section 22 of the Medical Registration Act 1997 as a specialist in any branch of medicine;
 - (ii) registration under section 22A of the Medical Registration Act 1997 as a family physician in the Register of Family Physicians;
 - (iii) full-time work experience as a medical practitioner for a continuous period of at least 5 years or an aggregate period of at least 5 years during a continuous period of 10 years, in treating patients —
 - (A) in the provision of an outpatient medical service, outpatient renal dialysis service, acute hospital service or a community hospital service provided in a private hospital, medical clinic or healthcare establishment (as the case may be) licensed under the Private Hospitals and Medical Clinics Act 1980; or
 - (B) in the provision of an outpatient medical service, outpatient renal dialysis service, acute hospital service or a community hospital service licensed under the Act; and
- (c) where the licensee is approved to provide an outpatient medical service by remote provision — has completed any course or programme relating to the remote provision of an outpatient medical service, that may be specified by the Director-General.

General requirements relating to personnel

8.—(1) A licensee must —

- (a) establish, implement and regularly review policies and the appropriate processes for the training and competency assessment of the licensee's personnel to ensure that the personnel are able to perform their work effectively, safely and in compliance with the applicable laws, guidelines, policies, processes, procedures and protocols; and
- (b) monitor and regularly review the work performance of the licensee's personnel to ensure compliance by the personnel with the applicable laws, guidelines, policies, processes, procedures and protocols.

(2) A licensee who is approved to provide an outpatient medical service by remote provision must ensure that every medical practitioner or collaborative prescribing practitioner employed or engaged by the licensee and involved or intended to be involved in the remote provision, completes any training or course relating to the remote provision of an outpatient medical service, that may be specified by the Director-General.

No employment or engagement of unauthorised persons to practise medicine

9. A licensee must not employ or engage any person to practise medicine or do any act as a medical practitioner unless the person is a medical practitioner.

PART 4

PREMISES, CONVEYANCES, EQUIPMENT, ETC.

Standards for approved permanent premises

10. A licensee must —

- (a) ensure that every approved permanent premises is sufficiently spacious and appropriately equipped to enable the outpatient medical service (including any essential life-saving measure) to be provided to patients in a proper, effective and safe manner;
- (b) ensure that there is sufficient lighting and ventilation at every approved permanent premises;
- (c) ensure that every approved permanent premises is designed, built and equipped to enable and facilitate —
 - (i) access to and from the approved permanent premises by patients with physical disability; and
 - (ii) movement within the approved permanent premises by patients with physical disability;
- (d) if the licensee designates a separate area (called in this regulation the waiting area), whether inside or outside the approved permanent premises, where a patient may wait to receive the outpatient medical service or for any matter that is related to the provision of the outpatient medical service by the licensee, including making payment or collecting medicine, ensure that the waiting area is —
 - (i) within the direct line of sight of at least one personnel; and
 - (ii) sufficiently spacious and adequately equipped to ensure the reasonable comfort of every patient waiting in the waiting area;
- (e) ensure that toilet facilities are available in every approved permanent premises, or assistance with toileting needs is provided to patients where needed;

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- (f) ensure that any care or treatment (other than an essential life-saving measure) is provided to a patient only in an area at the approved permanent premises that is sufficiently spacious, appropriately equipped and, if necessary, partitioned (whether on a permanent or temporary basis) from the other parts of the approved permanent premises to ensure the patient's comfort, safety and privacy; and
 - (g) prevent unauthorised access to every approved permanent premises.

Standards for approved conveyances

11. A licensee must —

- (a) ensure that every approved conveyance is sufficiently spacious and appropriately equipped to enable the outpatient medical service (including any essential life-saving measure) to be provided to patients in a proper, effective and safe manner;
- (b) ensure that there is sufficient lighting and ventilation in every approved conveyance;
- (c) ensure that every approved conveyance is sufficiently spacious to enable at least one patient (whether or not disabled) to move into and within the approved conveyance and receive care and treatment from such number of personnel of the licensee as may be necessary, whether the patient is standing up, sitting or lying down;
- (d) ensure that every approved conveyance is designed, built and equipped to enable and facilitate —
 - (i) access to and from the approved conveyance by patients with physical disability; and
 - (ii) movement within the approved conveyance by patients with physical disability;
- (e) if the licensee designates a separate area (called in this regulation the waiting area), whether inside or outside the approved conveyance, where a patient may wait to receive the outpatient medical service or for any matter that is

related to the provision of the outpatient medical service by the licensee, including making payment or collecting medicine, ensure that the waiting area is —

- (i) within the direct line of sight of at least one personnel; and
 - (ii) sufficiently spacious and adequately equipped to ensure the reasonable comfort of every patient waiting in the waiting area;
- (f) ensure that assistance with toileting needs is provided to patients where needed;
- (g) ensure that there is a fire extinguisher in every approved conveyance;
- (h) ensure that care or treatment (other than an essential life-saving measure) is provided to a patient only in an area within the approved conveyance that is sufficiently spacious, appropriately equipped and, if necessary, partitioned (whether on a permanent or temporary basis) from the other parts of the approved conveyance to ensure the patient's comfort, safety and privacy;
- (i) ensure that every approved conveyance is not used for any purpose other than to provide the outpatient medical service by the licensee;
- (j) prevent unauthorised access to every approved conveyance; and
- (k) cause to be conspicuously displayed on every approved conveyance the business name by which the licensee provides the outpatient medical service.

Standards for facilities and equipment — general

12.—(1) A licensee must ensure that every equipment or facility that is used in the licensee's provision of the outpatient medical service is safe and effective.

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- (2) Without limiting paragraph (1), a licensee must ensure that —
- (a) every equipment or facility must be installed, and used or operated properly, in accordance with the instructions of the manufacturer of the equipment or facility;
 - (b) where the licensee is approved to provide the outpatient medical service using an approved conveyance, every equipment, instrument, appliance, material or facility that is necessary for the provision of the outpatient medical service is —
 - (i) fit for use in the approved conveyance;
 - (ii) if necessary, calibrated for use in the approved conveyance; and
 - (iii) securely fastened or stored in a manner so as not to pose a threat or risk to the safety of any person in the approved conveyance while the approved conveyance is in motion;
 - (c) where the licensee is approved to provide the outpatient medical service by remote provision — every equipment, instrument, appliance, material or facility that is necessary for the provision of the outpatient medical service by remote provision is checked regularly, and maintained properly and according to the manufacturer’s specification, so as to ensure that it is adequate, functional and effective; and
 - (d) where the possession, use or operation of any equipment or facility requires any certification or licence, at all times when the licensee is in possession of the equipment or facility —
 - (i) the licensee holds the valid certification or licence for the possession, use or operation of the equipment or facility; and

- (ii) the equipment or facility is checked regularly, and maintained properly and according to the manufacturer's specification, so as to ensure that it is adequate, functional and effective.

Standards for facilities and equipment — remote service kiosks

13. Where a licensee is approved to provide an outpatient medical service by remote provision and the licensee carries out or intends to carry out the remote provision through one or more remote service kiosks, the licensee must —

- (a) ensure that every remote service kiosk is kept clean and sanitary, by establishing, implementing and regularly reviewing measures and processes for regular cleaning and additional ad-hoc cleaning to minimise the spread of pathogenic organisms;
- (b) ensure that every remote service kiosk is sufficiently spacious and appropriately equipped to enable the outpatient medical service to be provided to patients in a proper, effective and safe manner;
- (c) ensure that the remote service kiosk is appropriately equipped to ensure every patient's privacy and confidentiality of the process during which the outpatient medical service is provided to the patient;
- (d) where a remote service kiosk includes a booth for a patient to receive the outpatient medical service, ensure that the booth has sufficient lighting and ventilation;
- (e) regularly check and properly maintain every remote service kiosk so as to ensure that the remote service kiosk is at all times in a good state of repair;
- (f) keep and maintain proper and accurate records of every check and maintenance that is conducted on every remote service kiosk under paragraph (e);

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- (g) where a remote service kiosk includes a vending machine or similar equipment which dispenses medicinal products or health products, prevent unauthorised access to the medicinal products or health products; and
 - (h) cause to be conspicuously displayed at or on the remote service kiosk —
 - (i) the business name by which the licensee provides the outpatient medical service;
 - (ii) the email address or telephone number at which the licensee may be contacted;
 - (iii) a statement that the remote service kiosk is being used by the licensee to provide the outpatient medical service by remote provision; and
 - (iv) a statement that any person who needs any essential life-saving measure should not seek to receive such measure by remote provision from the licensee.

Environment cleaning

14. A licensee must ensure that every approved permanent premises and every approved conveyance (as the case may be) is kept clean and sanitary by establishing and implementing measures and processes for regular cleaning and additional ad hoc cleaning to minimise the spread of pathogenic organisms.

Infection control

15. A licensee must prevent the occurrence of, or manage, control and contain the spread of any infection that is, or is suspected to be, connected with the licensee's provision of an outpatient medical service at any approved permanent premises, temporary premises or using any approved conveyance by ensuring that —

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- (a) only equipment, material or article that is reprocessed through high-level disinfection or sterilisation in accordance with the specifications by the manufacturer of the equipment, material or article (as the case may be) and is not subsequently contaminated, is used in any endoscopic, operative or any other invasive procedure on a patient;
 - (b) every equipment, material or article that is used in every endoscopic, operative or any other invasive procedure is —
 - (i) reprocessed through high-level disinfection or sterilisation in accordance with the specifications by the manufacturer of the equipment, material or article, as the case may be; and
 - (ii) kept and stored under the appropriate conditions to ensure that the equipment, material or article remains fit for use until it is used in the next endoscopic, operative or invasive procedure; and
 - (c) every equipment that is used to reprocess or sterilise any other equipment, material or article is checked regularly and maintained properly in accordance with the specifications by the manufacturer of the equipment, so as to ensure its proper and effective operation.

PART 5

REQUIREMENTS RELATING TO PATIENT CARE

Division 1 — General

General requirements relating to provision of patient care

16.—(1) A licensee must ensure that every patient is properly assessed and the appropriate medical care or treatment is provided to the patient in a proper, effective and safe manner.

(2) Subject to paragraphs (3) and (4), a licensee must ensure that —

(a) no personnel provides a service or does an act beyond his or her professional expertise and qualifications; and

(b) the provision of any service, or carrying out of any act, that is necessary to support the provision of an outpatient medical service and requires the provision of direct care to a patient by any personnel who is not a medical practitioner, is supervised by the medical practitioner who is charged with the care of the patient.

(3) Paragraph (2)(a) does not prevent a collaborative prescribing practitioner of the licensee from providing a collaborative prescribing service for and on behalf of the licensee.

(4) Paragraph (2)(b) does not apply to a service that is provided, or an act carried out, by a healthcare professional in the course of his or her practice as a healthcare professional.

Provision of accommodation

17. A licensee must not, in relation to the provision of an outpatient medical service, provide any patient with accommodation for a period exceeding 12 hours.

Work processes

18. A licensee must establish, implement and regularly review written protocols relating to —

(a) preparation, dispensing and administration of medication;

(b) collection, packing and labelling of specimens;

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- (c) precautions to be taken to avoid contamination and degradation of specimens;
 - (d) proper and safe use of medical and surgical equipment, instruments, appliances, materials and facilities; and
 - (e) where the licensee is approved to provide an outpatient medical service at one or more approved permanent premises, any temporary premises or using one or more approved conveyances — prevention, management, control and containment of the spread of any infection at those approved permanent premises, temporary premises or approved conveyances, as the case may be.

Staff strength

19. A licensee must ensure that there is an adequate number of personnel —

- (a) present at every approved permanent premises and every temporary premises during the period when any outpatient medical service is provided at the approved permanent premises and temporary premises; and
- (b) present in every approved conveyance during the period when any outpatient medical service is provided using the approved conveyance,

so as to enable the licensee to provide the outpatient medical service to every patient at those premises or using that conveyance (as the case may be) in a proper, effective and safe manner.

Conduct of ultrasound imaging

20.—(1) A licensee must not conduct any ultrasound imaging on a patient unless a medical practitioner or collaborative prescribing practitioner who is the licensee's personnel orders the ultrasound imaging for the patient.

(2) A licensee must ensure that any ultrasound imaging conducted on a patient is conducted —

- (a) only as a service that is incidental to the provision of an outpatient medical service;

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- (b) at the licensee's approved permanent premises or temporary premises or in the licensee's approved conveyance, as the case may be; and
 - (c) by the licensee's personnel who is —
 - (i) a medical practitioner who is trained in the conduct of ultrasound imaging;
 - (ii) a radiographer who is a duly qualified allied health professional; or
 - (iii) a sonographer.

Testing of specimen

21.—(1) Subject to paragraph (2), a licensee must not test any specimen for a patient unless —

- (a) a medical practitioner or collaborative prescribing practitioner who is the licensee's personnel orders the test for the patient;
- (b) the testing of the specimen only involves the conduct of a simple in vitro diagnostic test; and
- (c) the testing of the specimen is provided only as a service incidental to the provision of an outpatient medical service.

(2) A licensee who is approved to provide an outpatient medical service by remote provision must not, in the course of providing the service by that service delivery mode, direct a patient to conduct a self-administered test on himself or herself if the testing material for the self-administered test is a “professional use only” medical device within the meaning given by regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010).

Instructions for self-collection of specimens

22. Where any specimen is to be collected from a patient by the patient himself or herself, for the purpose of conducting any test on it (whether or not the test is to be self-administered by the patient), a licensee must provide the patient with —

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- (a) instructions on how and when the specimen is to be collected; and
 - (b) the precautions that are to be taken to avoid contamination and degradation of the specimen.

Conduct of simple in vitro diagnostic test

23.—(1) A licensee must ensure that any simple in vitro diagnostic test on a specimen or a patient must be conducted —

- (a) using testing material in respect of which —
 - (i) the expiry date has not passed; and
 - (ii) the personnel who is administering the test does not suspect or have any reason to suspect that the testing material is no longer fit for use; and
- (b) in accordance with the instructions specified by the manufacturer of the testing material.

(2) A licensee must ensure that any testing material that may be used to conduct any simple in vitro diagnostic testing is stored under the conditions, and handled in the manner, specified by the manufacturer of the testing material so as to lower the risk of contamination, unnecessary exposure of the testing material to the environment and early deterioration of the testing material.

Anaesthesia service

24.—(1) A licensee must not administer, or cause or permit to be administered, any anaesthetic to cause general anaesthesia in any patient.

(2) In paragraph (1), “general anaesthesia” has the meaning given by paragraph 2 of the First Schedule to the Act.

Surgical procedure

25. A licensee must not conduct any surgical procedure on a patient, unless it is a minor surgical procedure.

Essential life-saving measures must be available

26.—(1) A licensee must —

- (a) ensure that adequate and appropriate facilities, equipment and drugs for the provision of any essential life-saving measure to a patient are readily available at every approved permanent premises, temporary premises and approved conveyance; and
- (b) at all times, be capable of providing essential life-saving measures to any patient who is at risk of death.

(2) Without limiting paragraph (1), a licensee must ensure —

- (a) that only resuscitation drugs that have not passed their expiry dates and are fit for use and resuscitation equipment that is fit for use are made available for use in the provision of any essential life-saving measure;
- (b) the establishment and implementation of protocols for the rapid and accurate assessment of any patient who is in need of essential life-saving measures; and
- (c) every personnel who provides any essential life-saving measure to a patient is adequately trained —
 - (i) to provide the essential life-saving measure in a proper, effective and safe manner; and
 - (ii) in the use of the equipment that is needed to deliver the essential life-saving measure.

(3) A licensee who is approved to provide an outpatient medical service by remote provision, must provide, or cause to be provided, any essential life-saving measures to a patient where —

- (a) the patient is in need of any essential life-saving measure, or the patient becomes in need of any essential life-saving measure, during the process of receiving an outpatient medical service by remote provision from the licensee; and
- (b) the licensee knows where the patient is located.

(4) A licensee must ensure that each protocol mentioned in paragraph (2)(b) is documented and that all personnel are trained and proficient in implementing the protocol.

Division 2 — Specific requirements for provision of outpatient medical service using approved conveyance, at temporary premises or by remote provision

Requirements for provision using approved conveyances

27.—(1) This regulation applies to a licensee who is approved to provide an outpatient medical service using an approved conveyance.

(2) Subject to paragraph (3), a licensee —

- (a) must not provide an outpatient medical service to any patient unless the approved conveyance is stationary and properly parked;
- (b) without limiting regulation 19, must ensure that at least one healthcare professional is present in the approved conveyance during the period when an outpatient medical service is provided using the approved conveyance;
- (c) must inform the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient on any follow-up care and treatment including how the patient may obtain follow-up care and treatment; and
- (d) if a medical practitioner who is the licensee's personnel, is of the opinion that the patient requires a particular medical treatment or care which cannot be provided in the approved conveyance in a proper, effective and safe manner, must make alternative arrangements for the patient to receive the medical treatment or care and inform the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient of the alternative arrangements.

(3) Paragraph (2)(a) does not apply to the provision of any essential life-saving measure to a patient.

(4) In this regulation, “driving licence” has the meaning given by section 2(1) of the Road Traffic Act 1961.

Requirements for provision at temporary premises

28.—(1) This regulation applies to a licensee who is approved to provide an outpatient medical service at temporary premises.

(2) For every patient who receives an outpatient medical service at any temporary premises, a licensee must —

- (a) ensure that in determining whether a particular aspect of outpatient medical service may be provided at the temporary premises in a proper, effective and safe manner, a medical practitioner (who is the licensee’s personnel) attending to the patient must take into account —
 - (i) the patient’s medical condition and history;
 - (ii) the medical practitioner’s qualifications, experience, competency and skills; and
 - (iii) the facilities, equipment, medical supplies and other resources that are available at the temporary premises;
- (b) establish, implement and regularly review guidelines to assist a medical practitioner in making the determination mentioned in sub-paragraph (a);
- (c) inform the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient on any follow-up care and treatment including how the patient may obtain follow-up care and treatment; and
- (d) if a medical practitioner who is the licensee’s personnel is of the opinion that the patient requires a particular medical treatment or care which cannot be provided to or conducted on the patient in the temporary premises in a proper, effective and safe manner, make alternative arrangements for the patient to receive the medical treatment or care and inform the patient or (if the patient is a minor or lacks

mental capacity) a next-of-kin or carer of the patient of the alternative arrangements.

(3) A licensee must ensure that every personnel who attends to a patient at any temporary premises carry proof of the personnel's identity and his or her role or designation for which the personnel is engaged or employed by the licensee, and show the proof to the patient.

Requirements for remote provision

29.—(1) This regulation applies to a licensee who is approved to provide an outpatient medical service by remote provision.

(2) A licensee must —

(a) ensure that the following matters are completed before any outpatient medical service is provided to a patient by remote provision:

(i) ascertaining the identity, contact information and location of the patient;

(ii) informing the patient that he or she should not seek to receive any essential life-saving measure by remote provision;

(iii) informing the patient of the identity of the licensee's personnel who will be providing the outpatient medical service, and his or her role or designation for which the personnel is engaged or employed by the licensee;

(b) establish, implement and regularly review guidelines on —

(i) the circumstances in which —

(A) the licensee would provide an outpatient medical service by remote provision to any patient;

(B) the licensee must not provide or must cease to provide an outpatient medical service by remote provision to a patient, and advise the

patient to seek medical attention at any other place; and

- (C) the licensee must provide or cause to be provided any essential life-saving measure to a patient who is receiving an outpatient medical service by remote provision; and
 - (ii) the type of patients to whom an outpatient medical service may be provided by remote provision, taking into account —
 - (A) the patient’s medical condition and history;
 - (B) the qualifications, experience, competency and skills of the medical practitioner who is providing the outpatient medical service; and
 - (C) the patient’s ability to receive the outpatient medical service by remote provision;
 - (c) where the provision of any outpatient medical service to a patient by remote provision cannot be completed for any reason, ensure that the patient is advised of the ways to seek medical attention for his or her condition;
 - (d) inform the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient on any follow-up care and treatment, including how the patient may obtain the follow-up care and treatment; and
 - (e) if a medical practitioner who is the licensee’s personnel is of the opinion that a patient requires a particular medical treatment or care or a physical examination which cannot be carried out by remote provision, make alternative arrangements for the patient to receive the medical treatment or care or physical examination and inform the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient of the alternative arrangements.
- (3) For every outpatient medical service provided to a patient by remote provision, a licensee must —

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- (a) document the date and time of the outpatient medical service provided, and the method of remote communication that was used, as part of the patient's patient health record;
 - (b) ensure that the patient is informed of the name and designation of the licensee's personnel who is providing the outpatient medical service to the patient, before the outpatient medical service is provided to the patient;
 - (c) where the remote provision is by means of a website or software application — ensure that all of the following information is conspicuously displayed on the website or software application at all times when the outpatient medical service is being provided to the patient:
 - (i) the business name by which the licensee provides the outpatient medical service;
 - (ii) the email address or telephone number at which the licensee may be contacted;
 - (iii) the fact that the licensee is approved to provide an outpatient medical service by remote provision;
 - (iv) a statement that any person who needs any essential life-saving measure should not seek to receive such measure by remote provision from the licensee; and
 - (d) where the outpatient medical service is provided by remote provision using any other means — ensure that the information mentioned in sub-paragraph (c)(i) to (iv) is conveyed to the patient before the outpatient medical service is provided to the patient.
- (4) Except as provided in paragraph (5), a licensee must take reasonable measures to ensure that a patient who receives an outpatient medical service by remote provision is not prescribed any drug that is specified in the First Schedule to the Misuse of Drugs Act 1973 in the course of the remote provision.
- (5) A medical practitioner who is the licensee's personnel may in the course of the remote provision prescribe a drug mentioned in

paragraph (4) for the patient if the medical practitioner has previously conducted a physical examination on the patient and assessed that the patient requires the drug.

(6) In this regulation, “method of remote communication” means communication through —

- (a) the Internet;
- (b) the telephone or other communication device; or
- (c) any other kind of electronic or other technology for facilitating communication remotely.

Restriction on remote provision

30.—(1) Subject to paragraph (2), a licensee must not provide an outpatient medical service by remote provision to a first-time patient.

(2) Despite paragraph (1), a licensee may provide an outpatient medical service by remote provision to a first-time patient if —

- (a) the outpatient medical service is provided through real-time 2-way interactive audiovisual communications;
or
- (b) the outpatient medical service is provided in response to an emergency or a disaster, including but not limited to, prescribing any empiric or prophylactic treatment to prevent or control an infectious disease outbreak.

(3) In this regulation, “first-time patient”, in relation to a licensee, means a patient who has not received an outpatient medical service from the licensee.

Requirements for video consultations

31.—(1) Where a licensee provides an outpatient medical service by remote provision to a patient by means of a video consultation, the licensee must ensure that —

- (a) the provision of the outpatient medical service is through real-time 2-way interactive audiovisual communications;
and

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- (b) to enable the outpatient medical service to be provided to the patient effectively while ensuring the confidentiality of the proceedings of the video consultation and the privacy of the patient —
- (i) only such number of personnel as is necessary for the provision of the outpatient medical service attends the video consultation; and
 - (ii) the personnel conducts the video consultation in a place that is closed and private.
- (2) Without limiting paragraph (1)(b), the licensee must ensure that —
- (a) the place at which the licensee’s personnel conducts the video consultation is equipped with sufficient lighting and other appropriate equipment or facility;
 - (b) at all times when the outpatient medical service is provided, the patient has a full view of the face of the personnel who is providing the outpatient medical service; and
 - (c) the patient is informed of the identity of the personnel who is providing the outpatient medical service, and his or her role or designation for which the personnel is engaged or employed by the licensee.
- (3) If the licensee requires the consultation to be recorded as part of the patient’s patient health record, the licensee must obtain the patient’s consent for the consultation to be recorded and keep a record of the giving of the consent.

Division 3 — Provision of specified service

Blood transfusion service

32. A licensee must not provide a blood transfusion service to a patient, unless that service is necessary to support the provision of an oncology service or a haematology service by the licensee to the patient.

PART 6
MISCELLANEOUS

Keeping of other records

33. A licensee must maintain proper, complete and accurate records in respect of all of the following:

- (a) the qualifications and competencies (including training and competency assessments) of each personnel, that are relevant to the provision of the outpatient medical service;
- (b) every programme, policy, system, measure, protocol or process that the licensee is required to implement under these Regulations, and every activity undertaken under that programme, policy, system, measure, protocol or process;
- (c) the installation, maintenance, servicing and repair of all equipment used in the provision of the outpatient medical service.

Price transparency

34. A licensee must, upon request by a patient or any person who intends to receive an outpatient medical service from the licensee, inform the patient or person (as the case may be) of the applicable charges (including any administrative fee) for the outpatient medical service.

Display of charges, etc.

35.—(1) A licensee must —

- (a) ensure that the fees charged by the licensee for an outpatient medical service are displayed or otherwise made available —
 - (i) at every approved permanent premises, temporary premises or approved conveyance, as the case may be; and
 - (ii) where the licensee provides the outpatient medical service through a remote service kiosk — at the remote service kiosk; and

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- (b) where the licensee provides the outpatient medical service by remote provision other than through a remote service kiosk — ensure that the licensee’s personnel informs the patient of the fees.
- (2) The charges mentioned in paragraph (1) for an outpatient medical service must include —
- (a) the consultation fee that is applicable to the patient; and
- (b) any administrative fee or any other charge that is to be imposed in respect of the outpatient medical service on the patient.

Disclosure of approved institution status

- 36.—**(1) A licensee who is an approved institution must —
- (a) display or otherwise make available at every approved permanent premises, temporary premises or approved conveyance, the fact that the licensee is an approved institution;
- (b) display or otherwise make available at every remote service kiosk through which the outpatient medical service is provided, the fact that the licensee is an approved institution; and
- (c) where the licensee provides the outpatient medical service by remote provision and the provision is not through a remote service kiosk — ensure that the licensee’s personnel informs the patient of the fact that the licensee is an approved institution.
- (2) A licensee who is not an approved institution must not —
- (a) represent to any person or give any person the impression that the licensee is an approved institution; or
- (b) otherwise mislead any person as to whether the licensee is an approved institution.
- (3) In this regulation, “approved institution” means any of the following:

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- (a) an approved medical institution within the meaning of regulation 2(1) of the Central Provident Fund (Medisave Account Withdrawals) Regulations (Rg 17);
 - (b) an approved medical institution approved by the Minister under the MediShield Life Scheme Act 2015;
 - (c) an accredited clinic under the scheme established by the Government known as the Community Health Assist Scheme or any other similar public scheme providing financial assistance established by the Government.

Financial counselling

37.—(1) This regulation applies in relation to the provision of any claimable outpatient medical service by a licensee to a patient.

(2) A licensee must, before providing any claimable outpatient medical service to a patient, provide information on the fees charged by the licensee for the claimable outpatient medical service, to the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient.

(3) For the purposes of paragraph (2), the information on the fees for a claimable outpatient medical service must include —

- (a) the estimated range of fees for the claimable outpatient medical service;
- (b) the fee benchmark for the same or similar claimable outpatient medical service that is published on the website of the Ministry of Health at <https://www.moh.gov.sg> (if available);
- (c) whether any part of the fees mentioned in sub-paragraph (a) may be —
 - (i) deducted from any medisave account;
 - (ii) reimbursed under the MediShield Life Scheme; or
 - (iii) reduced by any subsidy or grant under a public scheme; and

(d) any other benefit that the MediShield Life Scheme provides to the patient in respect of the outpatient medical service, if any.

(4) A licensee need not comply with paragraph (2) if the patient is assessed by a medical practitioner to be in a critical condition and needs to receive the outpatient medical service without delay.

(5) The licensee must, after providing the information mentioned in paragraph (3) to the patient or the next-of-kin or carer of the patient, obtain an acknowledgment from the patient, next-of-kin or carer (as the case may be) and keep the acknowledgment as part of the patient's patient health record.

(6) In this regulation —

“claimable outpatient medical service” means an outpatient medical service provided by a licensee to a patient who may claim under the MediShield Life Scheme for reimbursement (whether wholly or in part) of the charges incurred in receiving the service;

“medisave account” means a medisave account maintained under section 13 of the Central Provident Fund Act 1953.

Offences

38.—(1) A person who contravenes regulation 9, 10(a) or (f), 11(a), (h) or (i), 12(1) or (2), 15(1), 16(1) or (2), 24(1), 25, 26(1) or (2) or 32 shall be guilty of an offence.

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

(a) to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both; and

(b) in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

FIRST SCHEDULE

Regulation 4 and Second Schedule

SPECIFIED SERVICES

1. A specified service for an outpatient medical service is any of the following:

- (a) blood transfusion service;
- (b) collaborative prescribing service;
- (c) electrocardiography stress testing service;
- (d) endoscopy service;
- (e) liposuction;
- (f) proton beam therapy;
- (g) radiation oncology and radiation therapy.

2. In this Schedule —

“electrocardiography stress testing service” means the procedure of subjecting a patient to physiological stress (for example, by requiring the patient to use a treadmill or an ergometer) for the purpose of eliciting evidence of ischemic heart disease or any arrhythmia, to assess cardiac functional status, or both;

“endoscopy service” means the inspection of a body organ or tissues inside a human body by the use of an endoscope;

“liposuction” means the surgical removal of localised fat deposits in a human body by aspiration in order to treat deposits of subcutaneous fat distributed in aesthetically unpleasing proportions, the injection or transfer of the removed fat into another part of the human body, or both;

“proton beam therapy” means the performance of a procedure that involves the application of a high-energy proton beam to a patient in a clinical setting for a therapeutic purpose;

“radiation oncology and radiation therapy” means a treatment of any condition or disease using ionising radiation that —

(a) is emitted from —

- (i) a sealed source (as defined in regulation 2 of the Radiation Protection (Ionising Radiation) Regulations 2023 (G.N. No. S 85/2023)); or

FIRST SCHEDULE — *continued*

- (ii) an irradiating apparatus (as defined in regulation 2 of the Radiation Protection (Ionising Radiation) Regulations 2023); and

(b) does not involve the application of a proton beam.

SECOND SCHEDULE

Regulation 5(2)

<i>First column</i>	<i>Second column</i>
<i>Specified service</i>	<i>Prohibited service delivery modes</i>
1. Blood transfusion service	(a) At temporary premises (b) Using a conveyance (c) By remote provision
2. Electrocardiography stress testing service	(a) At any temporary premises (b) By remote provision
3. Endoscopy service	By remote provision
4. Liposuction	(a) At temporary premises (b) Using a conveyance (c) By remote provision
5. Proton beam therapy	(a) At temporary premises (b) Using a conveyance (c) By remote provision
6. Radiation oncology and radiation therapy	(a) At temporary premises (b) Using a conveyance (c) By remote provision

In this Schedule, “electrocardiography stress testing service”, “endoscopy service”, “liposuction”, “proton beam therapy” and “radiation oncology and radiation therapy” have the meanings given by paragraph 2 of the First Schedule.

Made on 20 June 2023.

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

[MH 78:44/1; AG/LEGIS/SL/122E/2020/22 Vol. 1]